# Health Evidence Review Commission

## May 18, 2017

**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 18, 2017*

*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 (3/9/17) | Som Saha | X |
| 3 | 1:40 PM | Director's Report | Darren Coffman | |
| 4 | 1:45 PM | Value-based Benefits Subcommittee Report | Ariel Smits<br>Cat Livingston | X |
| 5 | 2:15 PM | Continued Discussion of Process for Prioritizing Novel Treatments With Marginal Clinical Benefit, Low Cost-Effectiveness and/or High Cost | Cat Livingston<br>Darren Coffman | |
| 6 | 3:00 PM | Low Back Pain: Corticosteroid Injections<br>• Coverage Guidance<br>• Prioritized List changes | Adam Obley<br>Cat Livingston | X |
| 7 | 3:50 PM | Breast Cancer Screening in Women at Above Average Risk<br>• Coverage Guidance<br>• Prioritized List changes | Adam Obley<br>Wally Shaffer | X |
| 8 | 4:20 PM | Next Steps<br>• Schedule next meeting – August 10, 2017 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 9, 2017

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

**Members Absent:** Derrick Sorweide, DO.

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

**Also Attending:** Jesse Little (Oregon Health Authority); Adam Obley, MD, MPH, Craig Mosbaek (OHSU Center for Evidence-based Policy); Gloria Tapia (Salud); Craig Gonzales (EGS); Carl Stevens, MD (CareOregon).



**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 11/10/2017 meeting as written. *CARRIES 12-0.***

**Director's Report**

*Subcommittee Membership:*
Coffman said Dr. Farris resigned from the Health Technology Assessment Subcommittee (HTAS) in December. He recommended Dr. Kathryn Schabel to replace him on HTAS. Dr. Schabel's CV and Conflict of Interest (COI) declaration were vetted by leadership and approved.

**MOTION: Appoint Dr. Schabel to HTAS effective immediately. *Carries: 12-0.***

Dr. Devan Kansagara is an internist and colleague of Dr. Saha, who is recommending to be appointed to participate on the Evidence-based Guidelines Subcommittee (EbGS). His CV and COI were similarly vetted and approved.

**MOTION: Appoint Dr. Kansagara to EbGS effective immediately. *Carries: 12-0.***

*Potential changes to the opioid use policy:*
Coffman asked members for data requests to analyze the impact of the back line changes that went into effect 7/1/16, particularly the guideline on the use of opioids. He said he has already begun working with the OHA Health Analytics manager about the data needed, noting we will be unable to use the All Payers All Claims (APAC) data this time but data from MMIS will serve nicely. Ideas suggested at VbBS included the number of new opioid prescriptions for back conditions, length and average dose of existing opioid prescriptions, change in utilization of emergency services and of alternative therapies for back pain. Discussion is anticipated at the May and August meetings; any changes should be reflected in the October 1, 2017 Prioritized List.

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**Value-based Benefits Subcommittee (VbBS) Report on Prioritized List Changes**
Meeting materials page 128-229

Ariel Smits reported the VbBS met earlier in the day, March 9, 2017, as well as on February 2, 2017. She summarized the subcommittee's recommendations.

**February 2, 2017 meeting:**
RECOMMENDED CODE MOVEMENT (effective 10/1/2017)

- Add several dental procedures to covered lines
- Make various straightforward coding changes
- Add procedure codes for fecal microbiota transplant to a covered line with a new guideline to clarify coverage
- Add procedure codes for cholecystectomy to the pancreatitis line and delete from the intestinal ileus line
- Add limited coverage for tympanostomy tubes and adenoidectomy for high-risk children with hearing loss due to chronic otitis media older than age 5, with coverage limited through age 7 in the chronic otitis media with effusion guideline
- Add adenoidectomy procedure codes to the covered line for hearing loss in children age 5 and under to clarify coverage

RECOMMENDED GUIDELINE CHANGES (effective 10/1/2017)

- Revise the dental guideline regarding wisdom tooth extraction to clarify coverage
- Edit the guideline defining significant injuries to joints to include meniscal injuries
- Add a new guideline to define cholecystitis

2018 BIENNIAL REVIEW CHANGES (effective 1/1/2018)

- Merge two lines with injuries to major blood vessels; move codes from a third line to the new line to consolidate all diagnosis and treatment codes for major blood vessel injuries

**March 9, 2017 meeting:**
RECOMMENDED CODE MOVEMENT (effective 10/1/2017)

- Add several non-specific pain diagnoses to a non-covered line
- Make multiple straightforward coding changes

RECOMMENDED GUIDELINE CHANGES (effective 10/1/2017)

- Add a new guideline specifying that pharmacogenetics testing is not covered for any psychiatric disorder
- Edit the pharmacist medication management guideline to remove the requirement for a provider to refer the patient and for the pharmacist to collaborate with the referring provider
- Add a new guideline specifying that breast reduction for macromastia is not covered for the comorbid condition of neck or back pain
- Edit the elective surgery and smoking guideline to specify that tobacco replacement, including vaping, is allowed. Other guidelines which require longer periods of smoking cessation prior to specific procedures were modified to specify that any type of nicotine use (including vaping, smokeless tobacco, and nicotine replacement therapy) were not allowed.
- Edit the MRI for MS guideline to allow MRIs in limited clinical situations
- Edit the preventive services guideline to specify blood lead screening coverage

Biennial Review (Effective 1/1/2018)

- Create two new lines for treatments with marginal clinical benefit or low cost-effectiveness along with two guideline notes and a statement of intent. Further work will is required to further refine these lines and guidelines at the next few VbBS meetings.

Additional discussion took place on the topic of cholecystitis. Smits said VbBS recommends not covering gallbladder removal for pain/biliary colic only until there are certain objective finding such as evidence of inflammation, ultrasound findings characteristic of cholecystitis or a gallbladder ejection fraction <35%.

Saha noted that this treatment course goes against what he learned in medical school and asked for the evidence. Smits said the studies she found show a group of people with those symptoms will proceed to complications but there are no worse outcomes of morbity or mortality to wait to perform the surgery until complications arise. Pain is not covered until there is a complication. She said she found one study of 75 patients where one person in the *waiting group* died and 14 of the 40 required hospital admission. Further, the area expert who was consulted on this issue recommended biliary colic coverage before complications.

Saha summed up his thoughts about the only study found by stating the *surgery group* (received surgery within 24 hours of first bout of biliary colic) experienced no complications while the *waiting group* had 14 (of 40) serious complication admissions and 1 death. A laparoscopic gallbladder removal seems very safe compared to a complicated, potentially open procedure for a perforated gallbladder with pancreatitis. These are not simple complications, they are catastrophes. He struggled to find a valid reason to wait.

Smits said the initial staff recommendation was to allow surgery for recurrent (more than 1 episode) of biliary colic. Chan offered his support for this. Hodges objected saying there is no way to know if the patient will ever have a third bout of biliary colic and pain, and even in the presence of gallstones, there may not be causation.

Dr. Carl Stevens, CareOregon Medical Director, said the standard test in the ED is to perform a bedside ultrasound to confirm Murphy's sign. His CCO is allowing surgery for patients who we think it would be

risky for them to undergo emergent gallbladder removal, such as a patient with diabetes or immunosuppressed patients.

**MOTION: To return the topic of gallbladder surgery to VbBS to do more investigation.** ***Carries: 11-1 (Hodges opposed)***

*Biennial report: Novel Treatments*
Coffman said this is the last meeting before the biennial review is completed where we can add, create or delete lines. He asked the members to consider a proposal to add two new lines. For many years, this Commission has had explicit statutory authority to prioritize treatments, including drugs, based on cost-effectiveness as well as clinical effectiveness. Historically HERC has not used cost-effectiveness to regularly determine placement on the Prioritized List other than to occasionally not pair a treatment with a condition when another treatment is found to be more cost-effective.

For the biennial review, staff propose a new guideline on novel treatments with marginal clinical benefit or low cost-effectiveness. In additional to utilizing the line items and guideline notes for medical and surgical therapies, this would create a specific mechanism for prioritizing outpatient drugs, durable medical equipment and supplies, and certain other ancillary services that do not currently appear on the Prioritized List below the funding line. This is potentially cost-saving but may cause opposition on a variety of fronts.

The proposal would add one statement of intent, two new lines and two guideline notes as follows, with the higher of the two new lines prioritized at line 500 and the lower new line appearing as the last line of the list:

> STATEMENT OF INTENT 3, THERAPIES WITH MARGINAL CLINICAL BENEFIT OR LOW COSTEFFECTIVENESS
>
> Line 500
> CONDITION: CONDITIONS FOR WHICH CERTAIN TREATMENTS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS TREATMENT: MEDICAL AND SURGICAL TREATMENT
>
> Line YYY (~666)
> CONDITION: CONDITIONS FOR WHICH CERTAIN TREATMENTS HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS TREATMENT: MEDICAL AND SURGICAL TREATMENT
>
> GUIDELINE NOTE AAA, TREATMENTS WITH MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS FOR CERTAIN CONDITIONS
>
> GUIDELINE NOTE BBB, TREATMENTS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

Coffman noted that the proposal would not immediately populate the lines; it would create these lines in order to populate them at future meetings. He noted HERC is statutorily forbidden from doing drug class reviews; that job falls to OHA's Pharmacy & Therapeutics (P&T) Committee. Once P&T completes a review, HERC would be notified. HERC will review their study to determine appropriate prioritization, which would appear as a narrative listing of condition and prescription drug pairings within the new

guideline notes. Coffman also said this process could be used as a more transparent home for non-drug treatments such as those currently on the Services Recommended for Non-Coverage Table, which VbBS would like to review in May towards that end.

*Cost-effectiveness discussion:*
Livingston directed the members to pages 222-229 in the meeting packet, pointing out Figure 1.9 as a diagram always included in the Biennial Report to the Legislature but never used. Parts of it are unclear and other parts are incorrect. Staff recommends deleting Figure 1.9 from the upcoming biennial report in its entirety.

Coffman said further discussion on whether to define a threshold for what constitutes low cost-effectiveness for new line 500 can occur at the May meetings.

**MOTION: To accept the staff recommendation to create two new lines, one statement of intent and two new guideline notes in order to prioritize novel treatments as discussed and delete Figure 1.9 from the biennial report. Staff was given direction to modify the statement of intent language and its title to better capture the intent of Line YYY. *CARRIES: 12-0.***

**MOTION: To accept the VbBS recommendations on Prioritized List changes not related to coverage guidances or called out separately as stated above. *See the VbBS minutes of 2/2/2017 & 3/9/2017 for a full description. Carries: 12-0. Westbrook noted her objection against the recommendation on MRIs for MS, but was in favor of all other aspects of the vote.***

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**Coverage Guidance Topic: Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average-Risk Women**
Meeting materials page 231

Drs. Humphrey (could not attend) and Thomas (*via teleconference*) were appointed ad hoc experts for this topic and helped inform the process.

Obley presented an overview of the evidence. Though the breast cancer death rate has declined steadily over the past 15 years, 12% of women will develop invasive breast cancer during their lifetime. The decline in mortality can be attributed to better screening efforts, decreased use of hormone therapy post-menopause and improved treatment.

Digital breast tomosynthesis (DBT), approved by the FDA in 2011 and sometimes referred to as three-dimensional (3-D) mammography, involves producing multiple x-ray images of thin breast sections, compared to one image from conventional digital mammography (DM). DBT seeks to improve mammography by improving cancer detection and reducing the false-positive rate.

This scope of this coverage guidance looks at a population of women between 40 and 74 years referred for screening and *excludes* women with a history of breast cancer, certain BRCA mutations, Cowden and Li-Fraumein syndrome, certain familial breast cancer syndromes, high-risk lesions, and previous large doses of chest radiation therapy before age 30. Interventions compared are standard 2-D mammography with or without computer-aided diagnosis.

Outcomes judged include:
- All-cause mortality (critical outcome)

- Breast cancer morbidity (critical outcome)
- Test performance characteristics (important outcome)
- Cancer stage at diagnosis (important outcome)
- Recall rate/false-positive test results (important outcome)

Comments collected through the official 30-day public comment period included the addition of new observational trials and comments on recall, and a request to change how all-cause mortality is framed, wanting instead to be subject to the normal evidentiary standards of screening tests.

HTAS reviewed evidence including four recent, high-quality systematic reviews of observational trials of DBT and DM compared to DM alone, six observational trials published since that last systematic review, and three economic analyses published recently. No randomized controlled trials of DBT have been published, although several are currently underway.

Obley explained evidence for DBT is limited to observational studies, most of which have methodological limitations and inadequate follow-up periods. Some conclusions include:

- Effects of DBT on all-cause mortality, breast cancer morbidity, and breast cancer stage at diagnosis are unknown
- Two studies with adequate follow-up to ascertain interval cancer rates reached differing conclusions
- One study showed increased sensitivity and similar specificity
- One study showed identical sensitivity and improved specificity
- Low-quality evidence showed mixed results that DBT+DM improves cancer detection rates
- Low-quality evidence that DBT+DM reduces recall rates, particularly when limited to U.S.-based studies
- There are no meta-analytic estimates available for any of the outcomes, except for women with dense breasts

Guidelines reviewed:

- U.S Preventive Services Task Force (2016):
    - Grade "I" statement for DBT, concluding that there was insufficient evidence to assess the benefits and harms of DBT
    - Grade "I" statement for adjunctive or supplemental screening, including DBT, for women with dense breasts
- Current evidence is insufficient to assess effectiveness of DBT:
    - American Congress of Obstetricians and Gynecologists
    - American Cancer Society
    - American College of Physicians
    - American Academy of Family Physicians
- National Comprehensive Cancer Network: recently added, "consider tomosynthesis"
- American College of Radiology: DBT is no longer investigational and has demonstrated improvement in outcomes compared to DM

Shaffer then read through the rationale (page 290) as well as the proposed coverage guidance recommendation from HTAS.

- It is likely that DBT decreases recall rates as compared with DM alone, based on observational studies performed in the US

- We have low confidence that DBT improves cancer detection rates
- We are not confident that any improvement in cancer detection rates with DBT, if clearly demonstrated, would result in cancers being detected at earlier stages and leading to earlier intervention that improves clinical outcomes
- Adding DBT to standard DM adds cost, and we are not confident that DBT is cost-effective, based on current analysis
- Randomized controlled trials are currently underway that should help with greater understanding of the risks and benefits of DBT+DM, including the critical issue of whether DBT improves clinical outcomes
- The recommendation against coverage is a weak recommendation because further evidence could change the recommendation

Saha added that the current evidence does not show that earlier breast cancer detection leads to better outcomes. There are such studies underway, which will be examined when it is available.

Dr. Thomas, the appointed expert stated that she disagreed with the recommendation for non-coverage.

**MOTION: To approve the proposed coverage guidance for Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average Risk Women as presented. *Carries 10-2 (Garside, Tippens opposed).***

**Approved Coverage Guidance:**

HERC Coverage Guidance

Digital breast tomosynthesis for breast cancer screening in average risk women is not recommended for coverage *(weak recommendation).*

**MOTION: To approve the VbBS recommendation to not cover DBT, which results in no change to the Prioritized List. *CARRIES: 10-2 (Garside, Tippens opposed).***

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**Coverage Guidance Monitoring (Rescan) Process**
Meeting materials page 307-376

Livingston said this section may seem confusing because HERC recently stopped the rescan process and moved to a passive monitoring process, but these topics were already in progress. As a result of rescans of the literature conducted by CEbP on these topics, HERC staff recommends the following for these coverage guidances:

*Rescanned & Reaffirm:*

- Imaging for Low Back Pain
- Nonpharmacologic Interventions for Treatment-Resistant Depression
- Indications for Hyperbaric Oxygen Therapy for Chronic Wounds and Burns

- Artificial Disk Replacement
    - may reconsider an update when the Washington HTA report is published
- Hip Resurfacing
- Lumbar Discography
- Viscosupplementation for Osteoarthritis of the Knee
- Osteoporosis Screening by Dual-Energy X-ray Absorptiometry (DXA)
- Osteoporosis Monitoring by Dual-Energy X-ray Absorptiometry (DXA)
- Hip Procedures for Femoroacetabular Impingement Syndrome
- Treatment of Obstructive Sleep Apnea in Adults

*Retire:*

- Prenatal Genetic Testing (not practical to rescan with new process)

*Update currently in progress:*

- Low Back Pain: Minimally Invasive and Non-Corticosteroid Percutaneous Interventions

*Passive Monitoring (no rescan conducted):*

- Chronic Otitis Media with Effusion in Children
    - VbBS is recommending a guideline note change for a minor change to OHP coverage
- Low Back Pain: NonPharm-Noninvasive
    - Moved from "reaffirm" category
    - New AHRQ review on the horizon
- Low Back Pain: Pharmacologic and Herbal
    - New AHRQ review on the horizon
- Planned Cesarean Section
- Routine Ultrasound in Pregnancy
- Neuroimaging for Dementia
- Knee Arthroscopy in Patients with Osteoarthritis
- Upper Endoscopy for Gastroesophageal Reflux Disease (GERD)

**MOTION: To affirm the coverage guidances and update the status of the other topics as recommended. *CARRIES 12-0.***

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**Review of Proposed New Coverage Guidance & Multisector Intervention Topics**

Obley reviewed scopes and scoring for each proposed new topic, stating some of these topics may later be bumped by higher-priority topics. All topics involve coverage guidances unless otherwise specified as a multisector intervention (MSI) report.

- Colon cancer screening modalities (page 379) ; Score: 21
    - Labhart said this screening is on the CCO metrics means thousands of dollars if his county if the quota is not met
- Prevention of unintended pregnancy (MSI) (page 381) ; Score: 23
- Opportunistic salpingectomy for ovarian cancer prevention (page 383) ; Score: ~~13~~ 19
    - Recommended as a replacement of tubal ligation/sterilization

- Public comment: Dr. Carl Stevens, CareOregon Medical Director, commented that he routinely denies this procedure for payment citing an ACOG statement that cancer isn't prevented
- Saha recommended this topic be reviewed sooner and to increase its score to equal the score of urine drug testing (from 13 to 19)

- Urine Drug Testing (page 385) ; Score: 19
  - Public comment: Dr. Carl Stevens, CareOregon Medical Director, commented that the urine opioid test interpretation can be difficult. If diversion is an important outcome of the test, experts must be employed. He suggested adding a question about central interpretation since the primary care physician may not have the specialized training and experience to do so.
- Acellular Dermal Matrix for Breast Reconstruction (page 387); Score: 12
- CardioMEMS for heart failure monitoring (page 390) ; Score: 16
- Gene Expression Profiling for Breast Cancer (page 391); Score: 17
- Gene Expression Profiling for Prostate Cancer (page 392); Score: 21
- Hepatic Artery Infusion Pump chemotherapy (page 393) ; Score: 12

Not scoped:

- Planned Out-of-Hospital birth (not scoped); Score 19
  - There is new evidence and requests to re-review coming from multiple fronts
- Recurrent Otitis Media
  - This is a legacy topic. Obley noted the coverage guidance includes the recommended use of chronic suppressive antibiotic therapy, which is no longer recommended by the American Academy of Pediatrics.

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**Prioritization of Coverage Guidance Topics**

This is simply a vote to reaffirm the prioritization resulting from the scoring of the topics just reviewed, though discussion was conducted on breaking ties. EbGS and HTAS will take up topics in the following order (including legacy topics), although staff was granted permission to skip to the next topic to avoid reviewing two particularly difficult topics at the same time.

| EbGS | HTAS |
|---|---|
| Prevention of unintended pregnancy (MSI) | Colon cancer screening modalities |
| Urine drug testing | Gene expression profiling for prostate cancer |
| Opportunistic salpingectomy for ovarian cancer prevention | Gene expression profiling for breast cancer |
| Planned out-of-hospital birth | Acellular dermal matrix for breast reconstruction |
| CardioMEMS for heart failure monitoring | Prostatic urethral lifts for the treatment of benign prostatic hypertrophy |
| Recurrent otitis media | Hepatic artery Infusion pump chemotherapy |
| Gastrointestinal motility tests | Sacral nerve stimulation |
| | Genetic testing of thyroid nodules |

***MOTION: To approve the scope statements as amended and the topic rankings as adjusted. CARRIES: 12-0.***

**Other Business**

Coffman gave a brief overview of legislative happenings and mandate bills. There is a bill that would allow PT/OT to be done with the use of a horse (hippotherapy) that is currently excluded for payment in OHP by administrative rule. He commented this therapy uses standard PT and OT billing codes, as the horse is akin to another piece of therapy equipment. Another bill is for immediate placement of LARCs postpartum, which we have a guideline note requiring coverage for OHP, so that bill seems unnecessary.

Regarding the Prioritized List, there is some talk about moving the funding level up 25-50 lines. However, the waiver does not allow for changing the funding level, so this would require a waiver amendment.

**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 18, 2017 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 9, 2017

*For specific coding recommendations and guideline wording, please see the text of the 3/9/2017 VbBS minutes.*

**RECOMMENDED CODE MOVEMENT (effective 10/1/2017 unless otherwise noted)**

- Add several non-specific pain diagnoses to a non-covered line
- Make multiple straightforward coding changes

**RECOMMENDED GUIDELINE CHANGES (effective 10/1/2017)**

- Edit the preventive services guideline to specify blood lead screening coverage
- Add a new guideline specifying that pharmacogenetics testing is not covered for any psychiatric disorder
- Edit the pharmacist medication management guideline to remove the requirement for a provider to refer the patient and for the pharmacist to collaborate with the referring provider
- Add a new guideline specifying that breast reduction for macromastia is not covered for the comorbid condition of neck or back pain
- Edit the elective surgery and smoking guideline to specify that nicotine replacement, including vaping, is allowed. Other guidelines which require longer periods of smoking cessation prior to specific procedures were modified to specify that any type of nicotine use (including vaping, smokeless tobacco, and nicotine replacement therapy) are not allowed.
- Edit the MRI for multiple sclerosis guideline to allow MRIs in limited clinical situations

**BIENNIAL REVIEW (Effective 1/1/2018)**

- Create two new lines for treatments with marginal clinical benefit or low cost-effectiveness along with two guideline notes and a statement of intent. Further work is required to further refine these lines and guidelines at the next few VbBS meetings.

**VALUE-BASED BENEFITS SUBCOMMITTEE**
**Clackamas Community College**
**Wilsonville Training Center, Rooms 111-112**
**Wilsonville, Oregon**
**March 9, 2017**
**9:00 AM – 1:00 PM**

**Members Present:** Kevin Olson, MD, Chair; David Pollack, MD; Susan Williams, MD; Mark Gibson; Irene Croswell, RPh; Holly Jo Hodges, MD; Vern Saboe, DC; Gary Allen, DMD.

**Members Absent:** None

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

**Also Attending:** Jesse Little (Oregon Health Authority); Jay Halaj, Ph.D. (Allevia Health); Leo Yasinski (Merck).

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

  The meeting was called to order at 9:10 am and roll was called. Minutes from the February 2, 2017 VbBS meeting were reviewed and approved.

  Staff asked members for requests for information on data to analyze the impact of the back line changes, particularly the opioid and back conditions guideline. Coffman noted that he has already begun working with OHA Analytics about the data needed. Ideas from staff and leadership include tracking initiation of new opioid prescriptions for back conditions, evaluation of length and average dose of established opioid prescriptions, change in utilization of ER and of alternative therapies for back pain. This discussion is anticipated to go over two meetings, May and August.

  <u>Public Testimony</u>
  Jay Halaj with Allevia Health, representing the manufacturer of Alpha Stim for cranial electrical stimulation (CES). Dr. Heather Kahn from Grants Pass has previously submitted literature to HERC staff regarding the utility of CES. Mr. Halaj testified to the utility of this device in terms of the treatment of pain, depression, anxiety, etc. Patients stop using medications such as opioids or SSRIs due to the utility of the device. Mr. Halaj indicated that he will be coming in May with practitioners to further testify regarding the utility of this therapy. CES is inexpensive, with no side effects. He previously sent staff additional literature to review and offered additional information for the Commission to review.

  Pollack requested additional information about what this technology involved. Mr. Halaj described CES as an electrical device that stimulates cranial nerves. CES is indicated for depression, anxiety and insomnia. The same instrument is also used locally for pain. Allen

asked about coverage for major insurance plans. Mr. Halaj indicated that CES is not covered by most insurers, which he argued is due to pharmaceutical company pressure, rather than lack of evidence of effectiveness. Hodges asked about how this is billed. The answer was that there are several billing codes used for this technology.

- **Topic: Straightforward/Consent Agenda**

**Discussion:** Smits and Livingston reviewed the topics on the consent agenda. There were clarifying questions only.

**Recommended Actions:**

1) Add P29.0 (Neonatal cardiac failure) to line 102 HEART FAILURE
    a. Remove P29.0 from line 2 BIRTH OF INFANT
2) Add 33475 (Replacement, pulmonary valve) to line 74 CONGENITAL PULMONARY VALVE ANOMALIES
3) Add 00102 (Anesthesia for procedures involving plastic repair of cleft lip) to line 305 CLEFT PALATE AND/OR CLEFT LIP
4) Remove S0265 (Genetic counseling, under physician supervision, each 15 minutes) from the Services Recommended for Non-Coverage Table
    a. Advise Health Systems Division (HSD) to add S0265 to the Diagnostic Procedures File
5) Remove 87338 (Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; Helicobacter pylori, stool) from line 60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE
    a. Advise HSD to add 87338 to the Diagnostic Workup File
6) Add 92002-92014 (Ophthalmological services: medical examination and evaluation with initiation of diagnostic and treatment program) to line 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT
7) Add 12011-12018 (Repair of wound of the face, ears, eyelids, nose, lips, and/or mucous membrane) to line 233 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
8) Remove 77338 (Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan) from line 160 CROMEGALY AND GIGANTISM
9) Remove H0048 (Alcohol and/or other drug testing: collection and handling only, specimens other than blood) from lines 4, 66, 59 and 614
    a. Advise HSD to add H0048 to the Diagnostic Procedures File
10) Add T1016 (Case management, each 15 minutes) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
11) Add R13.1 (Oral dysphagia) to line 350 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS

12) Add Z72.0 (Tobacco use) to line 5 TOBACCO DEPENDENCE
13) Add 92526 (Treatment of swallowing dysfunction and/or oral function for feeding) to lines 19 FEEDING PROBLEMS IN NEWBORNS, 153 FEEDING AND EATING DISORDERS OF INFANCY OR CHILDHOOD, 599 TONGUE TIE AND OTHER ANOMALIES OF TONGUE
14) Add 30020 (Drainage abscess or hematoma, nasal septum) to line 210 SUPERFICIAL ABSCESSES AND CELLULITIS
15) Add 31645 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with therapeutic aspiration of tracheobronchial tree, initial (eg, drainage of lung abscess)) to line 428 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
16) Add J98.09 (Other diseases of bronchus, not elsewhere classified) to line 62 BRONCHIECTASIS
17) Add 43300-43312 (Esophagoplasty (plastic repair or reconstruction), cervical or thoracic approach; with or without repair of tracheoesophageal fistula) to line 231 RUPTURED VISCUS
18) Add 43241 (Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube or catheter) to line 46 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION
19) Add ICD-10 P22.1 (Transient tachypnea of newborn) to line 2 BIRTH OF INFANT and remove from line 11 RESPIRATORY CONDITIONS OF FETUS AND NEWBORN
20) Add 99460-99463 (Initial and subsequent hospital care for normal newborns) to all newborn lines with possible minor conditions:
    a. 11 RESPIRATORY CONDITIONS OF FETUS AND NEWBORN
    b. 21 SYNDROME OF "INFANT OF A DIABETIC MOTHER" AND NEONATAL HYPOGLYCEMIA
    c. 22 OMPHALITIS OF THE NEWBORN AND NEONATAL INFECTIVE MASTITIS
    d. 27 INTRACRANIAL HEMORRHAGES; CEREBRAL CONVULSIONS, DEPRESSION, COMA, AND OTHER ABNORMAL CERERAL SIGNS OF THE NEWBORN
    e. 31 DRUG WITHDRAWAL SYNDROME IN NEWBORN
    f. 36 HEMATOLOGICAL DISORDERS OF FETUS AND NEWBORN
    g. 45 HYPOCALCEMIA, HYPOMAGNESEMIA AND OTHER ENDOCRINE AND METABOLIC DISTURBANCES SPECIFIC TO THE FETUS AND NEWBORN
    h. 106 HEMOLYTIC DISEASE DUE TO ISOIMMUNIZATION, ANEMIA DUE TO TRANSPLACENTAL HEMORRHAGE, AND FETAL AND NEONATAL JAUNDICE
    i. 149 ANEMIA OF PREMATURITY OR TRANSIENT NEONATAL NEUTROPENIA
    j. 296 ADRENAL OR CUTANEOUS HEMORRHAGE OF FETUS OR NEONATE
    k. 648 EDEMA AND OTHER CONDITIONS INVOLVING THE SKIN OF THE FETUS AND NEWBORN
21) Add CPT 45384 and 45385 (Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s)) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
22) For the January 2018 Biennial Review Prioritized List:
    a. Remove CPT 35207 (Repair blood vessel, direct; hand, finger) from line 82 INJURY TO MAJOR BLOOD VESSELS

b. Remove ICD-10 S27.9XXA, S27.9XXD (Injury of unspecified intrathoracic organ) from line 82 and add to line 84 INJURY TO INTERNAL ORGANS
c. Remove ICD-10 S45.301A, S45.301D, S45.302A, S45.302D, S45.309A, S45.309D, S45.311A, S45.311D, S45.312A, S45.312D, S45.319A, S45.319D, S45.391A, S45.391D, S45.392A, S45.392D, S45.399A, S45.399D (injury of superficial vein at shoulder and upper arm level) from line 82 and add to line 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT

23) Modify Guideline Note 106 as shown in Appendix A

**MOTION: To approve the recommendations as stated in the consent agenda. CARRIES 8-0.**

- **Topic: Biennial Review: Prioritization of Novel Treatments**

**Discussion:** Coffman introduced the topic. The prioritization of pairings of high cost or low efficacy treatments is a long standing issue for the HERC. Coffman reviewed the staff proposal is to create two new lines for high cost/low efficacy treatments, one line around line 500 for treatments with some evidence of benefit, but higher cost than other efficacious therapies and one line at the bottom of the list for treatments that are ineffective or where harms outweigh benefits.

Hodges asked about whether guideline notes alone would be adequate to deal with this issue. Coffman replied that only a few guideline notes have been used in this manner. HERC staff have been working with Department of Justice on this proposal. Prescription drugs and other ancillary services, services not normally addressed by the Prioritized List, can be tied to these lines as well as services with CPT codes. The OHA Pharmacy and Therapeutics (P&T) Committee can include prior authorization criteria for fee-for-service to deny coverage for a prescription medication as not being on a covered line on the List.

Hodges requested that all procedures on the Services Recommended for Non-Coverage (SRNC) table be placed on these lower lines to make their noncoverage explicit and available for the plans and the public to see. The SRNC table is currently only available to the public through use of the searchable list tool. Coffman said the SRNC table includes some experimental therapy that cannot be on the List, so staff would need to review the SRNC table prior to making recommendations for adding entries to the new high cost/low efficacy guidelines and can bring back to the next meeting.

Coffman said this meeting is the last meeting to create new lines and that the proposal would not necessarily populate the lines. VBBS/HERC would create these lines and then can populate them later.

Olson expressed concern that adding these lines would allow pairing through the co-morbidity rule. Coffman said guideline note language could be crafted to address potential

co-morbid conditions. Olson wanted to make sure the unintended consequences are considered.

Coffman noted that 3 years ago the HERC approved a guideline with many of these features, which was never implemented. P&T was going to make a list of high cost/low efficacy drugs and the guideline would point to this. This never happened, and now is not considered to be the best policy. P&T would still conduct the evidence reviews on medications, to inform the HERC decisions for inclusions on these lines. P&T has the ability to look at costs, which are not publically discussable. P&T can then inform HERC when they feel that a drug has too high a cost to be cost-effective.

Gibson stated that the objective in creating these two new "baskets" would improve clarity to our constituents. The decision today would not populate the lines, and the items for these lines could be approved by the HERC in the future. He suggested initially only approving the staff recommendation for creation of two new lines.

Pollack asked what would happen for a treatment of a condition with no other treatments available. The answer was that if the treatment was not sufficiently effective or very high cost, then it might be included on these new lines.

Livingston said this is a framework to make the HERC intent clear, and to explicitly define experimental, marginal benefit, etc.

Coffman then reviewed the statement of intent. There is now language in statute that statements of intent are part of the Prioritized List, and are therefore an effective way to convey the HERC's intent. Statements of intent can be modified at any time. Hodges said in her experience, statements of intent are useful for the CCOs. Olson said there needs to be consistency in the definition of marginal benefit or cost effectiveness. Upon further discussion, Gibson felt all the changes reflected in the proposal could move forward, with the ability to make modifications at future meetings as necessary.

At the May meeting there will be further discussion about the definition of cost-effectiveness and how to apply this definition. Potential services, focusing initially on those in the SNRC table, to populate the guideline notes will also be discussed.

**Recommended Actions:**

1) Create two new lines at line 500 and as the last line
    a. Line 500 CONDITION: CONDITIONS FOR WHICH CERTAIN TREATMENTS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS; TREATMENT: MEDICAL AND SURGICAL TREATMENT
    b. Line YYY CONDITION: CONDITIONS FOR WHICH CERTAIN TREATMENTS HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS; TREATMENT: MEDICAL AND SURGICAL TREATMENT
2) Adopt two new guidelines as shown in Appendix C

a. Will bring guidelines back to begin to fill in content at future meetings

3) Adopt a new statement of intent as shown in Appendix C

**MOTION: To approve the new lines, new guidelines and new statement of intent as presented. CARRIES 8-0.**

- **Topic: Pharmacogenetics Testing for Medications for Psychiatric Disorders**

**Discussion:** Smits reviewed the summary document. Pollack commented that for certain populations of patients (e.g. those who have failed multiple medications, patients with multiple side effects) this testing might be justified. However, this population is not clearly defined. Overall, Pollack agrees that this technology is not ready for clinical use. He also raised a concern about the lack of support and infrastructure for genetic counseling in the state.

**Recommended Actions:**

1) Adopt a new diagnostic guideline as shown in Appendix B

**MOTION: To approve the new guideline as presented. CARRIES 8-0.**

- **Topic: Pharmacist medication management guideline**

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

**Recommended Actions:**

1) Modify Guideline Note 64 as shown in Appendix A

**MOTION: To approve the guideline change as presented. CARRIES 8-0.**

- **Topic: Breast Reduction for Macromastia as Treatment for Neck and Back Pain**

**Discussion:** Smits reviewed the summary document. Olson said breast reduction was not a covered service for macromastia until the back line changes made it a possible co-morbid condition treatment; therefore the proposed guideline does not take away a long standing benefit from the OHP population. Williams noted that there was evidence of effectiveness, but that this evidence was low quality. She proposed adding wording to the proposed guideline to reflect this, such as “high quality” evidence. Saboe asked what the cost-effectiveness was of breast reduction. The answer was that no study on this was found in the staff review.

**Recommended Actions:**

1) Adopt a new guideline as shown in Appendix B

**MOTION: To approve the modified guideline. CARRIES 8-0.**

- **Topic: Elective Surgery Guideline and Electronic Cigarettes**

**Discussion:** Livingston introduced the summary on this topic. Pollack asked if this topic included marijuana use. Smits answered that limited evidence to date does not find that casual marijuana use has an impact on surgical outcomes for bariatric surgery. Data for other types of elective surgery is lacking. Hodges argued that the previous guideline wording was "smoking" and that her CCO interpreted this as including marijuana. The proposed modification would remove marijuana from the restrictions.

Allen stated that he was not in favor of allowing smokeless tobacco or vaping prior to elective surgery. Olson stated he was thinking along the same lines because of a perception of inconsistency. Pollack expressed concerned for unintended consequences for patients switching addictions. Williams noted that the evidence did not indicate either way. Gibson noted that smokeless tobacco can cause cancer and is otherwise harmful; more restrictive guidelines are appealing, but he felt that the first proposed staff option was the most consistent with the evidence. Williams argued in favor of staff option 2, as the evidence does not indicate that it is completely harm-free to use smokeless tobacco and e-cigarettes prior to surgery.

The subcommittee looked at the Ancillary Guideline proposed under option 1 and suggested adding wording to clarify that the guideline was about tobacco use and vaping prior to elective surgical procedures rather than "smoking cessation" if vaping and smokeless tobacco was going to be allowed.

There was a motion to approve option 1 to exclude e-cigarettes and smokeless tobacco from the elective surgery guideline (i.e. allow their use), that was seconded. It was voted down aby a 3-4 vote.

There was discussion that HERC did not want to appear to endorse or encourage vaping or smokeless tobacco due to their negative public health effects. However, there is no evidence published about the effect of vaping or smokeless tobacco on elective surgical outcomes.

There was discussion about the goal of this guideline—whether it was to reduce tobacco product use or improve outcomes of elective surgeries. The decision was that the goal was to reduce complications of surgical procedures and therefore reduce overall costs and improve outcomes.

There was a motion to approve option 2 which would disallow the use of e-cigarettes or smokeless tobacco one month prior to surgery. It was seconded, but failed to pass on a 3-4 vote.

Pollack then made a motion to revisit option 1. Subcommittee members agreed that smoking is understood to include marijuana.

There were questions raised about why there are 6 month abstinence requirements for certain surgeries such as spinal fusion. Williams clarified because of the need to get bone growth; the nicotine interferes with bone growth. Other spinal procedures involve removing bone spurs or taking pressure off, but these don't need bone growth for surgery to be successful. Smits clarified that the elective surgical guideline would only apply to surgeries other than those specified to require six-months of cessation. The guidelines with 6 month requirements were also approved.

**Recommended Actions:**

1) Modify Ancillary Guideline A4 as shown in Appendix A
2) Modify guideline notes 8, 100, 112, and 158 as shown in Appendix A

**MOTION: To approve the guideline modifications as presented [Option 1 for Ancillary Guideline A4]. CARRIES 4-3 (Williams, Saboe, and Croswell opposed; Olson abstaining).**

- **Topic: Non-specific Pain Diagnoses**

**Discussion:** There was no discussion about this topic.

**Recommended Actions:**

1) Add ICD-10 G89.21 (Chronic pain due to trauma), G89.28 (Other chronic postprocedural pain) and G89.29 (Other chronic pain) to line 533 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, AND RELATED DISORDERS
    a. Advise HSD to remove ICD-10 G89.21, G89.28 and G89.29 from the Undefined Diagnosis File
2) Staff will consider creation of a new line for the 2020 Biennial Review allowing coverage of limited treatments for chronic pain conditions. This may require the creation of a taskforce.

**MOTION: To approve the recommendations as presented. CARRIES 8-0**

- **Topic: MRI for MS Monitoring**

**Discussion:** Smits reviewed the summary document. The staff proposal was to allow MRIs for patients with multiple sclerosis (MS) with certain symptoms or for monitoring for

patients at high risk for certain medication complications. Olson noted the question of whether MS patients should receive MRIs in certain clinical situations or as a standard yearly test will never be decided with an RCT. Because this is considered standard, he doubts that there will ever be a RCT looking at MRIs with patients randomized to no MRIs, so better evidence is unlikely to be generated. The current proposal will not allow yearly monitoring of asymptomatic patients. The subcommittee members agreed that the current evidence does not support yearly MRIs for asymptomatic patients with MS.

Gibson said it is not right that neurologists are discharging patients from their practice because they cannot get this test. Williams noted that she could relate to the neurologists' frustration that they can't adequately care for their patients.

Hodges said the proposed guideline would be useful for the pharmacy directors of the CCOs to know when to approve an MRI for an MS patient through the exception process which improve consistency across OHP.

**Recommended Actions:**

1) Modify Diagnostic Guideline D10 as shown in Appendix A.

**MOTION: To approve the guideline modification as presented. CARRIES 8-0.**

- **Public Comment:**

  No additional public comment was received.

- **Issues carried forward for next meeting:**
  - Cranial Electrical Stimulation
  - Marginal Benefit/Low Cost-Effectiveness Guidelines for Inclusion of Specific Therapies

- **Next meeting:**

  May 18, 2017 at Clackamas Community College, Wilsonville Training Center, Wilsonville Oregon, Rooms 111-112.

- **Adjournment:**

  The meeting adjourned at 1:00 PM.

# Appendix A
# Revised Guideline Notes Effective 10/1/17

**ANCILLARY GUIDELINE A4, SMOKING CESSATION AND ELECTIVE SURGICAL PROCEDURES**

Smoking cessation is required prior to elective surgical procedures for active tobacco users. Cessation is required for at least 4 weeks prior to the procedure and requires objective evidence of abstinence from smoking prior to the procedure.

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. Reproductive, cancer-related and diagnostic procedures are excluded from this guideline.

The well-studied tests for confirmation of smoking cessation include cotinine levels and exhaled carbon monoxide testing. However, cotinine levels may be positive in nicotine replacement therapy (NRT) users, smokeless tobacco and e-cigarette users (which ~~is not a~~ are not contraindications to elective surgery coverage). In patients using ~~NRT~~ nicotine products aside from combustible cigarettes the following alternatives to urine cotinine to demonstrate smoking cessation may be considered:

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

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, 112 and 159.

**DIAGNOSTIC GUIDELINE D10, MRI IN MULTIPLE SCLEROSIS**

MRI is a diagnostic test for multiple sclerosis and should not be used for routine monitoring of disease.

MRI may be considered in the following circumstances:

1) Suspected drug failure in the setting of clinical relapse in patients with objective changes in neurological status or documented new clinical symptoms such as urinary urgency or cognitive changes
2) Evaluation of a clear objective progression in clinical symptoms in patients with previously relapsing disease to rule out ongoing inflammatory disease when conversion to secondary progressive MS is suspected
3) Patients who require enhanced pharmacovigilance, including
    a. Yearly monitoring for patients treated with natalizumab who are JCV seropositive

b. One MRI for patients who switch from natalizumab to other therapeutics (including fingolimod, alemtuzumab and dimethyl fumarate) one year after the switch from natalizumab

**GUIDELINE NOTE 8, BARIATRIC SURGERY**

*Lines 30,589*

A) Bariatric surgery is included under the following criteria:Age ≥ 18
B) The patient has
   1) a BMI ≥ 35 with co-morbid type II diabetes for inclusion on Line 30 TYPE 2 DIABETES MELLITUS; OR
   2) BMI >=35 with at least one significant co-morbidity other than type II diabetes (e.g., obstructive sleep apnea, hyperlipidemia, hypertension) or BMI >= 40 without a significant co-morbidity for inclusion on Line 589
C) No prior history of Roux-en-Y gastric bypass or laparoscopic adjustable gastric banding, unless they resulted in failure due to complications of the original surgery.
D) Participate in the following four evaluations and meet criteria as described.
   1) Psychosocial evaluation: (Conducted by a licensed mental health professional)
      a) Evaluation to assess potential compliance with post-operative requirements.
      b) Must remain free of abuse of or dependence on alcohol during the six-month period immediately preceding surgery. No current use of any nicotine product 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 illicit drugs. Tobacco and nicotine abstinence to be confirmed in ~~active smokers~~ users by negative cotinine levels at least 6 months apart, with the second test within 1 month of the surgery date.
      c) No mental or behavioral disorder that may interfere with postoperative outcomes[1].
      d) Patient with previous psychiatric illness must be stable for at least 6 months.
   2) Medical evaluation: (Conducted by OHP primary care provider)
      a) Pre-operative physical condition and mortality risk assessed with patient found to be an appropriate candidate.
      b) Optimize medical control of diabetes, hypertension, or other co-morbid conditions.
      c) Female patient not currently pregnant with no plans for pregnancy for at least 2 years post-surgery. Contraception methods reviewed with patient agreement to use effective contraception through 2nd year post-surgery.
   3) Surgical evaluation: (Conducted by a licensed bariatric surgeon associated with program[2])

a) Patient found to be an appropriate candidate for surgery at initial evaluation and throughout period leading to surgery while continuously enrolled on OHP.
b) Received counseling by a credentialed expert on the team regarding the risks and benefits of the procedure[3] and understands the many potential complications of the surgery (including death) and the realistic expectations of post-surgical outcomes.

4) Dietician evaluation: (Conducted by licensed dietician)
   a) Evaluation of adequacy of prior dietary efforts to lose weight. If no or inadequate prior dietary effort to lose weight, must undergo six-month medically supervised weight reduction program.
   b) Counseling in dietary lifestyle changes

E) Participate in additional evaluations:
   1) Post-surgical attention to lifestyle, an exercise program and dietary changes and understands the need for post-surgical follow-up with all applicable professionals (e.g. nutritionist, psychologist/psychiatrist, exercise physiologist or physical therapist, support group participation, regularly scheduled physician follow-up visits).

[1] Many patients (>50%) have depression as a co-morbid diagnosis that, if treated, would not preclude their participation in the bariatric surgery program.

[2] All surgical services must be provided by a program with current certification by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP), or in active pursuit of such certification with all of the following: a dedicated, comprehensive, multidisciplinary, pathway-directed bariatric program in place; hospital to have performed bariatrics > 1 year and > 25 cases the previous 12 months; trained and credentialed bariatric surgeon performing at least 50 cases in past 24 months; qualified bariatric call coverage 24/7/365;appropriate bariatric-grade equipment in outpatient and inpatient facilities; appropriate medical specialty services to complement surgeons' care for patients; and quality improvement program with prospective documentation of surgical outcomes. If the program is still pursuing (MBSAQIP) certification, it must also restrict care to lower-risk OHP patients including: age < 65 years; BMI < 70; no major elective revisional surgery; and, no extreme medical comorbidities (such as wheel-chair bound, severe cardiopulmonary compromise, or other excessive risk). All programs must agree to yearly submission of outcomes data to Division of Medicaid Assistance Programs (DMAP).

[3] Only Roux-en-Y gastric bypass, laparoscopic adjustable gastric banding and sleeve gastrectomy are approved for inclusion.

**GUIDELINE NOTE 64, PHARMACIST MEDICATION MANAGEMENT**

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

Pharmacy medication management services must be provided by a pharmacist who has:

1) A current and unrestricted license to practice as a pharmacist in Oregon

# Appendix A
# Revised Guideline Notes Effective 10/1/17

~~2) Services must be provided based on referral from a physician or licensed provider or health plan.~~

3) Documentation must be provided for each consultation and must reflect ~~collaboration~~ communication with the patient's primary care ~~physician or licensed~~ provider. Documentation should model SOAP charting; must include patient history, provider assessment and treatment plan; follow up instructions; be adequate so that the information provided supports the assessment and plan; and must be retained in the patient's medical record and be retrievable

**GUIDELINE NOTE 100, SMOKING AND SPINAL FUSION**

*Lines 51,154,205,259,351,366,406,482,532,561*

Non-emergent spinal arthrodesis (CPT 22532-22634) is limited to patients who are non-smoking and abstinent from any nicotine product for 6 months prior to the planned procedure, as shown by negative cotinine levels at least 6 months apart, with the second test within 1 month of the surgery date. Patients should be given access to appropriate smoking cessation therapy. Non-emergent spinal arthrodesis is defined as surgery for a patient with a lack of myelopathy or rapidly declining neurological exam.

**GUIDELINE NOTE 106, PREVENTIVE SERVICES**

*Line 3*

Included on this line are the following preventive services:

1. US Preventive Services Task Force (USPSTF) "A" and "B" Recommendations in effect and issued prior to January 1, 2016:
   http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/
   a. USPSTF "D" recommendations are not included on this line or any other line of the Prioritized List
2. American Academy of Pediatrics (AAP) Bright Futures Guidelines:
   http://brightfutures.aap.org. Periodicity schedule available at http://www.aap.org/en-us/professional-resources/practice-support/Periodicity/Periodicity%20Schedule_FINAL.pdf.
   a. Screening for lead levels is defined as blood lead level testing and is indicated for Medicaid populations at 12 and 24 months. In addition, blood lead level screening of any child between ages 24 and 72 months with no record of a previous blood lead screening test is indicated.
3. Health Resources and Services Administration (HRSA) Women's Preventive Services - Required Health Plan Coverage Guidelines:
   As retrieved from http://www.hrsa.gov/womensguidelines/ on 1/1/2017.
4. Immunizations as recommended by the Advisory Committee on Immunization Practices (ACIP):
   http://www.cdc.gov/vaccines/schedules/hcp/index.html

# Appendix A
# Revised Guideline Notes Effective 10/1/17

## 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 (ICD-10-CM J43.9) and all of the following:

A) BMI ≤31.1 kg/m2 (men) or ≤32.3 kg/m 2 (women)
B) Stable with ≤20 mg prednisone (or equivalent) dose a day
C) Pulmonary function testing showing
    1) Forced expiratory volume in one second (FEV 1) ≤ 45% predicted and, if age 70 or older, FEV 1≥ 15% predicted value
    2) Total lung capacity (TLC) ≥ 100% predicted post-bronchodilator
    3) Residual volume (RV) ≥ 150% predicted post-bronchodilator
D) $PCO_2$, ≤ 60 mm Hg (PCO 2, ≤ 55 mm Hg if 1-mile above sea level)
E) $PO_2$, ≥ 45 mm Hg on room air ( PO 2, ≥ 30 mm Hg if 1-mile above sea level)
F) Post-rehabilitation 6-min walk of ≥ 140 m
G) Non-smoking and abstinence from any nicotine product for 6 months prior to surgery, as shown by negative cotinine levels at least 6 months apart, with the second test within 1 month of the surgery date.

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).

*Editor's note: Line D) above (regarding PCO2 was unintentially omitted from meeting materials. There was no staff recommendation to eliminate that line.) It has been corrected here to show the intended guideline note.*

## GUIDELINE NOTE 159, 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 and abstinent from any nicotine product for 6 months prior to surgery, as shown by negative cotinine levels at least 6 months apart, with the second test within 1 month of the surgery date.

# Appendix B
# New Guideline Notes Effective 10/1/17

**DIAGNOSTIC GUIDELINE DXX, PHARMACOGENETICS TESTING FOR PSYCHIATRIC MEDICATION MANAGEMENT**

Pharmacogenetics testing for management of psychiatric medications is not a covered service.

**GUIDELINE NOTE XXX, BREAST REDUCTION SURGERY FOR MACROMASTIA**

*Line 563*

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

# Appendix C
# New Statement of Intent and Guideline Notes Effective 1/1/18

**STATEMENT OF INTENT 3, THERAPIES WITH MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS**

It is the intent of the Commission that therapies that exhibit one or more of the following characteristics generally be given low priority on the Prioritized List:

i. Marginal or clinically unimportant benefit
ii. Very high cost in which the cost does not justify the benefit
iii. Significantly greater cost compared to alternate therapies when both have similar benefit
iv. Significant budget impact that could affect the overall Prioritized List funding level

Where possible, the Commission prioritizes pairings of condition and treatment codes to reflect this lower priority, or simply does not pair a procedure code with one or more conditions if it exhibits one of these characteristics.

As codes for prescription drugs, durable medical equipment & supplies, certain adjunctive procedures and other ancillary services are not typically included on the Prioritized List and are not always billed in conjunction with diagnosis codes, it is more difficult to indicate the importance of these services through the prioritization process. Through evidence reviews conducted by one of its subcommittees, the Pharmacy and Therapeutics Committee, or other reputable sources and based on these reviews, HERC prioritizes such services regarded as having low importance when prescribed for certain conditions on Line 500 or Line YYY and lists the relevant condition/treatment pairings in Guideline Notes AAA or BBB.

**GUIDELINE NOTE AAA, TREATMENTS WITH MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS FOR CERTAIN CONDITIONS**

The following treatments are prioritized on Line 500 for the conditions listed here:

| CONDITION | TREATMENT |
|---|---|
| *<Note: to be populated at future meetings>* | |
| | |
| | |

# Appendix C
# New Statement of Intent and Guideline Notes Effective 1/1/18

**GUIDELINE NOTE BBB, TREATMENTS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS**

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

| CONDITION | TREATMENT |
|---|---|
| *<Note: to be populated at future meetings>* | |
| | |
| | |

**MINUTES**

**Evidence-based Guidelines Subcommittee**

Clackamas Community College
Wilsonville Training Center, Rooms 111-112
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
April 6, 2017
2:00-5:00pm

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**Members Present**: Wiley Chan, MD, Chair; Beth Westbrook, PsyD; Alison Little, MD, MPH; Kim Tippens, ND, MSAOM, MPH; George Waldmann, MD; Devan Kansagara, MD.

**Members Absent:** Eric Stecker, MD, MPH, Vice-Chair;

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

**Also Attending**: Adam Obley, MD, Val King MD, MPH, and Craig Mosbaek (OHSU Center for Evidence-based Policy), Veronica Tofflemire (Patient), Larry McKnight (patient family), Tracy Titus (Patient), Martha Sevchik (Patient), Mary Ellen Edwards (Patient), Laura Samson (Patient), Marjory Cicerich (Patient), Dick Bancraft (Patient), David Sibell (OHSU), Carl Balog, Ginger Pearson (Patient), Sandy Christiansen (OHSU), Sydney Rose (OHSU), illegible (OHSU), Lucille Guill (OHSU), Kim Mauer, OHSU, Rebeca Monreal (Salem Pain and Spine), Mary Seimens (patient) .

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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

Minutes from the February 2, 2017 meeting were reviewed and approved 6-0.

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## 3. STAFF REPORT

Coffman introduced Devan Kansagara, MD. Dr. Kansagara is an internist at the Portland Veteran's Administration Hospital and is on the faculty at OHSU. Coffman also reviewed the upcoming new coverage guidance topics. He expects that staff will take advantage of the discretion the Commission gave to allow it to take topics out of order in order to optimize staff resources. Upcoming topics include the following:

- Multisector Interventions for Prevention of Unintended Pregnancies (initial review will be delayed until September)
- Opportunistic Salpingectomy for Ovarian Cancer Prevention
- Urine Drug Testing
- Planned Out-of-Hospital Birth
- CardioMems for Heart Failure Monitoring
- Recurrent Otitis Media
- Gastrointestinal Motility Tests

## 4. LOW BACK PAIN: CORTICOSTEROID INJECTIONS

Adam Obley reported the results of the additional evidence search requested by the committee at the February meeting. One request was to report results for pain-related outcomes, which had been excluded from scope of the original report. Obley presented a new table showing the results. In the Chou systematic review, epidural steroid injections were associated with a small but statistically significant improvement in immediate-term pain compared with controls. However the benefit did not extend beyond the immediate term and did not reach the prespecified threshold for minimal clinically-important differences. Additional studies published after the end of the Chou review showed mixed results, with the highest-quality studies showing no benefit over comparators.

The second request from the subcommittee was to review studies which limited the study population to patients with radiculopathy associated with imaging correlates of spinal stenosis or a herniated disc, and which used an image-guided transforaminal approach. In this case, some studies showed a small but statistically-significant benefit for pain and function. The benefits did not reach thresholds of minimal clinically-important differences.

Livingston gave a brief overview of the studies which used the modern standard of care. The majority found no statistically significant differences.

Chan asked about the Ghahreman study cited at the last meeting as the "gold standard." It showed a benefit for pain but not function. But other studies used similar criteria and most showed no benefit for pain or function.

Livingston reviewed the GRADE table, with additional language describing the evidence regarding pain. She also reviewed the change that the recommendation for steroid injections for patients with radiculopathy, changing from a strong to a weak recommendation against coverage. The rationales have also been updated accordingly.

Chan said that the evidence doesn't show efficacy for a benefit in function or for a clinically important benefit for immediate-term pain. Thus the major question is whether the recommendation should be weak or strong in that context. Tippens said that this might be true for an intervention with few risks; Obley concerned that based on the evidence these procedures are safe and generally well-tolerated. Kansagara agreed that harms would be a factor. Waldman said that the evidence should take precedence. Kansagara said that it should be weak either for or against because of the lack of certainty of the ratio of benefit to harm.

Obley clarified that there is no meta analysis including the newer trials; rather this is just a list of the trials allowing the subcommittee to gauge whether these new studies would likely change the conclusions in the Chou review. Can you recommend against an intervention only based on evidence that there is no effect? Or can you recommend against because of the intervention cannot reliably be proven to be effective? Kansagara said that it depends on the condition—for an asymptomatic issue such as screening, the burden would fall one direction. For symptomatic conditions, it changes the burden. Chan agreed, but questioned whether it is appropriate to spend limited resources on something like this when we have other treatments for which there is greater confidence of benefit?

Kansagara suggested the committee might consider putting restrictions on such a procedure so that it would be used only in unusual circumstances rather than as an initial or routine treatment.

Coffman introduced Dr. Janna Friedly and Tim Keenen, ad hoc experts for this topic.

Dr. Timothy Keenen is board-certified as an orthopedic surgeon and practices as Pacific Spine Specialists in Tualatin. He is a member of the American Academy of Orthopaedic Surgeons, and is past president of the Oregon Chapter. He is a member of the North American Spine Society and several other professional societies. He is also a former member of HTAS. He has also received consulting fees and travel expenses from several device manufacturers, most prominently from Depuy Synthes for spine-related products.

Dr. Janna Friedly is a board certified physiatrist and UW assistant professor in the Department of Rehabilitation Medicine. She is the medical director of the outpatient Rehabilitation Medicine clinics and the Amputee Rehabilitation Program at Harborview Medical Center. She completed the Rehabilitation Medicine Scientist Training Program (RMSTP) K12 fellowship in 2008. Dr. Friedly conducts outcomes research related to back pain treatments in the Comparative Effectiveness, Cost and Outcomes Research Center at the University of Washington. She was a co-author on the Chou review that served as a basis for the report.

Dr. Friedly said the additional analysis performed appeared appropriate to her. Weighing the weak results with the strong preferences is appropriate as well.

Little expressed support for the updated draft coverage guidance, with the change to a weak recommendation against coverage for patients with radicular pain.

Several members of the audience (Tracy Titus, Martha Sevcik, Mary Ellen Edwards, Laura Samdow, Marjoy Cicerich, Richard Bancroft, Lucille Guill, Mary Steimens) gave testimony about personal experience as patients who received steroid injections or similar treatments. Each spoke of the pain they and their loved ones experience, and the disabling impact on their life as well as the lives of their families. Each spoke support of coverage of these procedures. Some mentioned lasting benefits from these injections, reductions in opioids or surgery, and the improved ability to function in daily life. Some mentioned the risk of suicide in patients whose pain cannot be treated. They said these injections improved their ability to drive, walk, leave a wheelchair, and live normal life with family and friends in meaningful ways.

One member asked whether any members of the subcommittee had personal experience with these procedures. Chan spoke of his own experience, clarifying that his experience wasn't like the experience of those who testified. He had radicular back pain, and at the time he would have said those injections prevented him from seeking surgery. The problem is that this is anecdotal evidence. He does not know

whether he would have gotten better or worse without the injection. In fact, there was a cardiologist undergoing the same procedure the same day but had no benefit and required surgery, ending up with post-laminectomy back pain. Individuals can have an effect that's better or worse than the average, but the evidence is the best thing we have to go on.

Staff and committee members acknowledged that these stories are common, but explained that randomized trials are the best way to understand the effect of medical treatments and the evidence appears to show no greater benefit than placebo injections and no difference in surgery rates or opioid use. Some patients brought other information supporting the use of these procedures.

In addition, several health care professionals spoke of the benefits of these interventions.

Sydney Rose, from OHSU compared this to uncomplicated hernias. If surgery is not covered for these patients they generally don't seek further treatment, whereas chronic pain patients generally seek treatment. Patients may end up seeking care in the emergency room or seeking surgery.

Chidi Ani, an anesthesiologist from OHSU said that he could not recognize disparities when his practice was limited to surgical anesthesia. Anesthetics are the same regardless of payer. When he went into chronic pain he saw disparities for Medicaid patients. Medicaid patients and those with few resources are most affected by these recommendations. These patients report having been rejected by various providers. Even a request for four visits may not be available for these patients. Cuts like this take away from people who have nothing, and the least ability to compensate for potential errors.

Carl Balog introduced himself as a pain management physician in Portland. First, he supported the information that was provided by several professional societies in support of their guidelines and criticisms of the Chou review. He said that the world of pain is watching Oregon. There will be vocal criticism because of some of the methodology the committee followed. He expressed concerned that no interventional pain specialist is involved. He said these injections are diagnostic and guide therapy. They help patients confirm the nature of their problem, then send them to a physician or surgeon as appropriate. Patients will suffer if they get no specialty or guideline-approved treatments.

Rebecca Monreal, a pain physician from Salem, she said she brought a stack of evidence she sees as strong evidence. There would be no pain medicine specialty if there were no evidence? How is it possible other insurers find enough evidence but the subcommittee sees a lack of evidence. She also said that chiropractic and acupuncture, while they can be helpful to some patients, are no better than placebo but are now covered for the Oregon Health Plan. Obley briefly reviewed the studies and determined that either they did not meet criteria to review, are related to other interventions or are already included in the coverage guidance.

Obley reviewed the methodology for the report.

Coffman noted that the subcommittee has published its response to over 90 comments, including some from the societies Balog mentioned. Livingston confirmed that diagnostic use of injections is outside of scope.

Keenen arrived and offered his perspective. He said that despite the study results reviewed, a certain group of patients with radiculopathy (pain down the buttocks, thigh, calf and foot) do benefit from transforaminal epidural steroid injections to the low back. For some the benefit lasts a few weeks until

the condition resolves; for others the benefit lasts until their surgery. He would hate to see the tool of steroid injections go away knowing there are cases where it makes a tremendous difference in people's lives. He said the literature isn't perfect and doesn't fit with his experience to say that it's an ineffective tool that should be abandoned. He said it is an overused tool, but there continues to be an effective use. He suggested adoption of a specific guidance which would cover transforaminal injection for radicular pain, with repeat injections only after documented relief for a significant time.

Chan said that anecdotal evidence is very prone to bias. Keenen acknowledged that it is a difficult position and that he appreciates the value of controlled prospective studies. Friedly said she has similar feelings. You see a big disconnect between the randomized trials and the anecdotal reports. She said that when physicians treat patients, they don't have a direct control like in a controlled trial. There is no easy answer. The breadth of the literature that has been reviewed is appropriate and there are no stones unturned in terms of the literature and how the data has been analyzed.

Kansagara asked for additional information—was the upper bound of the confidence interval near the threshold for minimally-clinical important difference? If so, it could be reasonable to offer these injections as a second line treatment. Livingston said that the weighted mean difference in pain was 7.55 on a 100-point scale. The upper bound of the confidence interval was an 11.4 point improvement. One a 100 point scale, the threshold for a clinically-important difference was defined a priori as 15 points.

Chan and Friedly discussed patient selection. Friedly said that studies have attempted to identify subgroups that improved with these injections. There are no imaging features that correlate with better outcomes, with the caveat that the patients with herniated discs and radiculopathy tend to do better than other diagnoses, but within that category it is difficult to predict who will get relief. Factors associated with poor outcomes include depression, anxiety and psychosocial issues which predict poor outcomes regardless of treatment.

Coffman asked about a bimodal distribution where there is a large group of responders and a large group of nonresponders, which could average out to no effect. Obley said that some studies included in the coverage guidance assessed categorical outcomes (whether the number of patients with a positive outcome differed among groups). The Chou review showed worse results for steroids with categorical outcomes than with average outcomes. Keenen agreed that he can't tell beforehand which patients will respond to injections. He said it is a matter of trying the injections once or twice and repeating only if there is a positive response. Keenen noted that a few years ago, the subcommittee discussed kyphoplasty, which wasn't supported by the evidence, but the group agreed to recommend coverage for a limited group of patients who were hospitalized with 4 weeks of symptoms. In other cases, the subcommittee recommended noncoverage and the room was empty—the number of people present testify to the value people place on these procedures.

The subcommittee discussed the option of offering coverage for a subgroup of patients. Staff presented the following language which was in line with recommendations from society guidelines and expert testimony.

## Proposed recommendation

Epidural steroid injections for low back pain are recommended for coverage (weak recommendation) when:

- Only with radicular pain
- Lumbar spine pain with radiculopathy is present for at least six weeks duration,
- Radicular pain is in a corresponding dermatomal distribution, and aligned (foraminal stenosis or herniated disk) with MRI/CT findings demonstrating nerve compression
- A transforaminal approach is used
- Pain is intractable and at least 6 weeks of evidence-based conservative therapy has failed,
- Continued noninterventional approaches are used
- Coverage of repeat injections requires clinically meaningful improvement for at least 2 weeks (>30% based on validated measures) in pain and function from a prior injection,
- There is a maximum of three injections in six months, AND
- Image guidance is used

Tippens said that this may be different than other situations because of the opioid use crisis and because people with chronic pain feel like they have no options. She expressed support for the language allowing coverage with the conditions above. Kansagara gave a rationale for supporting language like this because of the limited harms and evidence of limited benefit for immediate-term pain relief, especially in the context of study limitations. Westbrook suggested that there might be criteria based on disability.

Little said that she was the one that requested the additional table highlighting the studies that most closely matched the criteria above in terms of population and intervention and based on the results she could not vote to recommend coverage, even with limitations such as those proposed.

After additional discussion, there was a motion to refer the draft coverage guidance to VbBS and HERC as presented in the meeting materials.

Motion approved 5-1 (Tippens opposed).

After the motion passed there was additional discussion about the rationale but no motion was made.

## DRAFT HERC Coverage Guidance

Epidural corticosteroid injections are not recommended for coverage for the treatment of low back pain with radiculopathy (weak recommendation).

Epidural corticosteroid injections are not recommended for coverage for the treatment of low back pain without radiculopathy (e.g., spinal stenosis, non-radicular pain) (strong recommendation).

Corticosteroid injections (including facet joint, medial branch, and sacroiliac joint) are not recommended for coverage for the treatment of low back pain (strong recommendation).

## 5. LOW BACK PAIN: MINIMALLY INVASIVE AND NON-CORTICOSTEROID PERCUTANEOUS INTERVENTIONS

Due to lack of time the subcommittee did not discuss the draft coverage guidance but heard public testimony. Chan extended the meeting to allow testimony. Westbrook had to leave but other members were able to stay.

Several patients (Veronica Tofflemeier, Ginger Pearson, Richard Bancroft) gave testimony about the benefits of radiofrequency ablation and other technologies for the the disability and pain caused by various low back pain conditions. Some reported reductions in opioid use and ineffectiveness of other treatments. One reported abusing alcohol and contemplating suicide after opioid medications were cut off and before receiving a radiofrequency ablation which restored his quality of life.

Dr. Sandy Christiansen read a statement to Medicare contractor Noridian on behalf of Dr. Steve Cohen (OHSU) describing a study comparing intraarticular injections, medical branch blocks and sham saline intramuscular injections injections. Patients in the first two groups have had a higher success rate than the sham groups. He asked to withhold the decision until the study is published.

Sydney Rose, a physician and anesthesiologist at OHSU but also a patient and relative of patients who have benefit. She expressed concern about opioid overdoses and deaths related to opioids. Oregon has the second-highest rate of drug abuse in the nation. At the same time chronic pain is undertreated. Medical practitioners are in a bind—they need to find effective treatments without endangering public health. She referred to the CDC opioid guideline which refer to epidural steroid injections, medial branch blocks and denervation as an alternative for short-term relief. She recommended coverage these procedures to best serve patients.

David Sibell, professor at the OHSU comprehensive pain center. He discussed medial branch blocks and radiofrequency ablation. He said that there are a number of studies showing efficacy and others which do not. He said that the techniques used correspond with the outcomes. Studies using pulsed radiofrequency, inappropriate needle placement or the wrong enrollment criteria should not be weighted equally. He listed several studies which use the Spine Intervention Society criteria, and suggested these be weighted more heavily. He also encouraged looking at studies reporting 100 percent relief, and the studies have been repeated. The evidence is mixed but the good evidence is solid. He said he would be more likely to see patients on the Oregon Health Plan if he were allowed to treat them.

Kim Mauer, director of the OHSU Comprehensive Pain Center spoke next, and offered studies meeting the criteria above. She advocated for coverage for medial branch blocks and radiofrequency denervation. Patients don't have a lot of options, and few clinics will see them. She expressed appreciation for the work of the Commission and the difficult decisions before them.

Discussion of this topic will continue at the June 1 meeting.

## 7. ADJOURNMENT

The meeting was adjourned at 5:10 pm. The next meeting is scheduled for June 1, 2017 from 2:00-5:00 pm at Clackamas Community College, Wilsonville Training Center, Rooms 111-112, 29353 SW Town Center Loop E, Wilsonville, Oregon 97070

**MINUTES**

**Health Technology Assessment Subcommittee**

Clackamas Community College
Wilsonville Training Center, Rooms 111-112
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
April 20, 2017
1:00-4:00pm

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**Members Present**: Derrick Sorweide, DO, (Chair); Mark Bradshaw, MD; Vinay Prasad , MD, MPH; Chris Labhart; Kathryn Schabel, MD (arrived at 1:30).

**Members Absent:** Som Saha, MD, MPH; Leda Garside, RN, MBA.

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

**Also Attending**: Adam Obley, MD, Craig Mosbaek (OHSU Center for Evidence-based Policy); Bruce Boston (OHSU); Andrew Ahmann (OHSU); Joannie Kono (OHSU); Renee Taylor (Dexcom).

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## 1. CALL TO ORDER

Derrick Sorweide called the meeting of the Health Technology Assessment Subcommittee (HTAS) to order at 1:00 pm.

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## 2. MINUTES REVIEW

Minutes from the February 16, 2017 meeting were reviewed and approved 4-0 (Schabel not present).

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## 3. STAFF REPORT

Coffman reported that Dr. Kathryn Schabel has now been officially appointed to the subcommittee. He also reported that HERC approved the planned coverage guidance topics. Staff has been given discretion to alter the order in order to best use staff resources. The new topics are (in priority order):

- Colon Cancer Screening Modalities
- Gene Expression Profiling for Prostate Cancer
- Gene Expression Profiling for Breast Cancer
- Acellular Dermal Matrix for Breast Reconstruction
- Prostatic Urethral Lifts for Treatment of Benign Prostatic Hypertrophy
- Hepatic Artery Infusion Pump Chemotherapy
- Sacral Nerve Stimulation
- Genetic Testing of Thyroid Nodules

## 4. BREAST CANCER SCREENING IN WOMEN AT ABOVE-AVERAGE RISK

Adam Obley reviewed the public comment disposition. The subcommittee discussed some potential responses to the concerns addressed by the comments. Comments from Hologic referenced a letter required by state statute to be sent to women determined by their radiologist to have dense breasts and encourages women to discuss this with their doctors. However, the subcommittee reviewed the points leading to the recommendation for noncoverage of digital breast tomosynthesis for this population: there is poor inter-rater reliability as to what constitutes dense breasts; breast density changes over time, the evidence doesn't show that dense breasts alone increase breast cancer risk to a lifetime risk of 20%. In addition there is no evidence that enhanced screening reduces mortality, though there is some data about increased cancer detection and decreased false positives. Members expressed concerned that the letter will create confusion among patients and primary care providers since women will want to discuss the letter with their providers, but no interventions to address the increased risk associated with dense breasts show sufficient evidence to warrant coverage.

Shaffer presented suggested language to respond to the concerns raised in the public comment disposition. After discussion, the subcommittee accepted Shaffer's recommended responses for the public comment disposition.

In additional discussion, the subcommittee made a few clarifying edits to the recommendation language, GRADE-informed framework and public comment disposition document:

- On the bullet about other mutuations which result in a 20% lifetime risk, the subcommittee asked that the word "germline" be added to the coverage recommendation to distinguish the mutations under discussion from acquired mutations.
- Defined high dose chest irradiation as being >20 Grey.
- Corresponding edits were made to the relevant GRADE table recommendation and rationale columns.

A motion was made to refer the draft coverage guidance to HERC and VbBS. Motion approved 5-0.

DRAFT HERC Coverage Guidance

Annual screening mammography and annual screening MRI are recommended for coverage for women at above-average risk of breast cancer *(weak recommendation)*. This coverage, beginning at 30 years of age, includes women who have one or more of the following:

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

For women with a history of high dose chest radiation (>= 20 Grey) before the age of 30, annual screening MRI and annual screening mammography are recommended for coverage beginning 8 years after radiation exposure or at age 25, whichever is later *(weak recommendation).*

For women with both a personal history and a family history of breast cancer, annual mammography, annual breast MRI and annual breast ultrasound are recommended for coverage *(weak recommendation)*.

For women with increased breast density, supplemental screening with breast ultrasound, MRI, or digital breast tomosynthesis is not recommended for coverage *(weak recommendation)*.

Breast PET-CT scanning and breast-specific gamma imaging are not recommended for coverage for breast cancer screening in any risk group *(strong recommendation)*.

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**5. Continuous Glucose Monitoring in Diabetes Mellitus**

Dr. Schabel, who arrived during the discussion on the previous topic, introduced herself as an OHSU orthopedist specializing in hip and joint replacement.

Coffman and Gingerich introduced the ad hoc experts for this topic . Andrew Ahmann, MD, an adult endocrinologist, is Professor of Medicine at OHSU in the Division of Internal Medicine, Division of Endocrinology, Diabetes and Metabolism and the Harold Schnitzer Diabetes Health Center. Bruce Boston, MD, is a pediatric endocrinologist at OHSU.

Jessica Castle, MD (adult endocrinology) and Kathryn Woods, MD (pediatric endocrinology) are also appointed experts on this topic but were not available for today's meeting.

Obley reviewed the additional research conducted at the subcommittee's request on psychosocial outcomes and parental quality of life. Type 1 diabetes in general is associated with some poor neurocognitive outcomes. Hypoglycemia in particular shows an association with poor neurocognitive outcomes. Parental psychological distress is associated with poorer metabolic control in children with type 1 diabetes. He has also confirmed the experts' assertion that newer-model continuous glucose monitors are more accurate than devices from 10-15 years ago. Some of the studies in the literature were conducted with older monitors.

Shaffer reviewed the changes to the draft coverage guidance. Many edits to the GRADE table were simply for clarity or consistency. He reviewed the substantive changes.

In the draft presented for the meeting materials, coverage was recommended for children and adolescents with type 1 diabetes as well as adults. There are limitations of the evidence, but Shaffer added a recommendation for coverage based on values and preferences and the supplemental literature on parental quality of life and the potential developmental impacts of low-level hypoglycemia. The recommendation was initially made with the same criteria as for adults.

The criteria for adults was changed as well to allow coverage with adults with type 1 diabetes, HBA1c <8.0 and frequent or severe hypoglycemia (the previous draft required both frequent and severe

hypoglycemia). Sorweide asked about defining "frequent" and "severe." Experts said that severe hypoglycemia requires assistance from others, while frequent hypoglycemia has no standard definition.

Ahmann thanked staff for the thorough analysis but asked for consideration of clinical and practical experience of providers treating patients as well, since the studies do not address all outcomes. He described a blinded observational study which appeared to show that CGM detects hypoglycemia patients aren't aware of; it would be costly and difficult or impossible to conduct a large enough study to detect the impact of severe hypoglycemic events, as they are rare and patients aren't likely to test their blood sugar manually as often as would be needed for a comparison.

Boston added that for children, with manual monitoring, the child can get hypoglycemia between two checks. Parents may need to check the child's blood sugar every hour through the night and still miss some episodes. Patients of children with type 1 diabetes have a reasonable fear of the child dying during the night due to hypoglycemia, especially for younger children in whom CGM hasn't been studied. But he said parents have figured this out—they know about the "dead in bed syndrome." Before CGM, parents would take turns checking their child's blood glucose values multiple times through the night for years on end. CGM allows them to sleep through the night without fear of undetected hypoglycemia resulting in their child's death. He also said the cost of 20 to 30 manual checks per day is also a significant factor. Based on his experience and published studies, use of CGM in children is increasing rapidly and improves parental quality of life.

Obley confirmed that there is high confidence from the research that CGM improves parental quality of life. There is not good evidence it improves metabolic outcomes. Prasad said he sees parental quality of life as a hard outcome and the reason coverage is recommended. The rationale for recommending coverage for children is based on parental quality of life related to fear of hypoglycemia, not metabolic control (HbA1c levels). Since risk of hypoglycemia can occur regardless of HbA1c levels, and because of the concerns about hypoglycemia's effect on neurocognitive outcomes, the recommendation was altered to cover CGM for children and adolescents under age 21 with type 1 diabetes without the additional criteria used for adults. Shaffer noted that the recommendation also covers the combined insulin pumps/CGM units, at least one of which is approved for children.

Shaffer also described changes around coverage for pregnant women with type 1 diabetes. The meeting materials contained edits to allow continuation of continuous glucose monitors for women with type 1 diabetes already using CGM when they become pregnant. Gingerich read a comment from Dr. Castle, suggesting that the coverage guidance be clarified to allow continued coverage of CGM supplies for women on CGM when they become pregnant. She also said that much of the limited data for pregnant women was collected using older, less accurate devices. Risk of fetal harms is high in women with type 1 diabetes during pregnancy. Ahmann said that, in addition, some women may want to improve glycemic control when they become pregnancy or even when they prepare for pregnancy, as the fetus is actually quite vulnerable to variations in blood glucose even before women are aware they are pregnant. It is difficult to conduct a study on this population, so the limited evidence should take into account these difficulties as well as the likely difference between a research population and the typical population. The coverage recommendation was edited to allow initiation of CGM for women with type 1 diabetes who are pregnant or who plan to become pregnant.

The subcommittee discussed the duration of treatment and determined that once a patient qualifies for a CGM, coverage should not cease (for example, CGM coverage should not cease upon an adolescent reaching adulthood, the end of a pregnancy or an adult achieving an HbA1c level of 8.0 while using

CGM.) After testimony from Joannie Kono, a diabetes educator at OHSU, the subcommittee agreed this would also be true for children whose condition improves with CGM. Bradshaw stated that for a plan, it can be difficult to discontinue coverage for an approved device, and it creates an administrative burden in addition to the clinical issues. After discussion the subcommittee kept the language allowing continued coverage after a demonstration of adherence at the first follow-up visit.

Ahmann asked about the paragraph referencing insulin pumps. Obley explained that the paragraph was included to support coverage of units with an integrated insulin pump without regard to HbA1c, which does have a separate evidence base.

After discussion, the subcommittee decided to include adolescents in the criteria described for children, with adolescents defined as below age 21.

Ahmann said for now the evidence does not support CGM use in type 2 diabetes, but he expects new evidence to emerge soon that would support its use in patients taking 4 insulin injections per day. He also suggested lowering the HbA1c threshold from 8.0 to 7.5 for adults with type 1 diabetes. He said the evidence is better for people with higher HbA1c because there is more room for improvement in that population. Obley said that the entrance criteria for the trials varied from HbA1c 7.5 to 8.5. After discussion, the subcommittee made no additional changes to the recommendations.

Boston submitted a public comment signed by several members of his department.

A motion was made to refer the coverage guidance to be posted for public comment. Staff was given discretion to rewrite rationales based on the discussion at the meeting. The motion carried 5-0.

## DRAFT HERC Coverage Guidance

Real-time continuous glucose monitoring (CGM) is recommended for coverage *(weak recommendation)* in adults with type 1 diabetes mellitus:

- who receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit; and,
- who have baseline HbA1c levels greater than or equal to 8.0%, frequent or severe hypoglycemia, or impaired awareness of hypoglycemia.

Real-time CGM is recommended for coverage in children and adolescents under age 21 with type 1 diabetes *(weak recommendation)*.

Real-time CGM (including the CGM-enabled insulin pump) is recommended for coverage in adults with type 1 diabetes on insulin pump management *(weak recommendation)*.

Real-time CGM is not recommended for coverage in adults with type 2 diabetes *(weak recommendation)*.

Real-time CGM is not recommended for coverage in children and adolescents with type 2 diabetes *(strong recommendation)*.

Retrospective CGM is not recommended for coverage in patients of any age with type 1 or type 2 diabetes *(strong recommendation)*.

CGM is not recommended for coverage during pregnancy for type 2 diabetes or gestational diabetes *(weak recommendation)*.

CGM is recommended for coverage for women with type 1 diabetes who are pregnant or who plan to become pregnant within 6 months without regard to HbA1c levels *(weak recommendation)*.

## 6. NEXT TOPICS

Shaffer said the next topics will be colorectal cancer screening technologies, including CT Colonography and fecal DNA testing. An expert will not be needed for this topic since Prasad has knowledge in this area.

## 7. ADJOURNMENT

The meeting was adjourned at 3:20 pm. The next meeting is scheduled for June 15, 2017 from 1:00-4:00 pm at Clackamas Community College, Wilsonville Training Center, Room 210, 29353 SW Town Center Loop E, Wilsonville, Oregon 97070.

# Section 2.0

# VBBS Report

# Mild Psoriasis, Parapsoriasis, and Psoriatric Arthropathy

Questions:

1) Should the diagnosis code for psoriasis be placed on a low priority line to represent mild disease?
2) Should psoriatic arthropathies be moved from the psoriasis line to the inflammatory arthritis line?

Question sources:

1) Alison Little, MD, OHP medical director
2) HERC staff

Issue: The ICD-10 Dermatology group created a new line for moderate/severe psoriasis with a guideline for what defines moderate/severe and what treatments are covered. Prior to the ICD-10 review, moderate/severe psoriasis was on line 134 PYODERMA; MODERATE/SEVERE PSORIASIS and mild psoriasis was on line 564 MILD PSORIASIS ; DERMATOPHYTOSIS: SCALP, HAND, BODY, DEEP-SEATED. There are no specific ICD-10 codes that specify severity of psoriasis; the codes are generic.

There still exists the lower psoriasis line, 544 MILD PSORIASIS; DERMATOPHYTOSIS: SCALP, HAND, BODY, DEEP-SEATED, but no psoriasis ICD-10 codes appear on it. This line is also not referenced in the moderate/severe psoriasis guideline note. There is a separate mild psoriasis guideline attached to line 544.

As part of this review, HERC staff identified that psoriatic arthropathies, which are joint inflammation diseases, are on the severe psoriasis line when their prognosis, disability, and treatments are much more similar to rheumatoid arthritis.



Current Prioritized List

Line 430 SEVERE INFLAMMATORY SKIN DISEASE

Line 544 MILD PSORIASIS; DERMATOPHYTOSIS: SCALP, HAND, BODY, DEEP-SEATED

**GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE**

*Line 430*

Severe inflammatory skin disease is defined as having functional impairment (e.g. inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction) AND one or more of the following:

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

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

# Mild Psoriasis, Parapsoriasis, and Psoriatric Arthropathy

**GUIDELINE NOTE 57, MILD PSORIASIS**

*Line 544*

Mild psoriasis is defined as uncomplicated, having:

- No functional impairment; and/or,

Involving less than 10% of body surface area and no involvement of the hand, foot, or mucous membranes

Errata for correction:

1) Add psoriasis, parapsoriasis and similar ICD-10 codes to line 544 MILD PSORIASIS; DERMATOPHYTOSIS: SCALP, HAND, BODY, DEEP-SEATED
   a) L40.0 Psoriasis vulgaris
   b) L40.1 Generalized pustular psoriasis
   c) L40.2 Acrodermatitis continua
   d) L40.3 Pustulosis palmaris et plantaris
   e) L40.4 Guttate psoriasis
   f) L40.8 Other psoriasis
   g) L40.9 Psoriasis, unspecified
   h) L41.0 Pityriasis lichenoides et varioliformis acuta
   i) L41.1 Pityriasis lichenoides chronica
   j) L41.3 Small plaque parapsoriasis
   k) L41.4 Large plaque parapsoriasis
   l) L41.5 Retiform parapsoriasis
   m) L41.8 Other parapsoriasis
   n) L41.9 Parapsoriasis, unspecified
2) Add psoriatic arthropathy ICD-10 codes to line 50 RHEUMATOID ARTHRITIS AND OTHER INFLAMMATORY POLYARTHROPATHIES) and remove from line SEVERE INFLAMMATORY SKIN DISEASE
   a) L40.50 Arthropathic psoriasis, unspecified
   b) L40.51 Distal interphalangeal psoriatic arthropathy
   c) L40.52 Psoriatic arthritis mutilans
   d) L40.53 Psoriatic spondylitis
   e) L40.54 Psoriatic juvenile arthropathy
   f) L40.59 Other psoriatic arthropathy
3) Add line 544 to GN21
4) Add line 430 to GN57

## Consent Agenda Issues—May, 2017

| Code | Code Description | Line(s) Involved | Issue | Recommendation(s) |
|---|---|---|---|---|
| 44130 | Enteroenterostomy, anastomosis of intestine, with or without cutaneous enterostomy | 51 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS | HSD requested that 44130 pair with K63.1 (Perforation of intestine (nontraumatic)). 44130 is currently on lines 46, 75, 92, 105, 158, 220, 321. | Add 44130 to line 51 |
| 44110 | Excision of 1 or more lesions of small or large intestine not requiring anastomosis, exteriorization, or fistulization; single enterotomy | 170 ANAL, RECTAL AND COLONIC POLYPS | HSD requested that 44110 pair with K63.5 (polyp of colon). 44110 is currently on lines 32,46,105,220,243,642. There are no enterotomy codes on line 170; there are many polypectomy codes (colonoscopic) on that line. | Add 44110 to line 170 |
| 45340<br><br>46080 | Sigmoidoscopy, flexible; with transendoscopic balloon dilation<br>Sphincterotomy, anal, division of sphincter | 458 RECTAL PROLAPSE | HSD requested that 45340 and 46080 pair with K62.4 (Stenosis of anus and rectum). 46080 is currently on lines 105,400,529 while 45340 is on lines 32,46,105,161. | Add 45340 and 46080 to line 458 |
| 46614 | Anoscopy; with control of bleeding (eg, injection, bipolar cautery, unipolar cautery, laser, heater probe, stapler, plasma coagulator) | 60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE | HSD requested that 46614 pair with K62.5 (Hemorrhage of anus and rectum). 46614 is on lines 170,478,624. | Add 46614 to line 60 |
| 49422<br><br>75984 | Removal of tunneled intraperitoneal catheter<br>Change of percutaneous tube or drainage catheter with contrast monitoring (eg, genitourinary system, abscess), radiological supervision and interpretation | 51 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS | HSD requested that 75984 pair with K65.1 (Peritoneal abscess). 75984 is on lines 290,428. The initial placement code is Diagnostic. HSD also requested that 49422 pair with K65.9 (Peritonitis, unspecified) on line 51. | Add 49422 and 75984 to line 51 |

## Consent Agenda Issues—May, 2017

| Code | Code Description | Line(s) Involved | Issue | Recommendation(s) |
|---|---|---|---|---|
| E72.20 | Disorder of urea cycle metabolism, unspecified | 226 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE | HSD requested that Hyperammonemia pair with dialysis CPT codes. Hyperammonemia is best coded with ICD-10 E72.20 which is on lines 75,181,246,297,350,382. Line 226 has all dialysis CPT codes | Add E72.20 to line 226 |
| K63.81 | Dieulafoy lesion of intestine | 32 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE<br>60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE | HSD requested that K63.81 pair with 43255 (Esophagogastro-duodenoscopy, flexible, transoral; with control of bleeding, any method) which is on line 60. K63.81 is currently on line 32 but is better placed on line 60 | Add K63.81 to line 60<br>Remove K63.81 from line 32 |
| K63.89 | Other specified diseases of intestine | 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS<br>231 RUPTURED VISCUS<br>664 GASTROINTESTINAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY | HSD requested that K63.89 pair with 44205(Laparoscopy, surgical; colectomy, partial, with removal of terminal ileum with ileocolostomy). K63.89 is currently on line 231 but does not contain ruptured viscus as a subdiagnosis. The major subdiagnoses are colon mass or lesion. Similar code K62.89 (Other specified diseases of anus and rectum) is on lines 161 and 664. Line 161 contains 44205 | Add K63.89 to lines 161 and 664<br>Remove K63.89 from line 231 |
| 43273 | Endoscopic cannulation of papilla with direct visualization of pancreatic/common bile duct(s) | 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT | HSD requested that 43273 be paired with K91.89 (Other postprocedural complications and disorders of digestive system). K91.89 is on 290 and 531. 43273 is on lines 59, 199, 255, 298, 321, 439, 645 | Add 43273 to line 290 |

## Consent Agenda Issues—May, 2017

| Code | Code Description | Line(s) Involved | Issue | Recommendation(s) |
|---|---|---|---|---|
| 10160<br><br>43274<br><br><br><br><br><br><br>43275-<br>43276<br><br><br><br>49405 | Puncture aspiration of abscess, hematoma, bulla, or cyst<br>Endoscopic retrograde cholangiopancreatography (ERCP); with placement of endoscopic stent into biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent<br>Endoscopic retrograde cholangiopancreatography (ERCP); with removal and exchange of stent(s), biliary or pancreatic duct<br>Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); visceral (eg, kidney, liver, spleen, lung/mediastinum), percutaneous | 368 CYST AND PSEUDOCYST OF PANCREAS | HSD requested that K86.3 (Pseudocyst of pancreas) pair with 10160, 43274, and 49405. 10160 is on 7 lines, 43274 is on 11 lines, and 49405 is on lines 51, 290, 408. 43275 and 43276 are also appropriate if 43274 is added to this line. | Add 10160, 43274-43276, and 49405 to line 368 |
| 37244 | Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation | 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT | HSD requested that 37244 pair with K91.840 (Postprocedural hemorrhage of a digestive system organ or structure following a digestive system procedure). K91.840 is on Line 290 and 428. 37244 is on line 60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE | Add 37244 to line 290 |

## Consent Agenda Issues—May, 2017

| Code | Code Description | Line(s) Involved | Issue | Recommendation(s) |
|---|---|---|---|---|
| 10160<br><br>49405 | Puncture aspiration of abscess, hematoma, bulla, or cyst<br>Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); visceral (eg, kidney, liver, spleen, lung/mediastinum), percutaneous | 298 ANOMALIES OF GALLBLADDER, BILE DUCTS, AND LIVER | HSD requested that K76.89 (Other specified diseases of liver) pair with 10160 and 49405. K76.89 includes liver cyst. 10160 is on lines 51,210,290,390,428,484,596. 49405 is on lines 51, 290, 408. | Add 10160 and 49405 to line 298 |
| 44345 | Revision of colostomy; complicated (reconstruction in-depth) | 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT | HSD requested that 44345 pair with K94.02 (Colostomy infection). 44345 is on lines 32, 92, 105, 161, 428, 531. Similar code 44340 is on line 290. Similar code 44346 is on the other complication line (428). | Add 44345 to line 290 |
| 43255<br><br><br>44120<br><br><br>45382 | Esophagogastroduodenoscopy, flexible, transoral; with control of bleeding, any method<br>Enterectomy, resection of small intestine; single resection and anastomosis<br>Colonoscopy, flexible; with control of bleeding, any method | 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT | HSD requested that K91.840 (Postprocedural hemorrhage of a digestive system organ or structure following other procedure) pair with 43255, 44120 and 45382. 43255 is on lines 60, 516. 44120 is on 12 lines. 45382 is on 11 lines. | Add 43255, 44120 and 45382 to line 290 |
| 20610<br><br><br><br>20611 | Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance<br>With ultrasound guidance | 361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE | HSD requested that 20610 pair with M25.062 (hemarthrosis, knee). 20610 currently appears on 13 lines | Add 20610 and 20611 to line 361 |

## Consent Agenda Issues—May, 2017

| Code | Code Description | Line(s) Involved | Issue | Recommendation(s) |
|---|---|---|---|---|
| 28120<br><br><br><br><br>28122<br><br>28805<br><br>28810<br><br>28820<br><br>28825<br><br>13101-13113 | Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (eg, osteomyelitis or bossing); talus or calcaneus<br>Tarsal or metatarsal bone, except talus or calcaneus<br>Amputation, foot; transmetatarsal<br>Amputation, metatarsal, with toe, single<br>Amputation, toe; metatarsophalangeal joint<br>Amputation, toe; interphalangeal joint<br>Repair, complex wounds | 384 CHRONIC ULCER OF SKIN | HSD has requested that various wound repair codes and amputation codes be paired with stage 3 and 4 pressure ulcers and other non-pressure ulcers. | Add 28120, 28122, 28805, 28810, 28820, 28825, 13101-13113 to line 384 |
| M35.01 | Sicca syndrome with keratoconjunctivitis | 476 KERATOCONJUNCTIVITIS | HSD requested that M35.01 pair with ophthomology visit codes. M35.01 is currently only on line 335 SYSTEMIC SCLEROSIS; SJOGREN'S SYNDROME | Add M35.01 to line 476 |
| 21198 | Osteotomy, mandible, segmental | 561 BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE INCLUDING OSTEOID OSTEOMAS; BENIGN NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE | HSD requested that 21198 pair with M27.8 (Other specified diseases of jaws). Other jaw surgical codes appear on line 561 | Add 21198 to line 561 |

## Consent Agenda Issues—May, 2017

| Code | Code Description | Line(s) Involved | Issue | Recommendation(s) |
|---|---|---|---|---|
| 26123<br><br><br><br><br><br><br>26125 | Fasciectomy, partial palmar with release of single digit including proximal interphalangeal joint, with or without Z-plasty, other local tissue rearrangement, or skin grafting (includes obtaining graft);<br>Each additional digit | 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS | HSD requested that 26123 pair with M24.541 (contracture, hand). 26123 is on lines 290, 364, 392, 421, 431, 508, 530 | Add 26123 and 26125 to line 297 |
| 23462<br><br><br>29822<br><br>29823 | Capsulorrhaphy, anterior, any type; with coracoid process transfer<br>Arthroscopy, shoulder, surgical; debridement, limited<br>Extensive | 364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS | HSD requested that 23462 and 29822 pair with M24.41 (recurrent dislocation, shoulder). 29822 and 29823 are on lines 157,361,423. 23462 is on line 423. Similar shoulder surgeries are on line 364 | Add 23462, 29822 and 29823 to line 364 |
| 25230 | Radial styloidectomy | 361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE | HSD requested that 25230 be paired with M19.03 (Primary osteoarthritis, wrist). 25230 is on lines 136, 188, 205, 259, 360, 406, 561. Various wrist bone removal procedures are on line 361 | Add 25230 to line 361 |
| 96150-96155 | Health and behavior assessment | 111 GIANT CELL ARTERITIS, POLYMYALGIA RHEUMATICA AND KAWASAKI DISEASE<br>210 SUPERFICIAL ABSCESSES AND CELLULITIS | HSD requested that 96150 pair with L02.41 (cutaneous abscess of upper limb) and M35.3 (Polymyalgia rheumatic). 96150 is on 160+ lines | Add 96150-96155 to lines 111 and 210 |
| 28304 | Osteotomy, tarsal bones, other than calcaneus or talus | 382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION<br>530 DEFORMITIES OF UPPER BODY AND ALL LIMBS | HSD requested that 28304 pair with M21.07 (valgus deformity, NEC, ankle). 28304 is on lines 297,364,392,545. M21.07 is on lines 382,530. | Add 28304 to line 530 |

## Consent Agenda Issues—May, 2017

| Code | Code Description | Line(s) Involved | Issue | Recommendation(s) |
|---|---|---|---|---|
| 27033 | Arthrotomy, hip, including exploration or removal of loose or foreign body | 364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS | HSD requested that 27033 pair with M24.05 (Loose body in hip). 27033 is on line 187 FRACTURE OF PELVIS, OPEN AND CLOSED | Add 27033 to line 364 |
| 19020 | Mastotomy with exploration or drainage of abscess, deep | 210 SUPERFICIAL ABSCESSES AND CELLULITIS | HSD requested that 19020 pair with N61.1 (Abscess of the breast and nipple). 19020 is on line 51 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS | Add 19020 to line 210 |
| E23.7 | Disorder of pituitary gland, unspecified | 347 OTHER AND UNSPECIFIED ANTERIOR PITUITARY HYPERFUNCTION, BENIGN NEOPLASM OF THYROID GLAND AND OTHER ENDOCRINE GLANDS 656 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY | OHA Hearings questioned the placement of E23.7 on line 347. There are no subdiagnoses for E23.7 | Remove E23.7 from line 347<br><br>Add E23.7 to line 656 |
| 51700 | Bladder irrigation, simple, lavage and/or instillation | 75 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES | HSD requested pairing of 51700 with N31.8 (Other neuromuscular dysfunction of bladder). 51700 is currently on lines 219,275,279,332,334 | Add 51700 to line 75 |
| 52330 | Cystourethroscopy (including ureteral catheterization); with manipulation, without removal of ureteral calculus | 184 URETERAL STRICTURE OR OBSTRUCTION; HYDRONEPHROSIS; HYDROURETER | HSD requested that 52330 pair with N13.2 (Hydronephrosis with renal and ureteral calculous obstruction). 52330 is currently on line 357 URINARY SYSTEM CALCULUS. Most similar codes are on line 184 | Add 52330 to line 184 |

## Consent Agenda Issues—May, 2017

| Code | Code Description | Line(s) Involved | Issue | Recommendation(s) |
|---|---|---|---|---|
| 51102<br><br><br>51700 | Aspiration of bladder; with insertion of suprapubic catheter<br>Bladder irrigation, simple, lavage and/or instillation | 357 URINARY SYSTEM CALCULUS | HSD requested that 51102 and 51700 pair with N21.0 (Calculus in bladder). 51102 is currently on lines 75,84,91,332. 51700 is currently on lines 219,275,279,332,334 | Add 51102 and 51700 to line 357 |
| 50220 | Nephrectomy, including partial ureterectomy, any open approach including rib resection; | 184 URETERAL STRICTURE OR OBSTRUCTION;<br>HYDRONEPHROSIS;<br>HYDROURETER | HSD requested that 50220 pair with N13.5 (Crossing vessel and stricture of ureter without hydronephrosis). 50220 is currently on lines 25,51,53,84,91,219,275 | Add 50220 to line 184 |

# May 2017 Straightforward Guideline Changes

1) GN 104 includes CPT 20610 (Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance). It also should contain CPT 20611 (Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting).

   **GUIDELINE NOTE 104, VISCOSUPPLEMENTATION OF THE KNEE**

   *Lines 436,467*

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

   The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/herc/Pages/blog-viscosupplementation-knee.aspx

2) Add line 347 OTHER AND UNSPECIFIED ANTERIOR PITUITARY HYPERFUNCTION, BENIGN NEOPLASM OF THYROID GLAND AND OTHER ENDOCRINE GLANDS to Guideline Note 74, GROWTH HORMONE TREATMENT

# Back Surgery Guideline
# May 2017

Question: how should the back surgery guideline be modified based on feedback to date from CCOs and providers?

Question source: VBBS, HERC staff

Issue: HERC staff have been soliciting feedback on the back surgery guideline which was implemented in July, 2016, based on a request from VBBS/HERC. The Commission is seeking guidance on what changes, if any, should be implemented to assist the health plans and providers in using this guideline.

HERC staff have received the following feedback from the CCOs:

1) The section on coverage of spondylilithesis should clarify that this condition is only covered when it results in central canal stenosis and not foraminal stenosis.
2) The sections should be numbered for ease of use
3) The wording of the last entry should be cleaned up to remove double negatives

HERC staff have received the following feedback from HSD:

1) HSD would like the radiculopathy ICD-10 codes added to the higher back surgical line. The current back surgery guideline note defines when radiculopathy is a covered indication (when there is evidence of motor weakness, etc.). The back surgeon who assisted in creation of this guideline felt that the definition of radiculopathy in the guideline actually met the definition of myelopathy and therefore only the myelopathy codes were needed on the upper surgical line. HSD feels that the use of radiculopathy ICD-10 codes for these conditions is also valid as long as it meets the guideline criteria for being more severe than radiating pain. HSD is getting complaints from neurosurgeons regarding this. HSD has requested consideration of adding wording to GN37 saying radiculopathy causing only pain is not a covered condition for pain
    a. GN101 ARTIFICIAL DISC REPLACEMENT contains coverage for radiculopathy, which is currently not on the upper, covered line. Either add the radiculopathy ICD-10 codes to the upper line or change the wording of GN101.

**GUIDELINE NOTE 101, ARTIFICIAL DISC REPLACEMENT**

*Lines 351,532*

Artificial disc replacement (CPT 22856-22865) is included on these lines as an alternative to fusion only when all of the following criteria are met:

Lumbar artificial disc replacement

A) Patients must first complete a structured, intensive, multi-disciplinary program for management of pain, if covered by the agency;
B) Patients must be 60 years or under;
C) Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:
    - Failure of at least six months of conservative treatment
    - Skeletally mature patient
    - Replacement of a single disc for degenerative disc disease at one level confirmed by patient history and imaging

Cervical artificial disc replacement

D) Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:
    - Skeletally mature patient
    - Reconstruction of a single disc following single level discectomy for intractable symptomatic cervical disc disease (radiculopathy or myelopathy) confirmed by patient findings and imaging.

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/herc/Pages/blog-artificial-disc-replace.aspx

# Back Surgery Guideline
# May 2017

HERC staff have the following additional internal feedback:

1) Spinal pumps are covered for a trial of baclofen for spasticity on the dysfunction lines. The HERC has explicitly not wanted pumps covered for opioid pumps/pain control. Staff suggests adding wording to the guideline making this explicit.

HERC staff received the following feedback from the neurosurgery group working with PacificSource, through their medical director, Alison Little MD:

> …they raised the same concern that I had recently pertaining to spondylolisthesis. Their comment was "this is going to blow it wide open". They were also very skeptical of using spinal instability as a criteria, noting that even partners in the same practice don't agree on what that is. They recommend using clear criteria, something to the effect of "as demonstrated on flexion/extension films showing at least a 5 to 7 mm translation"

QHOC reacted to the staff recommendations by indicating that the ICD-10 codes for radiculopathy should indeed be included on the covered upper surgical line with the guideline. CCO representatives felt that this would make review of requests for surgery more straightforward.

# Back Surgery Guideline
# May 2017

HERC staff recommendations:

1) Consider adding radiculopathy ICD-10 codes to line 351 with wording in the guideline limiting the radiating pain use of these diagnoses. This allows coding for radiculopathy that meets guideline criteria, and also allows GN101 to continue to pair with radiculopathy diagnosis codes.
    a) M47.2 Other spondylosis with radiculopathy
    b) M50.1 Cervical disc disorder with radiculopathy
    c) M51.1 Intervertebral disc disorders with radiculopathy, thoracic, lumbar or sacral
    d) M54.1 Radiculopathy
2) Modify GN 37 as shown below

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

*Lines 351,532*

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

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. Neurologic impairment is defined as objective evidence of one or more of the following:
    a. Markedly abnormal reflexes
    b. Segmental muscle weakness
    c. Segmental sensory loss
    d. EMG or NCV evidence of nerve root impingement
    e. Cauda equina syndrome
    f. Neurogenic bowel or bladder
    g. Long tract abnormalities

Otherwise, these diagnoses are included on Line 532. Foraminal or central spinal stenosis causing only radiating pain (i.e. radiculopathic pain) is included only on line 532. Only decompression surgery is included on these lines for spinal stenosis~~;~~. ~~s~~Spinal fusion procedures are ~~not~~ included on ~~either~~ these lines for spinal stenosis ~~unless~~ only when:

1) the spinal stenosis is in the cervical spine OR
2) spondylolisthesis is present as above as demonstrated on flexion/extension films showing at least a 5 to 7 mm translation OR
3) there is pre-existing or expected post-surgical spinal instability (e.g. degenerative scoliosis >10 deg, >50% of foraminal joints expected to be resected)

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

- 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
- intrathecal or epidural drug infusion pumps for opioid or other pain medication infusion

# Opioids for Back Conditions Guideline
# Non-Interventional Treatments for Back Conditions Guideline
# May 2017

Questions:

1) How should the opioids for back conditions guideline be modified based on feedback to date from CCOs and providers?
2) How should the non-interventional treatments for back conditions guideline be modified based on feedback to date?

Question source: VBBS, HERC staff

Issues:

1) HERC staff have been soliciting feedback on the opioids for back conditions guideline which was implemented in July, 2016, based on a request from VBBS/HERC. The Commission is seeking guidance on what changes, if any, should be implemented to assist the health plans and providers in using this guideline.

   Staff requested feedback from the CCOs via email to the guidelines group and via discussion at QHOC meetings. The only feedback from CCO medical directors to date was a query about possibly excluding patients on low opioid doses who have been stable for a long period of time and had no red flags or concerns from the requirement to taper off completely.

2) HERC staff were also asked to solicit feedback on the non-interventional treatments for back conditions guideline, and to seek out data on the utilization of PT, CBT, CMT, OMT and acupuncture for back conditions. HERC staff reached out to the CCOs via the guidelines workgroup and at QHOC meetings.

   There was one query from a provider about the use of other validated tools to determine function. However, the current list is a suggested list of options, not a required list and the only tool requested for addition was not an assessment of function. Therefore staff do not recommend adding it to the list of options to assess function.

   As a part of the statewide Performance Improvement Project (PIP), data on all CCOs was collected on opioid prescribing rates and especially the rate of prescribing for high-dose opioid therapy. A presentation from the Quality and Health Outcomes Committee meeting April 10, 2017 displays the findings. This interim report compares utilization from calendar year 2014, calendar year 2015 and Dec. 1, 2015 through Nov. 30, 2016. Findings were summarized as follows:

   - Significant decrease in metrics from baseline (1.24% points on 120 mg MED; 1.27% points on 90 mg MED)
   - Decrease in number of people with any prescription for opioids
   - Greater decrease in patients age 12-17 with a high dose than patients age 18+
   - Wide variation among CCOs at baseline and in improvement

   HERC staff have received preliminary data on utilization of alternative therapies for back conditions; a handout (not part of the original packet) will describe the findings.

# Opioids for Back Conditions Guideline
# Non-Interventional Treatments for Back Conditions Guideline
# May 2017

HERC staff recommendations:

1) Make no changes to the current non-interventional back therapies guideline (GN56) or the current opioid guideline for back conditions (GN60)
2) Reassess data at some future date to be determined by discussion with the VBBS/HERC and report back to the VBBS/HERC

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

*Lines 366,407*

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

For patients who are determined to be low risk on the assessment tool, the following services are included on these lines:

- Office evaluation and education,
- Up to 4 total visits, consisting of the following treatments: OMT/CMT, acupuncture, and PT/OT. Massage, if available, may be considered.
- First line medications: NSAIDs, acetaminophen, and/or muscle relaxers. Opioids may be considered as a second line treatment, subject to the limitations on coverage of opioids in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE. See evidence table.

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

- Office evaluation, consultation and education
- Cognitive behavioral therapy. The necessity for cognitive behavioral therapy should be re-evaluated every 90 days and coverage will only be continued if there is documented evidence of decreasing depression or anxiety symptomatology, improved ability to work/function, increased self-efficacy, or other clinically significant, objective improvement.
- Prescription and over-the-counter medications; opioid medications subject to the limitations on coverage of opioids in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE. See evidence table.
- The following evidence-based therapies, when available, are encouraged: yoga, massage, supervised exercise therapy, intensive interdisciplinary rehabilitation. HCPCS S9451 is only included on Line 407 for the provision of yoga or supervised exercise therapy.
- A total of 30 visits per year of any combination of the following evidence-based therapies when available and medically appropriate. These therapies are only included on these lines if provided by a provider licensed to provide the therapy and when there is documentation of measurable clinically significant progress toward the therapy plan of care goals and objectives using evidence based objective tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).

1) Rehabilitative therapy (physical and/or occupational therapy), if provided according to Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES. Rehabilitation services provided under this guideline also count towards visit totals in Guideline Note 6
2) Chiropractic or osteopathic manipulation
3) Acupuncture

Mechanical traction (CPT 97012) is not included on these lines, due to evidence of lack of effectiveness for treatment of back and neck conditions. Transcutaneous electrical nerve stimulation (TENS; CPT 64550, 97014 and 97032) is not included on the Prioritized List for any condition due to lack of evidence of effectiveness.

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



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

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

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

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

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

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

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

# Opioids for Back Conditions Guideline
# Non-Interventional Treatments for Back Conditions Guideline
# May 2017

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

*Lines 351,366,407,532*

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

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

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

3) Chronic opioid treatment (>90 days) after the initial injury/flare/surgery is not included on these lines except for the taper process described below.

<u>Transitional coverage for patients on long-term opioid therapy as of July 1, 2016:</u>

For patients on covered chronic opioid therapy as of July 1, 2016, opioid medication is included on these lines only from July 1, 2016 to December 31, 2016. During the period from January 1, 2017 to December 31, 2017, continued coverage of opioid medications requires an individual treatment plan developed by January 1, 2017 which includes a taper with an end to opioid therapy no later than January 1, 2018. Taper plans must include nonpharmacological treatment strategies for managing the patient's pain based on Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND

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

# Cholecystitis and Biliary Colic

Questions:
1) Should biliary colic (single event or recurrent) be included on the upper gallstone line?

Question source: HERC

Issue: At the February, 2017 VBBS meeting, the gallstone lines were reviewed. There are currently two lines with gallstones on the prioritized list, one in the covered region of the List which includes cholecystitis and other complications of gallstones and one in the uncovered region of the List which include asymptomatic gallstones and other minor gallstone-related conditions.

At the February 2017 meeting, a new guideline defining cholecystitis was adopted. One staff option given for that new guideline was to include recurrent (more than one episode) biliary colic on the upper, covered gallstone line. The VBBS did not accept this recommendation. The guideline adopted did not include biliary colic as an indication for cholecystectomy on the upper, covered line. In addition, the VBBS modified the line title for the lower gallstone line to include biliary colic to clarify their desire for lack of coverage for pain alone (645 GALLSTONES WITHOUT CHOLECYSTITIS; BILIARY COLIC).

From the February, 2017 VBBS minutes:

> The group discussed whether to include biliary colic on the covered upper line. Gibson noted that the evidence for coverage of biliary colic was poor. Hodges noted that she did not agree with moving biliary colic alone without any other sign of problem to the covered line. Olson noted that there is no evidence about the natural history of what happens with recurrent biliary pain is not treated. The studies presented are all retrospective. Gibson suggested that the CCOs consider treatment of recurrent biliary colic as an exception.
>
> The subcommittee felt that all biliary colic, including recurrent colic, should be included on the lower gallstone line. There was discussion about how to word this in the guideline; the decision was to change the name of the lower line to include "biliary colic."

The HERC reviewed the VBBS recommendation at the March, 2017 meeting. There was concern that lack of treatment of biliary colic resulted in a high risk of serious complications, including hospitalization, which also increases costs, as well as very serious complications including death. Saha and Chan felt that the data did support recurrent biliary colic as an indication for surgery. Carl Stevens, a medical director from CareOregon, noted that his CCO is paying for cholecystectomies for high risk patients; he recommended including high risk patients (e.g. morbidly obese, immunocompromised, etc.) with biliary colic on the upper line as they are high risk for complications with emergent cholecystectomy. He also recommended adding sonographic Murphy's sign as a sign of inflammation in the part of the guideline on the diagnosis of cholecystitis. The decision was made to have VBBS reconsider this topic.

Previous testimony from various surgeons has recommended coverage for biliary colic, either single episode or recurrent.

Dr. Carl Stevens, medical director for HealthShare, suggested that the definition of biliary colic be changed to a "documented clinical encounter (ED, PCP, urgent care) for pain in RUQ or epigastric pain, with ultrasound visualization of the GB showing gallstones, and a positive sonographic Murphy's sign on

bedside or formal ultrasound performed during the encounter." He also suggested coverage of cholecystectomy on the upper line for "one documented episode of biliary colic in a patient at high risk of complications if they develop cholecystitis and/or biliary sepsis: immunocompromised, diabetic, advanced age (>65?), morbid obesity;" or "one episode of biliary colic with any of the following: elevated lipase (pancreatitis), elevated LFTs (transaminases or alkaline phosphatase) or dilated common bile duct on ultrasound." He suggested that recurrent biliary colic be defined as "three or more documented clinical encounters for biliary colic as defined above in a (one or two?) year period."

Current Prioritized List:
59 COMPLICATED STONES OF THE GALLBLADDER AND BILE DUCTS; CHOLECYSTITIS
645 GALLSTONES WITHOUT CHOLECYSTITIS; BILIARY COLIC

Guideline adopted by VBBS in February 2017 but not accepted by HERC

**GUIDELINE NOTE XXX, CHOLECYSTITIS**

*Lines 59, 645*

Cholecystitis is defined as

1) The presence of right upper quadrant abdominal pain, mass, tenderness or a positive Murphy's sign, AND
2) Evidence of inflammation (e.g. fever, elevated white blood cell count, elevated C reactive protein), OR
3) Ultrasound findings characteristic of acute cholecystitis or non-visualization of the gall bladder on oral cholecystegram or HIDA scan, or gallbladder ejection fraction of < 35%

ICD-10 K82.8 (Other specified diseases of gallbladder) is included on line 59 when the patient has

1) Porcelain gallbladder, or
2) Gallbladder dyskinesia with a gallbladder ejection fraction <35%.

Otherwise, K82.8 is included on line 645.

# Cholecystitis and Biliary Colic

Evidence—delayed cholecystectomy for uncomplicated biliary colic

1) **Gurusamy 2013**, **(Article not included in packet due to length; please view online:** http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD007196.pub3/epdf) Cochrane review of early vs delayed cholecystectomy for uncomplicated biliary colic
    a. N=1 trial (75 participants—35 early laparoscopic cholecystectomy, 40 delayed cholecystectomy)
        i. Mean waiting period for delayed group 4.2 months
        ii. Trial deemed at high risk of bias
    b. Mortality: 0/35 (early) vs 1/40 (delayed, 2.5%) (P > 0.9999).
    c. There were no serious adverse events related to the surgery in either group.
    d. Complications in delayed group: pancreatitis (n = 1), empyema of the gallbladder (n = 1), gallbladder perforation (n = 1), acute cholecystitis (n = 2), cholangitis (n = 2), obstructive jaundice (n =2), and recurrent biliary colic (requiring hospital visits) (n = 5). In total, 14 participants required hospital admissions for the above symptoms. The proportion of people who developed serious adverse events was 0/28 (0%) in the early group, which was significantly lower than in the delayed laparoscopic cholecystectomy group 9/40 (22.5%) (P = 0.0082). This trial did not report quality of life or return to work.
    e. There was no significant difference in the proportion of people who required conversion to open cholecystectomy in the early group 0/28 (0%) compared with the delayed group (6/35 or 17.1%) (P = 0.0743). There was a statistically significant shorter hospital stay in the early group than in the delayed group (MD -1.25 days, 95% CI -2.05 to -0.45). There was a statistically significant shorter operating time in the early group than the delayed group (MD -14.80 minutes, 95% CI -18.02 to -11.58).
    f. **Authors' conclusions:** Based on evidence from only one high-bias risk trial, it appears that early laparoscopic cholecystectomy (less than 24 hours after diagnosis of biliary colic) decreases the morbidity during the waiting period for elective laparoscopic cholecystectomy (mean waiting time 4.2 months), the hospital stay, and operating time. Further randomised clinical trials are necessary to confirm or refute these findings

Expert guidelines

1) Excerpt from **Society of American Gastrointestinal and Endoscopic Surgeons 2010**, guidelines for laparoscopic cholecystectomy (document is here: https://www.sages.org/publications/guidelines/guidelines-for-the-clinical-application-of-laparoscopic-biliary-tract-surgery/#)
    a. Asymptomatic gallstones are generally not an indication for laparoscopic cholecystectomy.
    b. Indications for laparoscopic cholecystectomy include but are not limited to symptomatic cholelithiasis, biliary dyskinesia, acute cholecystitis, and complications related to common bile duct stones including pancreatitis with few relative or absolute contraindications (Level II, Grade A).

Other policies:
All other major insurers and CMS cover cholecystectomy for biliary colic, as well as cholecystitis or other complications.

# Cholecystitis and Biliary Colic

Input from others:

Tracy Muday, MD, OHP medical director

> The diagnosis of chronic cholecystitis is often made post-op by the pathologist, and if we restrict to those that are positive on ultrasound, we will miss a lot of cases. (We have had a few cases where ultrasound showed stones but no thickening of the gallbladder wall, no other signs, but pathology came back with report of chronic cholecystitis.)
>
> I am pretty comfortable with a more inclusive view of what should be covered for surgery. I suspect that if we just included biliary colic on the covered line, it would not be a dramatic shift in the number of people who go to surgery. My biggest headaches are the people who have abdominal symptoms that are not classic for gallbladder disease and who have equivocal studies. I do think it is helpful to define biliary dyskinesia as <35% EF on HIDA.

HERC staff summary:

There has been a longstanding debate at the HSC/HERC regarding coverage of cholelithiasis with biliary colic or other pain related to gallstones. Expert guidelines recommend cholecystectomy for biliary colic. Poor quality studies show a significant complication rate for painful but otherwise uncomplicated cholelithiasis that is not treated by cholecystectomy, with approximately 20% of patients developing significant complications including death within 2 years. HERC has requested that VBBS reconsider recurrent biliary colic as an indication for coverage.

# Cholecystitis and Biliary Colic

HERC staff recommendations:

1) Reverse the previously VBBS adopted line name change for line 645 (not accepted by HERC and therefore not implemented)
    a. 645 GALLSTONES WITHOUT CHOLECYSTITIS~~; BILIARY COLIC~~
2) Accept modifications of the BBBS approved (not accepted by HERC and therefore not implemented) cholecystitis guideline as shown in blue below for lines 59 COMPLICATED STONES OF THE GALLBLADDER AND BILE DUCTS; CHOLECYSTITIS and 645
    a. Add sonographic Murphy's sign as an indication for inflammation for the diagnosis of cholecystitis
    b. Add recurrent biliary colic as a diagnosis on the upper, covered gallbladder line
    c. Add high risk patients with biliary colic to the upper line

**GUIDELINE NOTE XXX, CHOLECYSTITIS**

*Lines 59, 645*

Cholecystitis is defined as

1) The presence of right upper quadrant abdominal pain, mass, tenderness or a positive Murphy's sign, AND
2) Evidence of inflammation (e.g. fever, elevated white blood cell count, elevated C reactive protein), OR
3) Ultrasound findings characteristic of acute cholecystitis or non-visualization of the gall bladder on oral cholecystegram or HIDA scan, or gallbladder ejection fraction of < 35%

Biliary colic (i.e. documented clinical encounter for right upper quadrant or epigastric pain with gallstones seen on imaging during each episode) without evidence of cholecystitis or other complications is included on line 59 only when

1) recurrent (i.e. 2 or more episodes in a one year period), or
2) a single episode in a patient at high risk for complications with emergent cholecystitis (e.g. immunocompromised patients, morbidly obese patients, diabetic patients), or
3) when any of the following are present: elevated pancreatic enzymes, elevated liver enzymes or dilated common bile duct on ultrasound.

Otherwise, biliary colic is included on line 645.

ICD-10 K82.8 (Other specified diseases of gallbladder) is included on line 59 when the patient has

3) Porcelain gallbladder, or
4) Gallbladder dyskinesia with a gallbladder ejection fraction <35%.

Otherwise, K82.8 is included on line 645.

# Gender Dysphoria May 2017

Question: Should certain additional codes be added to the gender dysphoria line?

Question source: Megan Bird, MD

Issue: Dr. Bird requested that several codes for endometrial ablation be added to the gender dysphoria line (line 317). Per Dr. Bird: "These are often all a patient needs to address dysphoria related to internal genitals, menstrual cycles. There are also some patients who are not good surgical candidates for a major surgery but can tolerate a smaller procedure."

Endometrial ablation is not referenced in WPATH version 7. Essentially, Dr. Bird is requesting this treatment to allow the cessation of menses in female to male transgender persons who cannot/do not wish to take testosterone or have not had cessation of menses with adequate testosterone dosing, do not want other therapies such as progestin IUDs, and/or do not want or are not surgical candidates for more extensive procedures such as hysterectomy.

From the UCSF guidelines for treatment of gender dysphoria:

> Many transgender men chose not to undergo hysterectomy, oopherectomy and/or gender affirming genital procedures. For transgender men of reproductive age undergoing transition without hormones, or those whom have used testosterone and later discontinued it due to unwanted side effects such as balding, menses would be expected to be within standard reference ranges from 21-35 days between cycles with no inter-menstrual bleeding and lasting on average 2-6 days and ceasing on average at age 49.
>
> For those transgender men using physiologic doses of testosterone, cessation of menses is expected, typically within 6 months…The addition of an oral, injected, implanted, or intrauterine (IUD) progestogen may serve as an adjunct to induction of amenorrhea. Endometrial ablation can be considered for those transgender men who do not desire future fertility and who also either decline hysterectomy or have surgical complications. The levonorgestrel intrauterine system (IUS/IUD), which in non-transgender women can either significantly decrease menstrual flow or fully induce amenorrhea, has the added contraceptive benefit for those at risk of pregnancy since some may still ovulate despite male physiologic testosterone levels.

Current Prioritized List status:

On line 426 MENSTRUAL BLEEDING DISORDERS:

- CPT 58353 (Endometrial ablation, thermal, without hysteroscopic guidance)
- CPT 58356 (Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed)
- CPT 58563 (Hysteroscopy, surgical; with endometrial ablation (eg, endometrial resection, electrosurgical ablation, thermoablation))

HERC staff recommendation:

1) Add CPT 58353 (Endometrial ablation, thermal, without hysteroscopic guidance), 58356 (Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed), and 58563 (Hysteroscopy, surgical; with endometrial ablation (eg, endometrial resection, electrosurgical ablation, thermoablation)) to line 317 GENDER DYSPHORIA

# Tobacco cessation and elective surgery updates

Question: Shall the Smoking cessation and elective surgical procedures guideline be modified for clarity?

Question source: Various sources: CCO Medical Directors, surgeons (Dr. Raul Mirande)

Issue: A number of questions and concerns about the Tobacco cessation and Elective surgery guideline have arisen.

1. Does the exclusion for "reproductive procedures" include any relating to the reproductive system (e.g. hysterectomy for menstrual bleeding disorders)?
2. The "any" nicotine product suggests that elimination of one (and replacement of any other e.g. smokeless tobacco) is acceptable
3. Should grafts and flaps be required to have a longer smoking cessation requirement (i.e. 6 months) given their need for revascularization?

From Dr. Mirande:
1. Vasectomy is excluded from the cessation requirement as Reproductive
2. Six month smoking cessation for all cosmetic/plastic's reconstructions (grafts/flaps) except when the Only viable way to close a wound is to do a simultaneous flap/ graft ( i.e. After large skin cancer excision). I think breast reconstruction is almost always elective and can be staged until smoking cessation has been proven.
3. All gender reassignment procedures are elective and smoking cessation would need to be proven for each stage of this conversion.

Current Prioritized List Status

**ANCILLARY GUIDELINE A4, SMOKING CESSATION AND ELECTIVE SURGICAL PROCEDURES**

Smoking cessation is required prior to elective surgical procedures for active tobacco users. Cessation is required for at least 4 weeks prior to the procedure and requires objective evidence of abstinence from smoking prior to the procedure.

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. Reproductive, cancer-related and diagnostic procedures are excluded from this guideline.

The well-studied tests for confirmation of smoking cessation include cotinine levels and exhaled carbon monoxide testing. However, cotinine levels may be

positive in nicotine replacement therapy (NRT) users, smokeless tobacco and e-cigarette users (which are not contraindications to elective surgery coverage). In patients using nicotine products aside from combustible cigarettes the following alternatives to urine cotinine to demonstrate smoking cessation may be considered:

- Exhaled carbon monoxide testing
- Anabasine or anatabine testing (NRT or vaping)

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, 112 and 159.



**GUIDELINE NOTE 100, SMOKING AND SPINAL FUSION**

*Lines 51,154,205,259,351,366,406,482,532,561*

Non-emergent spinal arthrodesis (CPT 22532-22634) is limited to patients who are non-smoking and abstinent from any nicotine product for 6 months prior to the planned procedure, as shown by negative cotinine levels at least 6 months apart, with the second test within 1 month of the surgery date. Patients should be given access to appropriate smoking cessation therapy. Non-emergent spinal arthrodesis is defined as surgery for a patient with a lack of myelopathy or rapidly declining neurological exam.

**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 (ICD-10-CM J43.9) and all of the following:

A) BMI ≤31.1 kg/m2 (men) or ≤32.3 kg/m 2 (women)
B) Stable with ≤20 mg prednisone (or equivalent) dose a day
C) Pulmonary function testing showing
   1) Forced expiratory volume in one second (FEV 1) ≤ 45% predicted and, if age 70 or older, FEV 1≥ 15% predicted value
   2) Total lung capacity (TLC) ≥ 100% predicted post-bronchodilator
   3) Residual volume (RV) ≥ 150% predicted post-bronchodilator
D) $PCO_2$, ≤ 60 mm Hg (PCO 2, ≤ 55 mm Hg if 1-mile above sea level)
E) $PO_2$, ≥ 45 mm Hg on room air ( PO 2, ≥ 30 mm Hg if 1-mile above sea level)
F) Post-rehabilitation 6-min walk of ≥ 140 m
G) Non-smoking and abstinence from any nicotine product for 6 months prior to surgery, as shown by negative cotinine levels at least 6 months apart, with the second test within 1 month of the surgery date.

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).

**GUIDELINE NOTE 159, 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 and abstinent from any nicotine product for 6 months prior to surgery, as shown by negative cotinine levels at least 6 months apart, with the second test within 1 month of the surgery date.



Evidence Summary for flaps and grafts and smoking cessation

*Goltsman, 2017*

1. Analysis of the American College of Surgeons National Surgical Quality Improvement Program data set
2. Patients undergoing plastic surgery between 2007 and 2012
3. 40,465 patients included in data set. 15.7% were current smokers.
4. Surgeries included breast, upper and lower extremity, abdominal, and craniofacial procedures.
5. Results: Smokers had a higher likelihood of surgical (OR 1.37; $p < 0.0001$) and medical complications (OR, 1.24; $p = 0.0323$) and increased odds for wound complications (OR, 1.49; $p < 0.0001$) and wound dehiscence (OR, 1.84; $p < 0.0001$). Smokers were also found to have increased odds of these complications even when subgroup analysis was performed according to major Current Procedural Terminology categories. Smoking also increased the odds of superficial wound infections (OR, 1.40; $p < 0.0001$). No difference was observed in hospital length of stay between smokers and nonsmokers.
6. Author Conclusions: Smoking increases a multitude of postoperative complications after plastic surgery procedures.

*Hillam, 2017*

1. Multicenter retrospective study of the effects of smoking on reduction mammoplasty

2. Database review of the American College of Surgeons National Surgical Quality Improvement Program from 2009-2014
3. 13,984 patients
4. Results: After adjusting for potential confounders, smokers had a higher likelihood of any wound complication (OR 1.72; p Z 0.001) following reduction mammaplasty compared to nonsmokers.

*Sorenson, 2012*

1. Systematic review and metanalysis
2. 140 cohort studies including 479,150 patients
3. Results: The pooled adjusted odds ratios (95% CI) were 3.60 (2.62-4.93) for necrosis, 2.07 (1.53-2.81) for healing delay and dehiscence, 1.79 (1.57-2.04) for surgical site infection, 2.27 (1.82-2.84) for wound complications, 2.07 (1.23-3.47) for hernia, and 2.44 (1.66-3.58) for lack of fistula or bone healing. Former smokers and patients who never smoked were compared in 24 studies including 47,764 patients, and former smokers and current smokers were compared in 20 studies including 40,629 patients. The pooled unadjusted odds ratios were 1.30 (1.07-1.59) and 0.69 (0.56-0.85), respectively, for healing complications combined. In 4 randomized controlled trials, smoking cessation intervention reduced surgical site infections (odds ratio, 0.43 [95% CI, 0.21-0.85]), but not other healing complications (0.51 [0.22-1.19]).

*Pluvy, 2015 (abstract only available)* https://www.ncbi.nlm.nih.gov/pubmed/25447218

1. Systematic review of observational studies of smoking and cosmetic surgery
2. 60 observational studies
3. In the cosmetic surgery group, Odds Ratio of 2.3 [1.51-3.54] P<0.001 for surgical site infections and 2.5 [1.49-4.08] P<0.001 for delayed wound healing.
4. In the bariatric surgery sequelae group, we found a combined Odds Ratio of 3.3 [1.90-5.64] P<0.001 with regard to delayed wound healing and 3.1 [1.39-7.13] P=0.006 for cutaneous necrosis.
5. No proof was provided as to the possible influence of tobacco on the success rate of free flap microsurgery, but it is difficult to extrapolate results on the latter to digital reimplantation.
6. Author conclusions: heightened risk of cutaneous necrosis, particularly in the event of major detachment (cervico-facial lift, skin-sparing mastectomy, abdominoplasty), of additionally delayed wound healing and of addition surgical site infections. Rigorous preoperative evaluation of smokers could help to diminish these risks.

*Pluvy, 2015 (abstract only available*) https://www.ncbi.nlm.nih.gov/pubmed/25447216

1. Literature review from 1972 to 2014 of smoking and plastic surgery
2. Data from the literature recommend a preoperative smoking cessation period lasting between 3 and 8 weeks and up until 4 weeks postoperatively. Use of nicotine replacement therapies doubles the abstinence rate in the short term.

When a patient is heavily dependent, the surgeon should be helped by a tobacco specialist.

3. Total smoking cessation of 4 weeks preoperatively and lasting until primary healing of the operative site (2 weeks) appears to optimize surgical conditions without heightening anesthetic risk. Tobacco withdrawal assistance, both human and drug-based, is highly recommended.

*Coon, 2013*

1. Prospective cohort study of all patients undergoing plastic surgery with general anesthesia in a single-surgeon practice
2. Urine samples on day of surgery for nicotine metabolites.
3. F/u 3 months
4. 415 patients, 139 (33.5 percent) stated that they had quit smoking and 39 (9.4 percent) were admitted active smokers. For the 362 patients with urine nicotine analysis available, 54 showed active smoking. Fifteen of these (4.1 percent) had denied current tobacco use. Patients stating that they had quit smoking were more likely to be deceitful than those stating they had never smoked ($p < 0.001$).
5. Smokers had significantly higher overall complication rates (OR, 3.7; $p < 0.001$) and tissue necrosis rates (OR, 4.3; $p = 0.02$) and were likelier to require reoperation (OR, 3.7; $p < 0.001$).
6. Author Conclusions: In a large cohort study examining the prevalence and impact of nicotine in the general plastic surgery population, substantial rates of deception regarding smoking status were found. Furthermore, active smoking was strongly correlated with complications.



<u>HERC Staff Assessment</u>

1. Reproductive procedures can be misinterpreted to mean that any procedure done on reproductive organs would be exempt (such as hysterectomy or phalloplasty) from the smoking cessation guideline. This needs to be clarified that the intent is about reproductive procedures with the goal of contraception.
2. The guidelines that discuss needing to get rid of “any nicotine product” suggests that continuing another one is acceptable. This should be clarified to support the intent, which is that all nicotine product use needs to cease.
3. While smoking is clearly associated with worse outcomes for plastic surgeries involving grafts and flaps, the duration of cessation that optimizes outcomes is unclear based on the literature found.

<u>HERC Staff Recommendations</u>:
Modify Ancillary Guideline A4 as follows:

## ANCILLARY GUIDELINE A4, SMOKING CESSATION AND ELECTIVE SURGICAL PROCEDURES

Smoking cessation is required prior to elective surgical procedures for active tobacco users. Cessation is required for at least 4 weeks prior to the procedure and requires objective evidence of abstinence from smoking prior to the procedure.

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. Reproductive (i.e. for contraceptive purposes), cancer-related and diagnostic procedures are excluded from this guideline.

The well-studied tests for confirmation of smoking cessation include cotinine levels and exhaled carbon monoxide testing. However, cotinine levels may be positive in nicotine replacement therapy (NRT) users, smokeless tobacco and e-cigarette users (which are not contraindications to elective surgery coverage). In patients using nicotine products aside from combustible cigarettes the following alternatives to urine cotinine to demonstrate smoking cessation may be considered:

- Exhaled carbon monoxide testing
- Anabasine or anatabine testing (NRT or vaping)

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, 112 and 159.



## GUIDELINE NOTE 100, SMOKING AND SPINAL FUSION

*Lines 51,154,205,259,351,366,406,482,532,561*

Non-emergent spinal arthrodesis (CPT 22532-22634) is limited to patients who are non-smoking and abstinent from ~~any~~all nicotine products for 6 months prior to the planned procedure, as shown by negative cotinine levels at least 6 months apart, with the second test within 1 month of the surgery date. Patients should be given access to appropriate smoking cessation therapy. Non-emergent spinal arthrodesis is defined as surgery for a patient with a lack of myelopathy or rapidly declining neurological exam.

## 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 (ICD-10-CM J43.9) and all of the following:

H) BMI ≤31.1 kg/m2 (men) or ≤32.3 kg/m 2 (women)
I) Stable with ≤20 mg prednisone (or equivalent) dose a day
J) Pulmonary function testing showing
   1) Forced expiratory volume in one second (FEV 1) ≤ 45% predicted and, if age 70 or older, FEV 1≥ 15% predicted value
   2) Total lung capacity (TLC) ≥ 100% predicted post-bronchodilator
   3) Residual volume (RV) ≥ 150% predicted post-bronchodilator
K) $PCO_2$, ≤ 60 mm Hg (PCO 2, ≤ 55 mm Hg if 1-mile above sea level)
L) $PO_2$, ≥ 45 mm Hg on room air ( PO 2, ≥ 30 mm Hg if 1-mile above sea level)
M) Post-rehabilitation 6-min walk of ≥ 140 m
N) Non-smoking and abstinence from ~~any~~all nicotine products for 6 months prior to surgery, as shown by negative cotinine levels at least 6 months apart, with the second test within 1 month of the surgery date.

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).

**GUIDELINE NOTE 159, 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 and abstinent from ~~any~~all nicotine products for 6 months prior to surgery, as shown by negative cotinine levels at least 6 months apart, with the second test within 1 month of the surgery date.





VbBS Issue Summaries from May 18, 2017

# Novel Treatments

Issue: At its March 9, 2017 meeting, the HERC adopted changes to the Prioritized List that address novel treatments with marginal clinical benefit, low cost-effectiveness, and/or very high cost. These changes included two new lines and two new guidelines. The guidelines were adopted as blank tables, with HERC staff charged to identify items that should be considered for addition to these tables.

HERC staff was charged to work with the Pharmacy and Therapeutics (P&T) Committee regarding novel prescription medication(s) that would qualify. P&T is working on identifying medications and is expected to have one or more candidates identified at their May and/or July, 2017 meeting.

HERC staff was also charged with identifying items on the current Services Recommended for Non-Coverage (SRNC) table for movement to the new guideline tables. Such a move would make the placement of these services much more transparent to providers, plans, and other stakeholders as the SRNC list is currently available via the searchable Prioritized List but stakeholders have noted that it is not easy to find.

Staff have identified that there should be list of experimental services, either maintained as a separate table from the Prioritized List or included as part of the line 660 guideline note. Medicaid programs are prohibited by federal rule from covering experimental therapies.

There is also a list of therapies which are excluded due to Medicaid rules. These include coverage of travel vaccines, cosmetic procedures, etc.

Feedback from the OHP medical directors: they would like to continue to have the date last reviewed and links to the minutes, as these are very helpful. They did not feel that the rationale needed to be included in the table as the minutes would have a much more nuanced rationale. They did not feel that ICD-10 codes needed to be included on these lines, as many of these conditions have many ICD-10 codes and some may be inadvertently left off. General descriptions of conditions in the tables would be sufficient. They felt adding experimental therapies to the guideline note for line 660 was acceptable.

# Novel Treatments

HERC staff recommendations:

1) Discuss:
    a. How do you define marginal vs no clinical benefit?
        i. No clinical benefit
            1. No evidence of effectiveness found. Discuss when this would be experimental and when/what level of evidence would be considered lack of evidence of effectiveness
            2. Higher risk of harms that other effective treatments (ex: 15777 Acellular dermal matrix for soft tissue reinforcement)
        ii. Marginal clinical benefit
            1. Some improvement may be shown, but not of clinical significance (ex: obesity drugs)
            2. May have some effectiveness, but other therapies are more effective (ex: electromagnetic bone conduction hearing loss)
    b. Where should the list of experimental therapies be maintained?
        i. Part of line 660? Other location?
    c. How should excluded services such as travel vaccines and cosmetic procedures be indicated, or where should such a list be maintained?
2) Examples of possible modifications to Guideline Note 168 and 169 are shown below
    a. What detail should be included in these tables? ICD-10 codes? Rationale? Date of last review? Link to minutes? Other?



**GUIDELINE NOTE 168, TREATMENTS WITH MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS FOR CERTAIN CONDITIONS**

The following treatments are prioritized on Line 500 for the conditions listed here:

| CONDITION | CPT/HCPCS code | TREATMENT | Rationale |
|---|---|---|---|
| Obesity | | All prescription drugs | Minimally effective, concern for harms, lack of proven long-term benefit |
| Bladder incontinence | CPT 64566 | Posterior tibial neurostimulation | Minimally effective, no evidence of long term effectiveness |
| Hearing loss | CPT 68710<br><br><br><br>*HCPCS L8690-L8693* | Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone<br>*Auditory osseointegrated device* | Less effective than other therapies |
| Angina, coronary artery disease, chest pain, other cardiac conditions | CPT 75571<br>CPT 75572<br>CPT 75574<br><br>CPT 78459 | CT coronary calcium scoring<br>Computed tomography, heart<br>Computed tomographic angiography, heart | Insufficient evidence of benefit, unclear harms of radiation exposure |

| | | | |
|---|---|---|---|
| | CPT 78491-78492 | Myocardial imaging, positron emission topography (PET), metabolic evaluation<br>Myocardial imaging, positron emission tomography (PET), perfusion | |
| Back and neck pain, radiculopathy, other back conditions | CPT 64633-64634 | Radiofrequency ablation | Insufficient evidence of benefit |
| Back and neck pain, radiculopathy, other back conditions | CPT 64690-64692 | Facet joint injections | Insufficient evidence of benefit |
| Cancer tissue test | CPT 81504 | Biomarker tests for tumor tissue: Mammaprint, ImmunoHistoCHemistry 4 (IHC4) and Mammostrat for Breast Cancer, Microsatellite instability (MSI) for colorectal cancer, Urovysion for bladder cancer, Prolaris for prostate cancer, Multiple molecular testing to select targeted cancer therapy | Insufficient evidence of effectiveness. More costly than equally effective therapies for this condition |
| Urine leaks caused by vesicovaginal fistula, persistent urine leaks related to prior pelvic surgery, or persistent hematuria secondary to an unresectable malignancy | CPT 50705 | Ureteral embolization or occlusion. | Insufficient evidence of effectiveness |
| Cystic fibrosis, other chronic lung conditions | CPT 94669 | Mechanical chest wall oscillation | More costly than equally effective therapies for this condition |
| Stroke | CPT 61630 | Balloon angioplasty, intracranial (eg, atherosclerotic stenosis), percutaneous | Similar or worse outcomes than standard therapies |
| Musculoskeletal conditions | CPT 97024<br><br>CPT 97028<br><br>CPT 97034 | Application of a modality; Diathermy (eg, microwave)<br>Application of a modality; Ultraviolet<br>Application of a modality; contrast baths | Insufficient evidence of effectiveness |

# Novel Treatments

**GUIDELINE NOTE 169, TREATMENTS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS**

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

| CONDITION | CPT/HCPCS Code | TREATMENT | Rational |
|---|---|---|---|
| All conditions except Pompeii's disease | | Enzyme replacement therapy | No clinically important benefit |
| Sleep apnea | CPT 41512 | Tongue base suspension | No clinically important benefit |
| Tissue reconstruction, breast reconstruction | CPT 15777 | Acellular dermal matrix for soft tissue reinforcement (eg, breast, trunk) | Greater harms than other effective therapies |
| Any indication | CPT 90880 | Hypnotherapy | No clinically important benefit |
| Sleep apnea, other sleep disorders | CPT 95803 | Actigraphy | No clinically important benefit |
| Screening for breast cancer | CPT 93740 | Temperature Gradient Studies | Harms outweigh benefit, clear inferiority of the test compared to standard screening |
| Wounds | CPT 97610 | Low frequency, non-contact, non-thermal ultrasound | No clinically important benefit |
| Stroke, intracrancial vasospasm | CPT 61635 | Transcather placement of intravascular stent(s), intracranial (eg, athersclerotic stenosis), including balloon angioplasty, if performed | Results in significantly worse outcomes than medical management |
| Intracranial vasospasm | CPT 61640-61642 | Balloon dilation of intracranial vasospasm, percutaneous. | Evidence of harm |
| Musculoskeletal conditions, wounds | CPT 97036<br><br>CPT 97022 | Application of a modality; Hubbard tank<br>Application of a modality; Whirlpool | Evidence of harm |

**Cost-effectiveness Issue Summary**

Question**:** Should HERC deliberate on general guidelines for cost-effectiveness?

Question Source: HERC Staff

Issue: Historically the HERC has not used a pre-defined threshold for cost-effectiveness to determine placement on the Prioritized List. With the potential adoption of the new guideline on novel treatments with marginal clinical benefit or low cost-effectiveness, HERC may wish to consider having a general discussion of what may define low cost-effectiveness.

It has been years since HERC discussed cost-effectiveness thresholds. In the biennial report, HERC has previously used the following Figure 1.9. The specific thresholds of cost-effectiveness have not been revised since 2004. At the March meeting it was decided to remove Figure 1.9 from the 2017 Biennial Report.

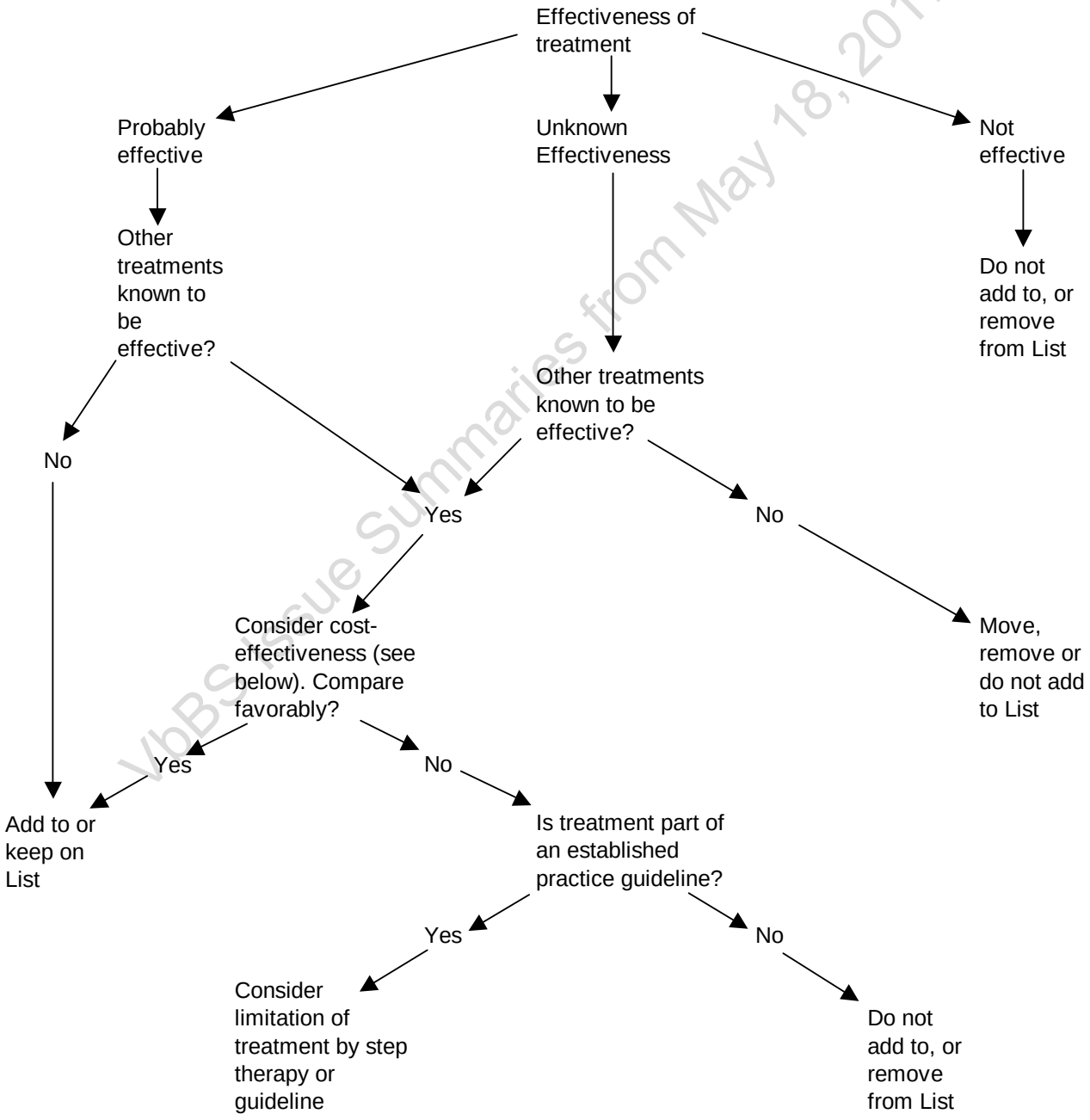
The potential biennial list changes related to novel treatments with marginal clinical benefit or low cost-effectiveness are going to beg the questions: What is low cost-effectiveness? What is very high cost in which the cost does not justify the benefit? What is significantly greater cost compared to alternative therapies?

In the statement of intent, these exact thresholds are not spelled out. Staff would propose that spelling them out clearly would be challenging, as each topic is going to need to be highly individualized.

The question then is whether VbBS/HERC have a general shared agreement as to what these definitions may be and is it necessary, or even possible, to further define them? Or will it be best to address each of these on an individual basis?

**FIGURE 1.9**
**PROCESS FOR INCORPORATING INFORMATION ON CLINCAL INFORMATION AND COST-EFFECTIVENESS INTO THE PRIORITIZED LIST**

HERC will review evidence as outlined in Figure 1.9. Evidence regarding the effectiveness of a treatment will be used according to the following algorithm:



## FIGURE 1.9 (CONT'D)
## PROCESS FOR INCORPORATING INFORMATION ON CLINCAL INFORMATION AND COST-EFFECTIVENESS INTO THE PRIORITIZED LIST

The cost of a technology will be considered according to the grading scale below, with "A" representing compelling evidence for adoption, "B" representing strong evidence for adoption, "C" representing moderate evidence for adoption, "D" representing weak evidence for adoption and "E" being compelling evidence for rejection:

- A = more effective and cheaper than existing technology
- B = more effective and costs < $25,000/LYS or QALY > existing technology
- C = more effective and costs $25,000 to $125,000/LYS or QALY > existing technology
- D = more effective and costs > $125,000/LYS or QALY > existing technology
- E = less or equally as effective and more costly than existing technology



Background

*Marseille, 2015* http://www.who.int/bulletin/volumes/93/2/14-138206/en/

- WHO Bulletin discussing issues related to approaching cost-effectiveness and willingness to pay
- Estimates of costs, health effects and ICERs provide clear guidance to policy-makers in three situations: (i) when the health-effect target is specified by policy-makers and the aim of the cost–effectiveness analysis is to minimize the expenditure needed to achieve that target; (ii) when a budget constraint is specified by policy-makers and the aim is to maximize the health benefits while keeping expenditure within budget; and (iii) when policy-makers have specified an explicit standard or threshold for what should be considered cost–effective.
- Three general approaches have been used: (i) thresholds based on per capita national incomes; (ii) benchmark interventions and (iii) league tables. In recent years, the most common approach has involved the use of thresholds based on per capita gross domestic product (GDP).
- 3 approaches and their limitations
    - Threshold approach – 2 to 3 times the per capita national income
        - Even if something is cost-effective, it may still not be the most useful priority for a country's budget. There may be other more impactful interventions.
        - It is too easy to reach the threshold
        - Social willingness to pay – an untested assumption

        - Affordability is not adequately appraised – highly prevalent conditions are a case in point
    - Benchmark interventions – $50,000/100,000/150,000 is the benchmark and so for anything below that, adoption is justified
        - Benchmarks may not represent willingness to pay (could have been based on political decisions, don't take into account opportunity costs or change in burden of disease)
        - Does not address alternatives that may be more cost-effective
            - Optimally would need to consider a range of interventions with ICERs
    - League tables – focus on largest health impact for the budget. The league-table approach is based on the principle that, for any budget, health outcomes are maximized if selection of the options for implementation begins at the top of the league table – i.e. with the option with the lowest ICER – and then moves down the list, to interventions with successively higher ratios, until the budget is exhausted.
        - ICERS may not be available for many interventions
        - The tables are also limited in the factors they include (e.g., missing the size of the affected population, whether the intervention is scalable, the health benefit per recipient and the degree of uncertainty around the ICERs)
    - Additional limitations: The comparators have to be appropriate. There is enormous between-study variability in CEA estimates.
- Authors conclusions: Need to consider both disease burden and the budget

*Neumann, 2014*

- NEJM perspective article about cost-effectiveness thresholds
- $50,000 per QALY has been standard although its origin is unclear (dialysis for ESRD in 1970s?) and widespread popularity started in the 1990s.
- Willingness to pay depends on a healthcare budget
- Not a hard stop. Generally <$50,000 per QALY is "favorable" v >$50,000 is "unfavorable"
- Some economists have argued for a higher thresholds

| Cost-Effectiveness Thresholds Referenced by Authors of U.S.-Based Cost-Utility Analyses, 1990–2012.* | | | |
|---|---|---|---|
| **Threshold** | **1990–1999 Analyses (N=207)** | **2000–2009 Analyses (N=851)** | **2010–2012 Analyses (N=444)** |
| | | *percent* | |
| $50,000 per QALY | 19.3 | 36.6 | 36.9 |
| $100,000 per QALY | 6.3 | 7.8 | 16.9 |
| Both $50,000 and $100,000 per QALY | 3.9 | 19.9 | 23.7 |
| Other | 18.4 | 10.6 | 7.4 |
| No threshold referenced | 51.9 | 25.1 | 15.3 |

* Data are from the Tufts Medical Center Cost-Effectiveness Analysis Registry (www.cearegistry.org). QALY denotes quality-adjusted life-year.

- The opportunity costs of making health care decisions are rarely known
- Authors recommend having multiple thresholds ($50k, $100k or $150k) depending on the available resources for the relevant decision maker and possible other uses of those resources

*Maciosek, 2010*

- Evaluates costs of adopting a bundle of 20 evidence-based clinical preventive services (e.g. breast cancer screening, colon cancer screening, hypertension screening)
- Demonstrates that very few preventive health care services are actually cost-saving in terms of annual net medical costs per person per year:
    - Childhood immunizations (more than 3 times any of the others)
    - Pneumococcal immunization
    - Discussing daily aspirin use
    - Smoking cessation advice and assistance
    - Alcohol screening and brief counseling
    - Obesity screening
    - Vision screening (adults)

*Neumann, 2010*

- Cost-effectiveness analysis registry review to identify low value services
- Define “low-value” – low value goes beyond waste and inappropriate care to include interventions that deliver positive but limited benefits relative to their costs. For purposes of this study, we defined low-value services to be those that make health worse (without saving money) or those that cost at least $100,000 per QALY gained

- Methods: We searched the Tufts Medical Center Cost-Effectiveness Analysis Registry (www.cearegistry.org) to identify examples of low-value services. We restricted our attention to papers published since 2000. We supplemented this literature review with a list of services recently rejected by NICE for coverage by the UK's National Health Service.
- Challenges relate to the underlying evidence base, the applicability of the study to the target population, and the strength of the cost-effectiveness evidence.
- Example services with low cost-effectiveness

**Table 1.** Selected Services With Relatively Unfavorable Cost-Effectiveness

| Service | Compared With: | Cost-Effectiveness (2007 US Dollars) |
|---|---|---|
| Lung volume reduction surgery | Continued medical treatment | $100,000-$300,000 per QALY[40] |
| Cetuximab for the treatment of metastatic colorectal cancer after failure of chemotherapy | Active/best supportive care | $110,000-$410,000 per QALY[41,42] |
| Anastrozole in women with estrogen-receptor positive breast cancer | Tamoxifen | $270,000 per QALY[43] |
| Transmyocardial revascularization for patients with severe angina refractory to standard medical therapy | Continued medical therapy | $440,000 per QALY[44] |
| Left ventricular assist devices | Optimal medical care | $500,000-$1.4 million per QALY[45] |
| Pemetrexed to treat non–small-cell lung cancer | Docetaxel<br>Erlotinib and docetaxel | $870,000 per QALY[46]<br>Increases cost and results in worse health outcomes[47] |
| Positron emission tomography in Alzheimer's disease | Standard examination | Increases cost and results in worse health outcomes[48] |

QALY indicates quality-adjusted life-year.

*Chambers, 2010*

- Evaluation of the use of cost-effectiveness in Medicare National Coverage Determinations (NCDs)
- 1999-2007, N= 103
- Reviewed the cost-effectiveness of the interventions included in NCD
- Results: Of the 64 coverage decisions determined to have a corresponding cost-effectiveness estimate, 49 were associated with a positive coverage decision and 15 with a noncoverage decision. Of the positive decisions, 20 were associated with an economic evaluation that estimated the intervention to be dominant (costs less and was more effective than the alternative), 12 with an incremental cost-effectiveness ratio (ICER) of less than $50,000, 8 with an ICER greater than $50,000 but less than $100,000, and 9 with an ICER greater than $100,000. Fourteen of the sample of 64 decision memos cited or discussed cost-effectiveness information.
- Author conclusions: CMS is covering a number of interventions that do not appear to be cost-effective, suggesting that resources could be allocated more efficiently. Although

the authors identified several instances where cost-effectiveness evidence was cited in NCDs, they found no clear evidence of an implicit threshold.

*National Institute for Clinical Excellence (NICE) (from https://www.nice.org.uk/process/pmg9/resources/guide-to-the-methods-of-technology-appraisal-2013-pdf-2007975843781 and NICE blog https://www.nice.org.uk/news/blog/carrying-nice-over-the-threshold)*

- Our independent committees use a threshold for recommending treatments of between £20,000 and £30,000 per quality adjusted life year. We think it represents a reasonable compromise between ensuring everyone has fair and equitable access to the NHS and enabling access to new and innovative treatments.
- At this threshold, NICE currently recommends 8 out of 10 drugs or other technologies that it appraises, including 6 out of 10 cancer drugs. So we are careful about protecting, as much as we can, the interests of those who don't benefit from the newest treatments.
- The focus on cost-effectiveness analysis is justified by the Institute's focus on maximising health gains from a fixed NHS and personal social services budget and the more extensive use and publication of these methods compared with cost–benefit analysis. Currently, the QALY is considered to be the most appropriate generic measure of health benefit that reflects both mortality and health-related quality of life effects.



HERC Staff Summary

There are multiple ways to address cost-effectiveness. The "benchmark approach" of $50,000 per QALY still appears to be the most common in the US, although there is a trend towards higher amounts per QALY in US cost-effectiveness literature. Medicare does not appear to abide by a strict cutoff. NICE in the UK still uses 20,000-30,000 pounds as their cutoff (roughly USD $25,000-39,000).

Figure 1.9 included an algorithm, when previously HERC decided to no longer use an algorithm for decision-making because of an inability to capture the necessary nuance. It also included specific cost-effectiveness thresholds that no longer seem to relate to the current literature.

**Cost-effectiveness Thresholds**

HERC Staff Recommendations

1) Discuss if there will be a generally accepted definition of low cost-effectiveness, or very high cost, or significantly higher cost compared to other alternative treatments.

# Vision Training

Question: Should vision training be paired with any diagnosis other than intermittent exotropia and intermittent esotropia?

Question source: HERC staff

Issue: Vision therapy (also known as orthoptic and/or pleoptic training) was once on many lines on the Prioritized List. During the biennial review of 2000, it was noted that evidence only supported use of vision therapy for intermittent exotropia and intermittent esotropia. The CPT code for vision therapy (92065 Orthoptic and/or pleoptic training, with continuing medical direction and evaluation) was removed from all lines other than line 473, which is the equivalent of current line 399. It was noted that CPT 92065 now appears on three lines on the Prioritized List, likely due to like splitting and other line changes since 2000. HERC staff was asked to determine whether there were any diagnoses which has evidence to support vision therapy on one or both of these additional lines.

Vision therapy involves the use of lenses, prisms, and specialized testing and vision training procedures. Vision training, or "eye exercises," are used, not to strengthen the eye muscles, but rather to improve coordination, efficiency, and functioning of the vision system.



Current Prioritized List status:
CPT 92065:
356 STRABISMUS DUE TO NEUROLOGIC DISORDER (contains strabismus and ophthalmoplegia diagnoses)
375 AMBLYOPIA
399 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN (contains intermittent esotopia and exotopia diagnoses)

HSC/HERC history:
HOSC January 2000

*Visual training* -- The optometrists at Pacific University recommend treating reading disability with visual training. The American Academy of Pediatrics does not endorse this therapy. The Vision Guide at the Office of Medical Assistance Programs limits vision therapy visits to five per year and this service is being reviewed as part of the comprehensive review of ancillary services. At this time the relevant CPT code (92065) is included as part of the medical therapy codes on the medical lines on the Prioritized List (571 lines). Discussion today suggests the code 92065 may be appropriate only for the lines with the diagnoses for intermittent exotropia or intermittent esotropia.

The Subcommittee decided to review the research materials from earlier meetings and form a subcommittee chaired by Dr. Glass to develop formal recommendations for the biennial review.

HOSC February 2000

Vision Therapy

It was decided at last month's meeting that Dr. Glass would convene a task force to review vision therapy. However, research has shown that the Ancillary Services Workgroup considered eliminating this service and found that the fee-for-service program had expenditures of only $2500. Therefore, it has been decided that this is a very small problem and that all the codes for which the Oregon Optometric Association considers vision therapy efficacious are on Line 473 of the Prioritized List of

# Vision Training

Health Services. For the 2000 Biennial Review, the plan is to reconfigure the Medical Therapy code ranges to have vision therapy appear on Line 473 only. Darren Coffman will draft a letter to the optometric association explaining this decision.

At this point Dr. Glass teleconferenced into the meeting and reviewed the progress and decisions that had been made. He endorsed the changes that had been recommended and had no further input to the dental recommendations that will be reviewed this afternoon.

Evidence:
No literature was identified examining vision training, orthoptic and/or pleoptic training with amblyopia, ophthalmoplegia, or any other diagnosis appear on lines 356 or 175.

Small case series were identified which supported the use of vision training for patients for intermittent esotropia and exotropia.

Current utilization
For the past 6 months, there were 2,226 paid claims for a total of $237,881.06 for vision training. Only 20 (0.8%) paid claims pair with intermittent esotropia/exotropia. 1471 (66%) paid claims involve diagnostic codes which appear on line 399 but not intermittent esotropia/exotropia.

HERC staff recommendations:

1) Remove CPT 92065 (Orthoptic and/or pleoptic training, with continuing medical direction and evaluation) from lines 356 STRABISMUS DUE TO NEUROLOGIC DISORDER and 375 AMBLYOPIA
    a. No evidence for use with any diagnoses appearing on these lines
    b. Unclear how these codes were added to these lines
2) Add a new coding specification to line 399 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN
    a. "CPT 92065 is included on line 399 only for pairing with ICD-10 H50.31 (Intermittent monocular esotropia), H50.32 (Intermittent alternating esotropia), and H50.33 (Intermittent alternating exotropia)."

Issue: At the October, 2015 VBBS meeting, as part of the 2016 CPT code review, a new code for intrastromal corneal ring segments (ICRS) was discussed, and the subcommittee members agreed with the HERC staff recommendation to add this code to a covered line with a new guideline. At the October meeting, however, the CPT codes were not officially available and no official vote took place. At the November, 2015 VBBS meeting, the new CPT code was mistakenly added to the Services Recommended for Non-Coverage table and the guideline was never adopted. This appears to be due to staff error. A CCO has recently queried HERC staff regarding this code and the error was discovered. Because the code was voted into an incorrect placement and the guideline never adopted, HERC staff felt that this topic should be re-addressed by the VBBS/HERC. HERC staff have updated this review and updated the guideline note. The updated guideline note include reference to the actual CPT code and includes a corneal thickness requirement.

Intrastromal corneal rings are small devices implanted in the eye to correct vision or to treat keratoconus. A typical vision correction using corneal rings would involve an ophthalmologist making a small incision in the cornea of the eye, and inserting two crescent or semi-circular shaped ring segments between the layers of the corneal stroma, one on each side of the pupil. The embedding of the rings in the cornea has the effect of flattening the cornea and changing the refraction of light passing through the cornea on its way into the eye.

Current Prioritized List status:
CPT 65785 (Implantation of intrastromal corneal ring segments)—Services Recommended for Non-Coverage



Evidence

**Poulson 2015**, review

1) ICRS are a well-tolerated and effective treatment for patients with corneal ectasia, particularly keratoconus, offering long-term improvement in visual, refractive, and keratometric measures. ICRS do not consistently decrease corneal aberrations. Patients with mild-to-moderate keratoconus, known to have less predictable outcomes with ICRS, may be better selected and treated with the use of customized nomograms, accounting for factors such as internal astigmatism. Corneal collagen cross-linking performed after ICRS implantation is an important complementary treatment in preventing the progression of ectasia, whereas subsequent treatment with either photorefractive keratectomy or toric intraocular lens implantation offers a significantly improved visual and refractive result.

**Park 2013**, review

1) ICRS variably improve visual acuity. Numerous questions concerning ICRS remain, including the duration of the effects of ICRS and the changes that ICRS induce on a biomechanical level. The optimal method for combined CXL and ICRS placement has not

yet been determined. Further well-designed randomized controlled studies with long-term follow-up are needed for clarification.

Other policies

1) **Aetna 2016**
    a. **Intrastromal corneal ring segments (INTACS)** are considered not medically necessary for adults with mild myopia (from -1.0 to -3.0 diopters) that have less than 1 diopter of astigmatism. Aetna considers intrastromal corneal ring segments experimental and investigational for children, for persons with moderate-to- severe myopia (greater than -3.0 diopters), for persons with more than 1 diopter of astigmatism, and for hyperopia because their effectiveness for these indications has not been established. Intrastromal corneal ring segments are considered medically necessary for reduction or elimination of myopia or astigmatism in persons with keratoconus or pellucid marginal degeneration who are no longer able to achieve adequate vision using contact lenses or spectacles and for whom corneal transplant is the only remaining option, in persons with a clear central cornea and corneal thickness of 450 microns or greater at the proposed incision site. Intrastromal corneal ring segments are considered experimental and investigational for other indications because their effectiveness for indications other than the ones listed above has not been established.
2) **BCBST 2016**
    a. Intrastromal corneal ring segments for the treatment of keratoconus is considered **medically appropriate** if **ALL** of the following criteria are met:
        i. Age of 21 years or older
        ii. Progressive deterioration in vision
        iii. Best correction using contact lenses or spectacles unable to achieve 20/40 or better
        iv. Central cornea is clear
        v. Corneal thickness of 450 microns or greater at proposed incision site
        vi. Inability to perform activities of daily living (ADLs) in current visual state
        vii. Procedure intended to achieve **ALL** of the following:
            1. Reduce or eliminate myopia and/or astigmatism associated with keratoconus
            2. Restore functional vision
            3. Defer the need for a corneal transplant procedure as the only remaining treatment option

HERC staff recommendations:

1) Add CPT 65785 (Implantation of intrastromal corneal ring segments) to line 315 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA
    a. Contains keratoconus (ICD-10 H18.6)
2) Adopt the following guideline for line 315

**GUIDELINE NOTE XXX INTRASTROMAL CORNEAL RING SEGMENTS**

*Line 315*

Insertion of intrastromal corneal ring segments (CPT 65785) is included on this line only for reduction or elimination of myopia or astigmatism in adults age 19 and older with keratoconus who are no longer able to achieve adequate functional vision to perform ADLs with best correction using contact lenses or spectacles, who have a corneal thickness of 450 microns or greater at proposed incision site, and for whom corneal transplant is the only remaining option to improve their functional vision.

# Nasal Endoscopy for Acute Recurrent Sinusitis

Questions:

1) Should nasal endoscopy sinus surgery or any other sinus surgery be paired with treatment of acute recurrent rhinosinusitis?
2) Should open sinus surgery continue to be paired with acute sinusitis?
3) Should the current sinus guideline be clarified regarding what is meant by "several courses" of antibiotics and "a trial" of nasal steroids?

Question sources:

1) HSD
2) HERC staff
3) Tracy Muday, MD, medical director

Issue: HSD has requested pairing of sinus endoscopy procedures with acute recurrent sinusitis diagnoses. The AAO-HNS (2015) defines recurrent acute sinusitis (RARS) as four or more episodes per year of acute bacterial rhinosinusitis without signs or symptoms of rhinosinusitis between episodes; each episode must meet criteria for diagnosis of acute sinusitis. In contrast, chronic rhinosinusitis (CRS) is defined as twelve weeks or longer of 2 or more signs and symptoms with documented inflammation based on imaging or direct visualization. Endoscopic sinus surgery involves using an instrument to remove tissue from the sinuses with the goal of better drainage and aeration.

ICD-9 did not have codes for recurrent acute rhinosinusitis (RARS); codes only existed for acute rhinosinusitis and chronic rhinosinusitis. The prioritization of RARS was reviewed in 2012 as part of the ICD-10 ENT review, with the ENT reviewers not suggesting any change to the GEM mapping placement of RARS on the acute sinusitis line.

Procedures for pairing with acute sinusitis was last reviewed in April 2012, as part of the ICD-10 ENT review. At the 2012 review, the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) 2007 guideline found no recommendation for sinus endoscopy for acute sinusitis, and found that sinus endoscopy was given a Grade D (expert opinion) option for treatment/evaluation of recurrent acute rhinosinusitis. Based on this guideline, endoscopy sinus procedures were removed from the acute sinusitis line (now line 369). One CPT code (31256 Nasal/sinus endoscopy, surgical, with maxillary antrostomy) was mistakenly not removed from this line. In the 2015 update of the AAO-HNS sinusitis guideline, endoscopy continues to be not mentioned as a treatment for acute sinusitis. There remain a series of direct (not endoscopic) sinus surgeries on the acute sinusitis line. It is unclear from the ICD-10 ENT review whether the direct sinus surgeries were also intended for removal from this line; these procedures are rarely done now that endoscopic surgery has become mainstream due to the less invasive nature of endoscopic surgery.

From the April 2012 VBBS minutes:

> The group agreed that there was no evidence for adding nasal endoscopy to the acute sinusitis line and agreed with the suggestion that the 4 CPT codes for these types of procedures which currently appear on this line be removed. There was then discussion about whether nasal endoscopy should be covered for chronic sinusitis. Dr. Paul Flint, the ENT expert who came to discuss the ENT ICD-10 changes, was asked about this question. His response was that endoscopic surgery was effective for the treatment of chronic sinusitis. He reported that studies comparing medical management of chronic sinusitis with surgical therapy found that surgical patients had

better outcomes. He agreed with the suggestion to not add these endoscopy codes to the acute sinusitis line.

The Prioritized List contains a guideline which defines the criteria that a patient must meet to have covered sinus surgery. One criteria is "4 or more episodes of acute rhinosinusitis in one year," which would qualify as recurrent acute sinusitis under the AAO-HNS definition. This guideline was written in 2004 due to concerns for overuse of sinus surgery. This guideline was reviewed as part of the ICD-10 ENT review; there are no notes for any suggested changes to the guideline as part of that review.

Chronic sinusitis was reviewed with the ENT ICD-10 review, and the effectiveness of surgery was scored at 50%.

Dr. Tracy Muday, an OHP medical director, has asked for clarification of requirements in the current sinus surgery guideline.

> We have struggled with the definition of "several courses of antibiotics" and "trial on inhaled and/or oral steroids." We define "several" as 3. My other ENT says this is not fair and that I'm changing the guidelines without telling them. They think one fill of inhaled or oral steroids is adequate. I have asked for at least two fills, and that the fluticasone be at least 2 sprays daily for adults. Again, "going beyond the guidelines."



Current Prioritized List status:
Diagnostic nasal/sinus endoscopy (CPT 31231-31235): diagnostic procedures list
Line 369 ACUTE SINUSITIS: contains ICD-10 codes for acute sinusitis (ICD-10 J01.x0) and for recurrent acute sinusitis (ICD-10 J01.x1). Contains various procedures codes for open sinus surgery
Line 469 CHRONIC SINUSITIS: contains ICD-10 codes for chronic sinusitis (ICD-10 J32). Contains various procedure codes for sinus surgery (endoscopic and open)

The following guideline applies to the acute and chronic sinusitis lines:
**GUIDELINE NOTE 35, SINUS SURGERY**
*Lines 369,469*
Sinus surgery (other than adenoidectomy) is indicated in the following circumstances:

A) 4 or more episodes of acute rhinosinusitis in one year

OR

B) Failure of medical therapy of chronic sinusitis including all of the following:
- Several courses of antibiotics AND
- Trial of inhaled and/or oral steroids AND
- Allergy assessment and treatment when indicated
  AND
- One or more of the following:
- Findings of obstruction of active infection on CT scan
- Symptomatic mucocele
- Negative CT scan but significant disease found on nasal endoscopy

OR

C) Nasal polyposis causing or contributing to sinusitis

OR

D) Complications of sinusitis including subperiosteal or orbital abscess, Pott's puffy tumor, brain abscess or meningitis

OR

E) Invasive or allergic fungal sinusitis

OR

F) Tumor of nasal cavity or sinuses

OR

G) CSF rhinorrhea

Adenoidectomy (CPT 42830, 42835) is included on Line 469 only for treatment of children with chronic sinusitis who fail appropriate medical therapy.

# Nasal Endoscopy for Acute Recurrent Sinusitis

Evidence:

**Orlandi 2016**: International Consensus Statement on Allergy and Rhinology: Rhinosinusitis (study not included due to length. Available online

1) No mention of endoscopy for treatment or evaluation of acute sinusitis
2) Recurrent acute sinusitis:
    a. N=3 cohort studies (N=19, 14, 21 patients) for patient outcomes after endoscopy sinus surgery (ESS)
        i. Significant improvement in rhinosinusitis symptom inventory, antihistamine use, number of workdays missed, and number of acute infectious episodes. No significant change in antibiotic utilization
        ii. Harms may occur; significant costs associated with surgery
        iii. Aggregate Grade of Evidence: C (Level 3b: 3 studies)
        iv. Value Judgments: Properly selected patients with RARS may benefit both symptomatically and medically from ESS. This option should be assessed and utilized cautiously, however, because data remains limited.
        v. Policy Level: Option.

**Costa 2015**, retrospective cohort study of medical vs surgical therapy for RARS

1) A total of 220 RARS patients treated between 2006 and 2014 were retrospectively divided into 3 cohorts: medical only (MED); surgical only (SURG); or medical crossing over into surgical (CROSS).
    a. Surgical intervention: standard maxillary antrostomy and partial ethmoidectomy was performed for patients with negative computed tomography (CT) scans, and for patients with more extensive disease, additional sinuses were opened according to the distribution of disease.
    b. Medical therapy: oral antibiotics as well as nasal and/or oral corticosteroids for management of acute episodes of rhinosinusitis; they also received saline irrigations and allergy treatment when appropriate.
    c. Patients opting for medical therapy were given the option to elect endoscopic surgical treatment at any point during their care.
1) The SURG cohort showed greater reduction of SNOT-22 scores compared to the MED cohort at 3, 6, and 12 months follow-up ($p < 0.0001$).
2) In the CROSS vs SURG comparison, the CROSS cohort showed a comparable magnitude of reduction of SNOT-22 scores after surgery compared to the SURG cohort (p range from 0.1 to 0.5).
3) ***Conclusion:*** RARS patients can benefit from both medical and surgical treatment strategies, but surgical treatment results in greater symptomatic improvement compared to medical treatment.



Expert guidelines:

**American Academy of Otolaryngology--Head and Neck Surgery (2015)** practice guideline:

-Diagnosis of CHRONIC RHINOSINUSITIS (CRS) OR recurrent ACUTE RHINOSINUSITIS (ARS): Clinicians should distinguish CRS and recurrent ARS from isolated episodes of acute bacterial rhinosinusitis (ABRS) and other causes of sinonasal symptoms. *Recommendation based on cohort and observational studies with a preponderance of benefit over harm.*

-OBJECTIVE CONFIRMATION OF A DIAGNOSIS OF CHRONIC RHINOSINUSITIS (CRS): The clinician should confirm a clinical diagnosis of CRS with objective documentation of sinonasal inflammation, which may

be accomplished using anterior rhinoscopy, nasal endoscopy, or computed tomography. *Strong recommendation based on crosssectional studies with a preponderance of benefit over harm.*

Expert input:

Dr. Tim Smith, OHSU ENT

If the clinician is able to make the diagnosis of recurrent acute rhinosinusitis (it is a challenging diagnosis to make), and if the patient is managing inflammation of the nose with topical steroid therapy and saline irrigation therapy, and if they are still experiencing repeated bouts of acute bacterial rhinosinusitis, the literature is very clear that a limited form of endoscopic sinus surgery that would likely entail bilateral maxillary antrostomy and bilateral anterior ethmoidectomy, would be highly effective in reducing the number of infections, in improving quality of life, and in reducing exposure to repeated antibiotics and oral steroids (which have significant cost related to the long time Horizon of this disease--cataract formation, osteoporosis, resistant organisms, etc.). I have found that there is almost nothing more confusing to patients and clinicians when they are able to reach a diagnosis but their health insurance will not cover the treatment of that diagnosis.

Dr. Smith in later communications noted that acute sinusitis may require either endoscopic or open procedures when it is a complicated acute sinusitis. Since there are no codes for complicated acute sinusitis, it may be difficult to distinguish from acute, uncomplicated sinusitis.

After reviewing the staff evidence review, Dr. Smith noted that there are several other studies showing effectiveness of ESS for RARS from a couple of different institutions including ours. There are no RCTs available.

HERC staff summary:

Sinus/nasal endoscopy is not recommended by expert groups for evaluation or treatment of acute sinusitis. Sinus/nasal endoscopy is an option for treatment of recurrent acute rhinosinusitis based on expert opinion and case series/cohort studies when a patient has failed medical therapy. The evidence base for the effectiveness of surgery for RARS is limited.

It is confusing attempting to discern the history and intent of coverage for RARS based on minutes and review notes. It appears that the ENT reviewers intended to not cover surgery for acute sinusitis; it appears that the reviewers approved the prioritization of RARS with acute sinusitis; it appears that the ENT reviewers felt surgery was appropriate for 4 or more episodes of acute sinusitis (i.e. RARS) due to lack of change in the sinus surgery guideline. These three statements are mutually incompatible: either the guideline needs to be modified to remove the clause regarding 4 or more episodes of acute sinusitis as an indication or RARS needs to be paired with sinus surgery procedure codes. Our current expert, Dr. Tim Smith, is of the opinion that RARS should be paired with sinus surgery procedure codes.

# Nasal Endoscopy for Acute Recurrent Sinusitis

HERC staff recommendations:

*I. Biennial Review*:

1) Review prioritization and treatments for acute sinusitis, RARS and chronic sinusitis as part of the 2020 Biennial Review

*II. General Recommendations:*

Surgery for acute sinusitis:

1) Remove remaining sinus endoscopy CPT codes from the acute sinusitis line per ICD-10 ENT review intent
    a. Remove CPT 31256 (Nasal/sinus endoscopy, surgical, with maxillary antrostomy) from line 369 ACUTE SINUSITIS
2) Remove direct sinus surgery CPT codes from the acute sinusitis line as it appears the intent of the ICD-10 ENT reviewers was to remove sinus surgery from that line and current expert guidelines do not mention surgery of any type as a treatment option for acute sinusitis
    a. Remove the following CPT codes from line 369 ACUTE SINUSITIS
        i. 31020 Sinusotomy, maxillary (antrotomy); intranasal
        ii. 31030 Sinusotomy, maxillary (antrotomy); radical (Caldwell-Luc) without removal of antrochoanal polyps
        iii. 31032 Sinusotomy, maxillary (antrotomy); radical (Caldwell-Luc) with removal of antrochoanal polyps
        iv. 31040 Pterygomaxillary fossa surgery, any approach
        v. 31050 Sinusotomy, sphenoid, with or without biopsy;
        vi. 31051 Sinusotomy, sphenoid, with or without biopsy; with mucosal stripping or removal of polyp(s)
        vii. 31070-31087 Sinusotomy frontal
        viii. 61782 Stereotactic computer-assisted (navigational) procedure; cranial, extradural (List separately in addition to code for primary procedure)
3) Change the treatment description for line 369 to MEDICAL ~~AND SURGICAL~~ TREATMENT
4) Remove line 369 from GN35

Clarification of requirements in guideline note 35

1) Clarify “several courses” of antibiotics as “at least 3 courses”
2) Clarify “a trial” of nasal and/or oral steroids as “at least 2 prescriptions for”
3) Indent 3 requirements in one section for clarity

*III. Options for acute recurrent sinusitis*

**Option 1**

1) Allow pairing of surgery for RARS. This is based on expert opinion and a very limited evidence base. It conforms with the intent of the HSC/HERC from 2004, although it is unclear if this was actually the intent of the ICD-10 ENT reviewers
    a. Remove recurrent acute rhinosinusitis diagnosis codes from line 369 ACUTE SINUSITIS and add to line 469 CHRONIC SINUSITIS
        i. J01.01 Acute recurrent maxillary sinusitis
        ii. J01.11 Acute recurrent frontal sinusitis
        iii. J01.21 Acute recurrent ethmoidal sinusitis
        iv. J01.31 Acute recurrent sphenoidal sinusitis
        v. J01.41 Acute recurrent pansinusitis

vi. J01.81 Other acute recurrent sinusitis
vii. J01.91 Acute recurrent sinusitis, unspecified

2) Change line title of line 469 to ACUTE RECURRENT SINUSITIS; CHRONIC SINUSITIS
3) Modify GN35 as shown below
   a. Further defines when RARS qualifies for surgery

**GUIDELINE NOTE 35, SINUS SURGERY**

*Lines ~~369,~~469*

Sinus surgery (other than adenoidectomy) is indicated in the following circumstances:

A) 4 or more episodes of acute bacterial rhinosinusitis in one year without signs or symptoms of rhinosinusitis between episodes and have failed optimal medical management defined at nasal steroid therapy, nasal saline therapy, and, if indicated, allergy treatment and are compliant with oral antibiotics and/or oral corticosteroids for management of acute episodes of rhinosinusitis

OR

B) Failure of medical therapy of chronic sinusitis including all of the following:

- Several courses of antibiotics (3 or more) AND
- Trial of inhaled and/or oral steroids (2 or more prescriptions for adequate doses of one or both) AND
- Allergy assessment and treatment when indicated AND
- One or more of the following:
  - Findings of obstruction of active infection on CT scan
  - Symptomatic mucocele
  - Negative CT scan but significant disease found on nasal endoscopy

OR

C) Nasal polyposis causing or contributing to sinusitis

OR

D) Complications of sinusitis including subperiosteal or orbital abscess, Pott's puffy tumor, brain abscess or meningitis

OR

E) Invasive or allergic fungal sinusitis

OR

F) Tumor of nasal cavity or sinuses

OR

G) CSF rhinorrhea

Adenoidectomy (CPT 42830, 42835) is included on Line 469 only for treatment of children with chronic sinusitis who fail appropriate medical therapy.

**Option 2:**

1) Do not allow pairing of surgery with RARS. This conforms with the intent of the ICD-10 ENT reviewers to prioritize RARS with acute sinusitis but not with their intent regarding the guideline; there is limited evidence of effectiveness of surgery for RARS
   a. Keep ICD-10 J01._1 on line 369 ACUTE SINUSITIS
2) Modify GN 35 as shown below

# Nasal Endoscopy for Acute Recurrent Sinusitis

**GUIDELINE NOTE 35, SINUS SURGERY**

*Lines ~~369,~~469*

Sinus surgery (other than adenoidectomy) is indicated in the following circumstances:

~~A) 4 or more episodes of acute rhinosinusitis in one year~~

~~OR~~

A) ~~B)~~ Failure of medical therapy of chronic sinusitis including all of the following:

- Several courses of antibiotics (3 or more) AND
- Trial of inhaled and/or oral steroids (2 or more prescriptions for adequate doses of one or both) AND
- Allergy assessment and treatment when indicated AND
- One or more of the following:
  - Findings of obstruction of active infection on CT scan
  - Symptomatic mucocele
  - Negative CT scan but significant disease found on nasal endoscopy

OR

B) Nasal polyposis causing or contributing to sinusitis

OR

C) Complications of sinusitis including subperiosteal or orbital abscess, Pott's puffy tumor, brain abscess or meningitis

OR

D) Invasive or allergic fungal sinusitis

OR

E) Tumor of nasal cavity or sinuses

OR

F) CSF rhinorrhea

Adenoidectomy (CPT 42830, 42835) is included on Line 469 only for treatment of children with chronic sinusitis who fail appropriate medical therapy.

# Cranial Electrical Stimulation

Question: Should cranial electrical stimulation (CES) devices be included on the Prioritized List for pairing with any condition?

Question source: Alpha-Stim, manufacturer of one CES product; Dr. Heather Khan

Issue: Cranial electrotherapy stimulation (CES) is a form of non-invasive brain stimulation that applies a small, pulsed electric current across a person's head with the intention of treating a variety of conditions such as anxiety, depression and insomnia. CES is a form of transcutaneous electrical nerve stimulation (TENS). CES has been suggested as a possible treatment for headaches, fibromyalgia, smoking cessation and opiate withdrawal. CES is FDA approved for treatment of pain, insomnia, anxiety, and/or depression.

Cranial electrical stimulation has never been reviewed by the HSC/HERC. However, TENS has been reviewed and not found to be effective for any indication.

AllCare Health, an OHP CCO, conducted a small pilot project looking at the effectiveness of CES for treatment of pain. It is unclear how many patients were part of this trial, but it involved a single provider office. A trial of 8 sessions was approved, but patients received only very temporary relief of pain, if any. The CCO decided to end the pilot project due to lack of effectiveness.

Current Prioritized List status
Electrical stimulation CPT and HCPCS codes are all SRNC:
64550 Application of surface (transcutaneous) neurostimulator
97014 Application of a modality to 1 or more areas; electrical stimulation (unattended)
97032 Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
E0720 Transcutaneous electrical nerve stimulation (tens) device, two lead, localized stimulation
E0730 Transcutaneous electrical nerve stimulation (tens) device, four or more leads, for multiple nerve stimulation
G0283 Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care

Of note, these CPT codes are generic and can be used for other technology such as TENS units.

# Cranial Electrical Stimulation

Evidence

Chronic pain

1) **O'Connell 2014,** Cochrane review of CES for chronic pain
    a. N=6 studies, 270 participants
    b. no statistically significant difference was found between active stimulation and sham (low quality evidence)
    c. **Authors' conclusions:** The available evidence suggests that low-frequency rTMS, rTMS applied to the pre-frontal cortex, CES and tDCS are not effective in the treatment of chronic pain. There is a need for larger, rigorously designed studies, particularly of longer courses of stimulation. It is likely that future evidence may substantially impact upon the presented results.
2) **Boldt 2014,** Cochrane review of non-pharmacologic treatment of chronic pain from spinal cord injury (study not included due to length: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD009177.pub2/full)
    a. N=8 trials of electrical brain stimulation (transcranial direct current stimulation (tDCS) and cranial electrotherapy stimulation (CES)
    b. Trials using rTMS, CES, acupuncture, self-hypnosis, TENS or a cognitive behavioural programme provided no evidence that these interventions reduce chronic pain.

Depression

1) **Kavirajan 2014,** Cochrane review of CES for depression (study not included due to length: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD010521.pub2/full)
    a. No studies meeting inclusion criteria were identified
    b. There are insufficient methodologically rigorous studies of CES in treatment of acute depression.
    c. **Authors' conclusions:** There are insufficient methodologically rigorous studies of CES in treatment of acute depression. There is a need for double-blind randomized controlled trials of CES in the treatment of acute depression.

Anxiety

1) **Barclay 2014**, RCT of CES vs sham for anxiety with comorbid depression
    a. N=115 patients (N=60 CES group, N=55 sham group)
    b. RESULTS: Analysis of covariance revealed a significant difference between the active CES group and the sham CES group on anxiety (p=0.001, d=0.94) and on depression (p=0.001, d=0.78) from baseline to endpoint of study in favor of the active CES group.
    c. CONCLUSIONS: CES significantly decreases anxiety and comorbid depression.
2) Multiple other articles in submitted bibliography from Dr. Khan/manufacturer: see Appendix A for disposition
3) No other articles identified in MEDLINE

Insomnia

1) **Kirsh 2014,** survey of military members prescribed CES for anxiety, PTSD, insomnia or depression; no comparison group
    a. N=152 (98 indicated use for insomnia)
        i. Of the 98 patients using CES for insomnia, 1.3% reported complete remission of insomnia and 21.4% had marked remission (75-99%)
2) **Taylor 2013**, RCT for CES for fibromyalgia symptoms
    a. N=46 patients (CES=17, sham=14, usual care=16) [note: does not equal 46 total]

   b. The active CES group was the only group that reported decreased insomnia scores over the course of the study and completed the study with scores below the range of insomnia
3) **Lande 2012**, pilot RCT of CES for insomnia
   a. N=57 (28 treatment, 29 control), military patients
   b. No significant differences in hours of sleep time between treatment or control groups shown on days 2-5 or up to 10 days post treatment

Other policies:
1) Most private insurance carriers are not covering CES as experimental

HERC staff summary: There is no evidence of effectiveness for CES for treatment of chronic pain in trusted evidence sources (Cochrane). One study on CES for anxiety and depression was positive, but no other studies with reasonable methodology were identified and Cochrane judged the literature on depression to be insufficient. Based on several small studies, there are mixed results for use of CES for treatment of insomnia. Based on lack of data, use of CES for anxiety, depression or insomnia appears to lack sufficient evidence of effectiveness/is experimental.

HERC staff recommendation:
1) Do not add cranial electrical stimulation to the Prioritized List
   a. No evidence of effectiveness for treatment of chronic pain, insomnia, anxiety, depression, and all other indications
      i. Add entry to GN169 as shown below

**GUIDELINE NOTE 169, TREATMENTS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS**
The following treatments are prioritized on Line 660, CONDITIONS FOR WHICH CERTAIN TREATMENTS HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS, for the conditions listed here:

| CONDITION | CPT/HCPCS Code | TREATMENT | Rational |
|---|---|---|---|
| Chronic pain, anxiety, depression, insomnia, all other indications | CPT 64550, 97014, 97032 HCPCS E0720, E0730 | Cranial electrical stimulation | No clinically important benefit for chronic pain; insufficient evidence of effectiveness for all other indications |

Appendix A
Disposition of submitted articles/bibliography articles

CES for anxiety:
Kolesos 2013: unable to locate study in Medline
Mellon 2008: unable to locate study in Medline
Strentzsch 2008: non-published poster
Cork 2001: unable to locate study in Medline
Lichtbroun 2001: unable to locate study in Medline
Winick 1999: not relevant (dental study)
Hill 2005: dissertation
Lu 2014: unable to locate study in Medline

**Pigmented Villonodular Synovitis**

Question: Should synovectomy CPT codes be paired with ICD-10 M12.2 (villonodular synovitis (pigmented))?

Question source: HSD

Issue: Pigmented villonodular synovitis (PVNS) is a joint disease characterized by inflammation and overgrowth of the synovium. It usually affects the hip or knee. It can also occur in the shoulder, ankle, elbow, hand or foot. Currently, surgery remains the treatment of choice for patients with TGCT/PVNS. Surgery may be partial synovectomy (for local disease) or complete synovectomy (for more advanced disease). Recurrences occur in 8–20% of patients and are easily managed by re-excision. Patients who fail surgery may be treated with local radiation and/or joint replacement.

M12.2 (Villonodular synovitis (pigmented)) is on lines 406 BENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS and 561 BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE INCLUDING OSTEOID OSTEOMAS; BENIGN NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE with a guideline specifying that it is on the upper line "only when there are significant functional problems of the joint due to size, location, or progressiveness of the disease." Currently, there are no synovectomy CPT codes online 406 and the majority are not on line 561.

It has been suggested that synovectomy be added to the line(s) with villonodular synovitis to allow the more conservative treatment, rather than wait until a patient has progressed to the point of requiring joint replacement.

HERC staff recommendation:

1) Add the CPT codes listed in the table below to line 406 BENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS and line 561 (if absent) BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE INCLUDING OSTEOID OSTEOMAS; BENIGN NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE (if absent)

| CPT | Code description | Current Lines |
|---|---|---|
| 23105 | Arthrotomy; glenohumeral joint, with synovectomy, with or without biopsy | 188,259,423 |
| 23106 | Arthrotomy; sternoclavicular joint, with synovectomy, with or without biopsy | 423 |
| 24102 | Arthrotomy, elbow; with synovectomy | 157,212,361,364,392,530 |
| 25105 | Arthrotomy, wrist joint; with synovectomy | 157,212,361,364,392,530 |
| 25320 | Capsulorrhaphy or reconstruction, wrist, open (eg, capsulodesis, ligament repair, tendon transfer or graft) (includes synovectomy, capsulotomy and open reduction) for carpal instability | 135,136,205,212,259, 297,360,361,364,392, 406, 530,561 |
| 26130 | Synovectomy, carpometacarpal joint | 290,364,392,421,431, 508,530 |
| 27054 | Arthrotomy with synovectomy, hip joint | 188,205,406,561 |
| 27334 | Arthrotomy, with synovectomy, knee; anterior OR posterior | 205,436 |
| 27335 | Arthrotomy, with synovectomy, knee; anterior AND posterior including popliteal area | 205,436 |
| 28070 | Synovectomy; intertarsal or tarsometatarsal joint, each | 364,392,545 |
| 28072 | Synovectomy; metatarsophalangeal joint, each | 364,392,545 |
| 27625 | Arthrotomy, with synovectomy, ankle | 361,364,392 |
| 27626 | Arthrotomy, with synovectomy, ankle; including tenosynovectomy | 361,364,392 |
| 29820 | Arthroscopy, shoulder, surgical; synovectomy, partial | 361,423 |
| 29821 | Arthroscopy, shoulder, surgical; synovectomy, complete | 157,361,406,423 |
| 29835 | Arthroscopy, elbow, surgical; synovectomy, partial | 361 |
| 29836 | Arthroscopy, elbow, surgical; synovectomy, complete | 361 |
| 29844 | Arthroscopy, wrist, surgical; synovectomy, partial | 361 |
| 29845 | Arthroscopy, wrist, surgical; synovectomy, complete | 361 |
| 29863 | Arthroscopy, hip, surgical; with synovectomy | 136,157,314,361,364, 381,392,530 |
| 29875 | Arthroscopy, knee, surgical; synovectomy, limited | 136,360,361,436,601 |
| 29876 | Arthroscopy, knee, surgical; synovectomy, major, 2 or more compartments (eg, medial or lateral) | 136,360,361,436,601 |
| 29895 | Arthroscopy, ankle (tibiotalar and fibulotalar joints), surgical; synovectomy, partial | 136,297,361 |
| 29905 | Arthroscopy, subtalar joint, surgical; with synovectomy | 297,361,364,392,447,545 |

# Section 3.0

# Coverage Guidances

# HEALTH EVIDENCE REVIEW COMMISSION (HERC)
# COVERAGE GUIDANCE:
# LOW BACK PAIN - CORTICOSTEROID INJECTIONS

**DRAFT for 5/18/2017 VbBS/HERC meeting materials**

### HERC Coverage Guidance

Epidural corticosteroid injections are not recommended for coverage for the treatment of low back pain with radiculopathy *(weak recommendation).*

Epidural corticosteroid injections are not recommended for coverage for the treatment of low back pain without radiculopathy (e.g., spinal stenosis, non-radicular pain) *(strong recommendation).*

Corticosteroid injections (including facet joint, medial branch, and sacroiliac joint) are not recommended for coverage for the treatment of low back pain *(strong recommendation).*

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

## RATIONALE FOR DEVELOPMENT OF COVERAGE GUIDANCES AND MULTISECTOR INTERVENTION REPORTS

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as they seek to improve patient experience of care, population health, and the cost-effectiveness of health care. In the era of the Affordable Care Act and health system transformation, reaching these goals may require a focus on population-based health interventions from a variety of sectors as well as individually focused clinical care. Multisector intervention reports will be developed to address these population-based health interventions or other types of interventions that happen outside of the typical clinical setting.

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

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

Our reports are based on a review of the relevant research applicable to the intervention(s) in question. For coverage guidances, which focus on clinical interventions and modes of care, evidence is evaluated using an adaptation of the GRADE methodology. For more information on coverage guidance methodology, see Appendix A.

Multisector interventions can be effective ways to prevent, treat, or manage disease at a population level. For some conditions, the HERC has reviewed evidence and identified effective interventions, but has not made coverage recommendations, as many of these policies are implemented in settings beyond traditional healthcare delivery systems.

# 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 the assessments rendered by Chou and colleagues in the AHRQ review. Unless otherwise noted, estimated resource allocation, values and preferences, and other considerations are assessments of the Commission.

| **Coverage question: Should epidural corticosteroid injections (ESIs) be recommended for the treatment of low back pain with radiculopathy?** | | | | |
|---|---|---|---|---|
| **Outcomes** | **Estimate of Effect for Outcome/ *Confidence in Estimate*** | **Resource Allocation** | **Values and Preferences** | **Other Considerations** |
| **Long-term function** *(Critical outcome)* | No difference compared to controls<br>SMD -0.23, 95% CI -0.55 to 0.10<br>●●○○ *(Low confidence, based on 8 RCTs, N=950)* | Covering the intervention effectively requires coverage of diagnostic imaging (MRI or CT) to identify potential candidates who would not otherwise require imaging.<br><br>There is moderate-to-high cost for the initial imaging, the procedure, and associated image- | Patients with low back pain would highly value having effective treatments to improve their symptoms, and would likely prefer interventions that are less invasive, less time-consuming, less risky and less demanding on the patient. Given the variety of available | There is moderate confidence that ESIs result in immediate-term improvements in pain, although this does not reach predefined thresholds of a minimum clinically important difference.<br><br>There are a number of other evidence- |
| **Long-term risk of surgery** *(Critical outcome)* | No difference compared to controls<br>RR 0.97, 95% CI 0.75 to 1.25<br>●●●○ *(Moderate confidence, based on 14 RCTs, N=1208)* | | | |
| **Short-term function** *(Important outcome)* | No difference compared to controls<br>Standardized mean difference (SMD) -0.03, 95% CI -0.20 to 0.15<br>●●●○ *(Moderate confidence, based on 11 RCTs, N=1226)* | | | |

| Coverage question: Should epidural corticosteroid injections (ESIs) be recommended for the treatment of low back pain with radiculopathy? | | | | |
|---|---|---|---|---|
| **Outcomes** | **Estimate of Effect for Outcome/ *Confidence in Estimate*** | **Resource Allocation** | **Values and Preferences** | **Other Considerations** |
| **Change in utilization of other therapies** *(Important outcome)* | Reduced short-term risk of surgery<br>RR 0.62, 95% CI 0.41 to 0.92<br>●●○○ *(Low confidence, based on 8 RCTs, N=845)* | based guidance. Given a lack of proven benefit, they are unlikely to be cost-effective. | interventions for low back pain, patient preferences are likely to be highly variable. On the other hand, the large number of public comments EbGS received from providers of epidural steroid injections suggests a strong preference for this as a tool. | based treatments for back pain.<br>A review of selected studies using image-correlation, imaging guidance, and a transforaminal approach (consistent with current local standard of care) also demonstrated mixed results, with the majority favoring no effect. |
| **Adverse events** *(Important outcome)* | Few harms or serious adverse events compared to controls<br>●●●○ *(Moderate confidence, based on 29 RCTs, N=2792)* | | | |

**Balance of benefits and harms:** We have moderate confidence that ESIs for low back pain with radiculopathy produce no improvement in function in either the short or long term. The immediate-term benefit in pain did not reach predefined thresholds of a minimum clinically important difference. Despite anecdotal and noncomparative evidence, we find no clinically significant benefits from this intervention. Harms appear to be rare. The balance of benefits and harms appears to be neutral.

**Rationale:** We have low to moderate confidence that epidural corticosteroid injections for low back pain with radiculopathy do not affect functional outcomes compared to controls and that ESIs do not decrease rates of future surgery. There are immediate-term benefits in pain, however, they do not reach a threshold for a clinically important benefit. Epidural corticosteroid injections are more costly than evidence-based conservative management, and multiple other effective interventions are available. Therefore, we make a weak recommendation for noncoverage of these procedures. The recommendation would be strong except for the strong preferences for this procedure expressed in public comments, mostly from providers who perform these injections.

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| **Recommendation:** Epidural corticosteroid injections are not recommended for coverage for back pain with radiculopathy *(weak recommendation).* |

| **Coverage question: Should epidural corticosteroid injections be recommended for the treatment of low back pain with spinal stenosis?** | | |
|---|---|---|
| **Outcomes** | **Estimate of Effect for Outcome/ Confidence in Estimate** | ***(for Resource Allocation, Values and Preferences, and Other Considerations, see above)*** |
| **Long-term function** *(Critical outcome)* | No difference compared to controls<br>Weighted mean difference (WMD) 2.78, 95% CI -1.24 to 6.79<br>●●○○ *(Low confidence, based on 2 RCTs, N=160)* | |
| **Long-term risk of surgery** *(Critical outcome)* | No difference compared to minimally invasive lumbar decompression<br>RR 0.76, 95% CI 0.38 to 1.54<br>●●○○ *(Low confidence, based on 1 RCT, N=30)* | |
| **Short-term function** *(Important outcome)* | No difference compared to controls<br>SMD -0.03, 95% CI -0.31 to 0.26<br>●●●○ *(Moderate confidence, based on 5 RCTs, N=615)* | |
| **Change in utilization of other therapies** *(Important outcome)* | Insufficient data | |
| **Adverse events** *(Important outcome)* | Few harms or serious adverse events compared to controls<br>●●○○ *(Low confidence, based on 8 RCTs, N=821)* | |

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| **Balance of benefits and harms:** We have low to moderate confidence that there is no functional benefit from these interventions and that they do not decrease rates of future surgery. |
| **Rationale:** Based on the lack of benefit, multiple alternative interventions, and the cost of the interventions, we recommend noncoverage of these procedures. |
| **Recommendation:** Epidural corticosteroid injections are not recommended for coverage for low back pain with spinal stenosis *(strong recommendation*). |

| Coverage question: Should epidural corticosteroid injections be recommended for the treatment of non-radicular low back pain? | | |
|---|---|---|
| **Outcomes** | **Estimate of Effect for Outcome/ *Confidence in Estimate*** | ***(for Resource Allocation, Values and Preferences, and Other Considerations, see above)*** |
| **Long-term function** *(Critical outcome)* | No difference compared to controls<br>●●○○ *(Low confidence, based on 2 RCTs, N=240)* | |
| **Long-term risk of surgery** *(Critical outcome)* | Insufficient data | |
| **Short-term function** *(Important outcome)* | No difference compared to controls<br>●●○○ *(Low confidence, based on 2 RCTs, N=240)* | |
| **Change in utilization of other therapies** *(Important outcome)* | No difference in opioid use at 2 years compared to controls<br>●●○○ *(Low confidence, based on 2 RCTs, N=240)* | |
| **Adverse events** *(Important outcome)* | Few harms or serious adverse events compared to controls<br>●●○○ *(Low confidence, based on 2 RCTs, N=240)* | |

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| **Balance of benefits and harms:** We have low confidence that epidural corticosteroid injections for nonradicular low back pain do not affect functional outcomes or use of opioids compared to controls. We have insufficient evidence to determine whether they affect rates of surgery. |
| **Rationale:** Based on evidence of no benefit, the availability of effective alternative treatments, and the cost of this intervention compared to evidence-based conservative management, we recommend noncoverage for these procedures. |
| **Recommendation:** Epidural corticosteroid injections are not recommended for coverage for non-radicular low back pain *(strong recommendation*). |

| **Coverage question: Should facet joint corticosteroid injections (including medial branch injections) be recommended for the treatment of low back pain?** | | |
|---|---|---|
| **Outcomes** | **Estimate of Effect for Outcome/ *Confidence in Estimate*** | ***(for Resource Allocation, Values and Preferences, and Other Considerations, see above)*** |
| **Long-term function** *(Critical outcome)* | No difference compared to controls<br>●●○○ *(Low confidence, based on 2 RCTs, N=204)* | |
| **Long-term risk of surgery** *(Critical outcome)* | Insufficient data | |
| **Short-term function** *(Important outcome)* | No difference compared to controls<br>●●○○ *(Low confidence, based on 2 RCTs, N=171)* | |
| **Change in utilization of other therapies** *(Important outcome)* | No difference in analgesic or opioid use at up 2 years compared to controls<br>●●○○ *(Low confidence, based on 2 RCTs, N=204)* | |
| **Adverse events** *(Important outcome)* | Few harms or serious adverse events compared to controls<br>●●○○ *(Low confidence, based on 10 RCTs, N=823)* | |

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| **Balance of benefits and harms:** We have low confidence that facet joint corticosteroid injections for low back pain do not affect functional outcomes or use of analgesics compared to controls. We have insufficient evidence to determine whether they affect rates of surgery. |
| **Rationale:** Based on evidence of no benefit, the availability of effective alternatives, and the cost of the procedures relative to evidence-based conservative care, we make a strong recommendation for noncoverage of these procedures. |
| **Recommendation:** Facet joint corticosteroid injections are not recommended for coverage for low back pain *(strong recommendation*). |

| Coverage question: Should sacroiliac joint corticosteroid injections be recommended for the treatment of low back pain? | |
|---|---|
| **Outcomes** | **Estimate of Effect for Outcome/**<br>***Confidence in Estimate*** |
| **Long-term function**<br>*(Critical outcome)* | Insufficient data |
| **Long-term risk of surgery**<br>*(Critical outcome)* | Insufficient data |
| **Short-term function**<br>*(Important outcome)* | Insufficient data |
| **Change in utilization of other therapies**<br>*(Important outcome)* | Insufficient data |
| **Adverse events**<br>*(Important outcome)* | Insufficient data |
| **Balance of benefits and harms:** There is insufficient evidence to determine whether sacroiliac joint corticosteroid injections are effective or whether any benefits would outweigh potential harms for the treatment of low back pain. | |
| **Rationale:** We recommend against coverage because of the unproven benefit and unknown harms and moderate costs. Although future evidence could change the recommendation, at this point sacroiliac joint injections appear experimental. | |
| **Recommendation:** Sacroiliac joint corticosteroid injections are not recommended for coverage for low back pain *(strong recommendation*). | |

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

# EVIDENCE OVERVIEW

## Clinical background

Low back pain is the leading cause of disability in individuals under 45 years of age in the United States and globally (The American Academy of Pain Medicine, n.d.) (Bicket et al., 2013). Approximately 80% of adults experience low back pain at some point in their lifetimes. In one large survey, more than 25% of adults reported low back pain during the past three months (National Institute of Neurological Disorders and Stroke, 2015). Furthermore, the impact of low back pain on health in the U.S. has increased in recent years. A 1990 study ranked low back pain as the sixth most burdensome condition in the U.S. in terms of mortality or poor health. In a 2010 reproduction of the study, back pain was ranked as the third most burdensome condition, following ischemic heart disease and chronic obstructive pulmonary disease (National Institute of Neurological Disorders and Stroke, 2015). Low back pain is also associated with high economic costs: annual cost estimates are upward of $100 billion in the United States (Bicket et al., 2013).

A majority of low back pain is defined as acute, lasting a few days to a few weeks, and resolves on its own with self-care. However, about 20% of people affected by low back pain develop chronic low back pain and have persistent symptoms at one year. Many cases of low back pain are the result of a mechanical disruption influencing the way in which components of the back fit together and move. Low back pain is also often associated with spondylosis, which refers to general spinal wear and tear that typically occurs as people age. However, in rare cases, low back pain is related to more serious underlying conditions requiring immediate medical attention, such as infections, tumors, cauda equina syndrome, and abdominal aortic aneurysms (National Institute of Neurological Disorders and Stroke, 2015).

A variety of treatment options are used to address low back pain. Conservative treatment for low back pain includes rest, physical therapy, advice regarding posture and exercise, analgesics, and anti-inflammatory medications (Hayes, 2013). If symptoms persist, epidural steroid injections (ESIs), facet joint injections, and sacroiliac joint injections provide additional nonsurgical options to treat low back pain. Surgical options for treating low back pain include decompression, total disc arthroplasty, total facet arthroplasty, and fusion (Balgia et al., 2015).

## Indications

Low back pain is the fifth most common reason for all physician visits in the United States (American Academy of Family Physicians, 2016). Among the available procedural interventions for low back pain, ESIs are the most widely used. Facet and sacroiliac joint injects also may involve the injection of corticosteroids, but are less commonly practiced. Both ESI and surgery utilization rates have doubled in the last decade. Despite this increase in utilization, disability rates continue to rise as well (Bicket et al., 2013). Given the high costs, morbidity, and lack of certainty regarding the long-term benefits of operative interventions, steroid injections are often employed with the intention to not only reduce pain, but also to avoid surgical interventions (Bhatia et al., 2016).

# Technology description

Corticosteroids are a class of drugs commonly used to reduce swelling or inflammation. Injectable corticosteroids include methylprednisolone, hydrocortisone, triamcinolone, betamethasone, and dexamethasone (United States Food & Drug Administration, 2014). Injecting corticosteroids into the epidural space might inhibit inflammation and thus reduce low back pain. ESIs expose spinal nerve roots to higher concentrations of medications for a longer time period than a systemic administration technique does (Hayes, 2013).

There are three primary routes used to administer an ESI: caudal, interlaminar, and transforaminal. The origin of the patient's pain can determine the selection of the route. Caudal injections involve delivering the needle through the sacrococcygeal ligament and sacral hiatus into the caudal epidural space, which communicates with the posterior lumbar epidural space. An interlaminar approach entails guiding the injection fluid into the posterior epidural compartment, without assurance that it will flow into the anterior epidural compartment. Transforaminal injections are directed to the anterior epidural space and spinal nerve as it exits the neural foramen. Transforaminal injections are considered the most "targeted" injections and allow for the lowest use of steroid concentrations (Hayes, 2013).

Facet joint injections and sacroiliac joint injections are related techniques for administering corticosteroids to relieve a patient's pain. These approaches would be considered for patients with low back pain and a clinical suspicion that the pain is due to facet joint arthropathy or sacroiliitis. Both types of injections involve the insertion of a needle through a selected site of entry until it reaches the bone. Minor manipulation may be required to locate the needle into the joint space (Althoff, et al., 2015; Peh, 2011).

At some point prior to administration of corticosteroid injections, it is common for patients to receive an imaging test (e.g., CT or MRI) to identify potential causes of back pain. The procedure is then generally completed using fluoroscopic or ultrasound guidance with the patient lying prone, although it can also be done with the patient in the lateral position. After the injection, the patient is monitored before being discharged, and normal activity can usually be resumed the next day.

# Key Questions and Outcomes

The following key questions (KQ) guided the evidence search and review described below. For additional details about the review scope and methods, please see Appendix C.

1. What is the comparative effectiveness of corticosteroid injection therapies for low back pain?
2. Does the effectiveness of corticosteroid injection therapies for low back pain vary based on:
    a. Duration of back pain
    b. Etiology of back or radicular pain
    c. Choice of corticosteroid, dose, or frequency
    d. Anatomic approach
    e. Use of imaging guidance
    f. Previous back surgery

g. Response to previous diagnostic injections
h. Response to previous injection therapies

3. What are the harms of corticosteroid injections for low back pain?

Critical outcomes selected for inclusion in the GRADE table are long-term function, and long-term risk of undergoing surgery. Important outcomes selected for inclusion in the GRADE table are short-term function, adverse events and change in utilization of comparators (e.g., opioids, surgery).

# Evidence review

## Chou et al., 2015 (AHRQ Report)

This is a comprehensive, good-quality systematic review of randomized controlled trials (RCTs) of corticosteroid injection therapies for patients with low back pain. The review includes 78 RCTs of epidural steroid injections, 13 trials of facet joint injections, and one trial of sacroiliac injections. The included RCTs span adult patients with non-radicular low back pain; lumbosacral radiculopathy, a term that is not consistently defined in the included trials, but which Chou and colleagues define as "presence of leg pain (typically worse than back pain), with or without sensory deficits or weakness, in a nerve root distribution"; spinal stenosis; or post-surgical back pain. The trials compared steroid injection therapies to placebo or active controls (commonly local anesthetics). In their meta-analysis, the authors treated the various control treatments as placebos. An analysis by which type of control was used found no difference in effects. Specified outcomes of the review include pain, function, and the risk of back surgery at various time points. Those time points and their respective definitions were immediate (1 week to ≤2 weeks), short (2 weeks to ≤3 months), intermediate (3 months to <1 year), and long (>1 year). Several subgroup analyses and meta-regressions were performed to ascertain whether the evidence supported differential effects stemming from a variety of intervention, patient, and provider characteristics.

The authors of the review highlighted several general limitations of the evidence base including the small number of trials for epidural injections outside of the radiculopathy population; methodological limitations of the included studies (only nine were rated good quality); inconsistent control interventions; inconsistent blinding procedures; and the small number of trials that directly compared patient characteristics, steroid type and dose, or various techniques (including anatomic approach and imaging guidance).

## Key Question 1: What is the comparative effectiveness of corticosteroid injection therapies for low back pain?

### *Outcomes for Epidural Steroid Injections*

#### *Long-term Function – Radiculopathy*

In seven trials of ESIs compared with placebo interventions for patients with radiculopathy, there was low-strength evidence of no difference in long-term function (SMD -0.23, 95% CI -0.55 to 0.10). Similarly, in three trials of ESIs compared with placebo interventions for patients with radiculopathy, there was

low-strength evidence of no difference in long-term likelihood of a successful functional outcome (RR 1.15, 95% CI 0.97 to 1.35).

In one trial of ESIs compared to minimally invasive lumbar decompression for patients with radiculopathy, there was low-strength evidence that steroid injections improve long-term function as measured by a ≥ 13 point improvement on the ODI (RR 0.34, 95% CI 0.34 to 0.95). There was no difference in the long-term risk of undergoing surgery (RR 0.45, 95% CI 0.09 to 2.19).

### *Long-term Function – Spinal Stenosis*

In two trials of ESIs compared with placebo interventions for patients with spinal stenosis, there was low-strength evidence of no difference in long-term function (WMD 2.78, 95% CI -0.24 to 6.79). Similarly, in two trials of epidural ESIs compared with placebo interventions for patients with spinal stenosis, there was low-strength evidence of no difference in the long-term likelihood of a successful functional outcome (RR 0.95, 95% CI 0.71 to 1.26).

### *Long-term Function – Non-radicular Low Back Pain*

In two trials of ESIs compared with epidural local anesthetics for patients with non-radicular low back pain, there was low-strength evidence of no difference in long-term function (no meta-analysis was performed).

### *Long-term Risk of Surgery – Radiculopathy*

In 14 trials of ESIs compared with placebo interventions for patients with radiculopathy, there was moderate-strength evidence of no difference in the long-term risk of surgery (RR 0.97, 95% CI 0.75 to 1.25).

### *Long-term Risk of Surgery – Spinal Stenosis*

In one trial of ESIs compared with placebo interventions for patients with spinal stenosis, there was low-strength evidence of no difference in the long-term risk of surgery (RR 0.76, 95% CI 0.38 to 1.54).

### *Short-term Function – Radiculopathy*

In 11 trials of ESIs compared with placebo interventions for patients with radiculopathy, there was moderate-strength evidence of no difference in short-term function (SMD -0.03, 95% CI -0.20 to 0.15). Similarly, in six trials of ESIs compared with placebo interventions for patients with radiculopathy, there was low-strength evidence of no difference in short-term likelihood of a successful functional outcome (RR 1.01, 95% CI 0.74 to 1.38).

In one trial of transforaminal ESIs compared to etanercept for patients with radiculopathy, there was low-strength evidence that steroid injections improve short-term function as measured by the Oswestry Disability Index (ODI) at one month (difference -16 [of 100], 95% CI -26 to -6.27), but there was no difference in the long-term risk of undergoing surgery (RR 0.45, 95% CI 0.09 to 2.19).

### *Short-term Function – Spinal Stenosis*

In five trials of ESIs compared with placebo interventions for patients with spinal stenosis, there was moderate-strength evidence of no difference in short-term function (SMD -0.03, 95% CI -0.31 to 0.26). Similarly, in three trials of ESIs compared with placebo interventions for patients with spinal stenosis, there was low-strength evidence of no difference in short-term likelihood of a successful functional outcome (RR 0.91, 95% CI 0.70 to 1.18).

In one trial of ESIs compared to minimally invasive lumbar discectomy for patients with spinal stenosis, there was low-strength evidence of no difference in function at six weeks. In one trial of ESIs compared to intensive physical therapy for patients with spinal stenosis, there was low-strength evidence of no difference in function at two weeks to six months. In one trial of ESIs compared to etanercept for patients with spinal stenosis, there was low-strength evidence of no difference in function at one month.

### *Change in Utilization of Comparators*

Aside from the risk of surgery reported above, changes in the utilization of other treatments were not consistently reported in the included studies. In two trials of ESIs compared with epidural local anesthetics for patients with non-radicular low back pain, there was low-strength evidence of no difference in opioid use at two years (no meta-analysis was performed).

### *All Outcomes – Chronic Post-surgical Pain*

The authors found insufficient evidence to draw conclusions about the effectiveness of ESIs compared to placebo or active controls in patients with chronic post-surgical back pain.

### *Other Outcomes*

The authors found moderate-strength evidence for immediate-term improvement in pain (WMD -7.55 on a 100 point scale, 95% CI -11.4 to -3.74), low-strength evidence for immediate-term improvement in function (SMD -0.33, 95% CI -0.56 to -0.09), and low-strength evidence of a reduced short-term risk of surgery (RR 0.62, 95% CI 0.41 to 0.92) for ESIs in patients with radiculopathy. The authors observed that the differences in pain and function did not meet pre-specified thresholds of minimal clinically important differences and were not sustained at longer-term follow-up (as indicated above).

## *Outcomes for Facet Joint Injections (including medial branch injections)*

### *Long-term Function*

In two trials of medial branch steroid injection compared to medial branch local anesthetic injections, there was low-strength evidence of no difference in function at 12 to 24 months (no meta-analysis was performed).

### *Short-term Function*

Two trials of facet joint steroid injections compared to a saline placebo found low-strength evidence of no difference in function at one to three months. One trial of facet joint steroid injections compared to intramuscular steroid injections found low-strength evidence of no difference in function at up to six

months. One trial of facet joint steroid injections compared to hyaluronic acid found low-strength evidence of no difference in function at one month. In one trial that compared facet joint steroid injection plus sham neurotomy to medial branch radiofrequency neurotomy plus local anesthetic injection, there was low-strength evidence of no difference in pain at up to six months.

#### *Change in Utilization of Comparators*

In two trials of medial branch steroid injection compared to medial branch local anesthetic injections, there was low-strength evidence of no difference in opioid use at 12 to 24 months. In one trial that compared facet joint steroid injection plus sham neurotomy to medial branch radiofrequency neurotomy plus local anesthetic injection, there was low-strength evidence of no difference in analgesic use at up to six months (no meta-analysis was performed).

### *Outcomes for Sacroiliac Joint Injections*

The authors judged that there was insufficient evidence from a single, small (n=24) trial of sacroiliac steroid injections compared to local anesthetic injections to draw conclusions about the effectiveness of this procedure.

## KQ2: Does the effectiveness of corticosteroid injection therapies for low back pain vary based on:

a. Duration of back pain
b. Etiology of back or radicular pain
c. Choice of corticosteroid, dose, or frequency
d. Anatomic approach
e. Use of imaging guidance
f. Previous back surgery
g. Response to previous diagnostic injections
h. Response to previous injection therapies

The authors identified six trials in which it was possible to compare the effectiveness of ESIs based on the duration of symptoms. In five of those trials, there was no association between the duration of symptoms and the likelihood of responding to treatment. In the sixth study, a longer duration of symptoms was associated with a poorer response to injection therapies. This conclusion was based on low strength of evidence. The authors observed that most of the available evidence was for patients with back pain that lasted more than three months, and the number of studies of patients with pain of less than four weeks duration is very limited.

The effectiveness of ESIs for different types of back pain (radicular, non-radicular, and spinal stenosis) is discussed in KQ1. Inconsistent evidence from four trials led the authors to conclude that there was insufficient evidence to determine whether the etiology of radicular symptoms was associated with responsiveness to steroid injection therapies.

In the meta-regression of trials comparing epidural steroids to placebo, there was no apparent effect of steroid type on outcomes for pain, function, or risk of surgery. Four trials that directly compared different types of steroids for epidural injection in patients with radiculopathy found low-strength

evidence that there are “few differences” between steroid types, although some inconsistency in the results could have stemmed from differences in the steroid dose used. Similarly, the authors concluded that there was low-strength evidence of no clear difference in effectiveness of steroid injections for radiculopathy based on the steroid dose or number of injections. For patients with spinal stenosis, there was insufficient evidence to determine whether the effects of epidural steroid injections varies by type, dose, or frequency of injections (no meta-analysis was performed).

In three trials that directly compared a transforaminal approach to an interlaminar approach for ESIs, there was low-strength evidence of no difference in short-term function (SMD 0.39, 95% CI -.036 to 1.13). Similarly, in the one trial that reported on long-term function, there was no difference between the transforaminal and interlaminar approach (WMD -2.00, 95% CI -8.77 to 4.77). Although the long-term risk of surgery was not reported, in two trials there was low strength of evidence of no difference in intermediate-term risk of surgery based on the approach. There was low-strength evidence from mostly single trials that other approaches (caudal, oblique interlaminar, lateral parasaggital) did not offer clear comparative benefit. One trial that compared a ganglionic transforaminal approach to a preganglionic transforaminal approach provided low strength of evidence that the preganglionic approach was associated with greater likelihood of treatment success at one month, but no differences were found beyond five months. There were no trials of patients with spinal stenosis that randomly compared different approaches for ESIs. For facet joint injection, there was insufficient evidence from one trial to determine whether an intra- or extra-articular injection approach was more effective.

The authors found no trials that directly compared the use of image-guided ESIs to non-image-guided injections, and indirect comparisons were not possible because of the correlation between the use of imaging and the type of approach that was used. The authors noted that there was low-strength evidence from one trial that ESIs guided by MRI findings were no more effective than those based on history and physical exam with respect to outcomes of function and medication use.

In the meta-regression of trials of ESIs compared to placebo, there was no association between a history of lumbar surgery and the effectiveness of the treatment. In this review, the authors did not address whether response to prior diagnostic or therapeutic injection trials was associated with a difference in outcomes.

Testimony and public comments indicated that ESIs are most effective when performed on patients with radicular pain in a dermatomal distribution and the injections are performed using imaging guidance with a transforaminal approach. Many of the studies included in this evidence review had less restrictive patient selection criteria, did not use imaging guidance, or used other approaches. The table below summarizes results from the studies of patients with radicular pain in which the injections were performed using imaging guidance and a transforaminal approach. Although some studies showed a statistically significant benefit for pain or function at certain intervals, none reached commonly accepted thresholds of minimal clinically important difference. Table 1 summarizes these studies.

## Table 1. Summary of selected studies for back pain with radiculopathy

Studies selected included only patients with low back pain with radiculopathy with imaging correlates; all used a transforaminal approach and were performed using imaging guidance.

| **Study**<br>Intervention(s) vs. Comparator(s)<br>N | **Quality Assessment** | **Imaging Correlates** | **Imaging Guidance** | **Anatomic Approach** | **Results: Function** | **Results: Pain** |
|---|---|---|---|---|---|---|
| **Burgher et al., 2011**<br>Triamcinolone and lidocaine vs. clonidine with lidocaine<br>N=26 | Fair | Disc encroachment confirmed by MRI or CT | Yes | Transforaminal | Mixed: No statistically significant differences at 2 weeks, but small statistically significant benefit of ESI over clonidine at 4 weeks | No statistically significant differences |
| **Cohen et al., 2012**<br>Methlyprednisolone and bupivacaine vs. etanercept and bupivacaine vs. sterile water and bupivaciane<br>N=84 | Good | MRI evidence of pathologic disc condition | Yes | Transforaminal | No statistically significant difference for comparison of steroid with sterile water; statistically significant benefit of steroid over etanercept | No statistically significant differences |
| **Cohen et al., 2014**<br>Depomethylprednisolone and bupivacaine injection + placebo vs.<br>Sham injection + gabapentin<br>N=145 | Fair | MRI demonstrated HNP or spinal stenosis | Yes | Interlaminar or transforaminal | No statistically significant differences | No statistically significant differences for mean pain score<br><br>Statistically significant benefit for positive composite outcome in favor of ESI over comparator |

| **Study**<br>Intervention(s) vs. Comparator(s)<br>N | **Quality Assessment** | **Imaging Correlates** | **Imaging Guidance** | **Anatomic Approach** | **Results: Function** | **Results: Pain** |
|---|---|---|---|---|---|---|
| **Gerstzen et al., 2010**<br>Corticosteroid (various types and doses at clinician discretion) vs. Plasma disc decompression<br>N=90 | Fair | Imaging evidence of focal lumbar disc protrusion | Yes | Transforaminal | No statistically significant difference or benefit in favor of plasma disc decompression over ESI | No statistically significant difference or benefit in favor of plasma disc decompression over ESI |
| **Ghahreman et al., 2011**<br>Triamcinolone and bupivacaine vs. bupivacaine vs. saline vs. IM triamcinolone vs. IM saline<br>N=150 | Good | Imaging correlate required | Yes | Transforaminal | No statistically significant differences | Statistically significant benefit of ESI over comparators |
| **Karpinnen et al., 2001**<br>Methylprednisolone and bupivacaine vs. saline<br>N=163 | Good | MRI scans at baseline | Yes | Transforaminal | No statistically significant differences or benefit of saline over ESI | No statistically significant differences or benefit of saline over ESI |
| **Lee et al., 2016**<br>Dexamethasone and bupivacaine vs. pulsed radiofrequency treatment of the dorsal root ganglion<br>N=44 | Poor | Imaging findings of intervertebral disc pathology | Yes | Transforaminal | No statistically significant differences | No statistically significant differences |
| **Manchikanti et al., 2014**<br>Betamethasone and lidocaine vs. saline and lidocaine<br>N=120 | Fair | Imaging evidence of L4-L5 or L5-S1 disc herniation | Yes | Transforaminal | No statistically significant differences | No statistically significant differences |

| **Study**<br>Intervention(s) vs. Comparator(s)<br>N | **Quality Assessment** | **Imaging Correlates** | **Imaging Guidance** | **Anatomic Approach** | **Results: Function** | **Results: Pain** |
|---|---|---|---|---|---|---|
| **Riew et al., 2006**<br>Betamethasone and bupivacaine vs. bupivacaine<br>N=55 | Fair | Disc herniation or spinal stenosis by MRI or CT | Yes | Transforaminal | Not reported | Not reported |
| **Tafazal et al., 2009**<br>Methylprednisolone and bupivacaine vs. bupivacaine<br>N=150 | Fair | Disc herniation or foraminal stenosis by MRI | Yes | Transforaminal | No statistically significant differences | No statistically significant differences |

## KQ3: What are the harms of corticosteroid injections for low back pain?

In general, the authors found low- to moderate-strength evidence of few harms being associated with epidural or facet joint steroid injections, but noted that reporting of harms was sparse and inconsistent in this literature. However, the authors noted that observational studies of harms of steroid injections also found a low risk of serious adverse effects.

## Additional Studies

The following are randomized controlled trials that fit the inclusion criteria for the AHRQ systematic review (Chou et al., 2015) but were published after the search dates of that systematic review.

### *Chun et al., 2015*

This is a poor-quality randomized trial of different volumes of injectate used for epidural steroid injection. In this trial, 66 patients with lumbar radicular pain for at least six weeks despite conservative treatment and clinical and radiologic evidence of a herniated disc or spinal stenosis were randomized to receive lidocaine and 4 mg dexamethasone in either a 3 mL or 8 mL injectate. All injections were performed via the transforaminal route under fluoroscopy. The investigator who performed the injections was aware of the treatment assignments. There were baseline differences between the two groups at the beginning of the trial with respect to the duration of pain and history of laminectomy. The main outcome of interest was improvement in the Roland-Morris Disability Questionnaire (RMDQ) score at four weeks. Both groups showed statistically significant improvement in the mean RMDQ score (approximately three to four points) compared to baseline, but there were no between-group differences. The authors reported no serious adverse events in either group.

### *Cohen et al., 2015*

This is a fair-quality randomized trial comparing epidural steroid injections plus oral placebo to sham injections plus oral gabapentin. In this trial, 145 patients with lumbosacral radicular pain of greater than six weeks but less than four years and imaging findings of a herniated disc or spinal stenosis were randomized to undergo imaging-guided interlaminar or transforaminal ESI with 60 mg depomethylprednisolone and bupivacaine, followed by an oral placebo or a sham injection with saline, and then oral gabapentin titrated to a daily dose of 1,800 to 3,600 mg. At the beginning of the trial, there were more women in the ESI group, and there were high rates of attrition in both arms at three months. There were no statistically significant differences between the two groups in the ODI score at one or three months. Similarly, there was no difference in opioid doses, incidence of surgery at one year, or adverse events between the two groups.

### *Denis et al., 2015*

This is a poor-quality randomized trial comparing the use of equipotent doses of betamethasone or dexamethasone for ESI. In this trial, 56 patients with lumbosacral radicular pain and CT or MRI findings of a herniate disc or foraminal stenosis were randomized to 6 mg of betamethasone or 7.5 mg of dexamethasone delivered by transforaminal injection under fluoroscopy. There were baseline

differences between the two groups with respect to type of occupation (manual vs. non-manual) and smoking status. Both groups showed improvement in the ODI compared to baseline. At one month and three months follow-up, there was no difference between the two groups, but at six months the patients in the dexamethasone group showed greater improvement in the ODI. There were no significant adverse events in either arm. The authors acknowledged that the study was underpowered to detect a difference a between the two steroids.

### *Evansa et al., 2015*

This is a fair-quality single-center, single-operator randomized trial comparing ultrasound and fluoroscopically guided ESIs. In this trial, 112 patients (predominantly women) with chronic axial low back pain or lumbosacral radiculopathy for more than three months despite conservative treatment were randomized to interlaminar ESI with 80 mg methylprednisolone and lidocaine delivered under ultrasound or fluoroscopic guidance. The investigators and patients were not blinded. The patients were similar at baseline. Both groups showed statistically significant improvements in the ODI at one and three months compared to baseline, but there were no significant between-group differences. Dizziness, injection-site pain, and flushing were similar in both groups.

### *Ghai et al., 2015*

This is a poor-quality single-center randomized trial comparing injections of lidocaine alone and lidocaine plus steroid. In this trial, 69 patients under the age of 60 with more than three months of chronic low back or lumbosacral radicular pain despite conservative treatment were randomized to receive either lidocaine or lidocaine plus 80 mg methylprednisolone in equal volumes delivered via parasaggital interlaminar approach under fluoroscopy. Groups appeared to be similar at baseline. There were differences between the two groups with respect to the number of patients receiving more than three injections during the trial. There was also differential loss to follow-up at 12 months; more patients were lost in the lidocaine-only arm. With respect to functional outcomes, both arms showed improvement in the Modified Oswestry Disability Questionnaire (MODQ) compared to baseline. Patients in the lidocaine plus steroid arm showed statistically significantly greater improvement in the MODQ score at 3, 6, 9, and 12 months, although the magnitude of difference appears to be less than 10 points, a level of improvement that might not be clinically significant. One patient in the lidocaine-only group had a vagal reaction to the injection that was treated with atropine.

### *Kamble et al., 2016*

This is a poor-quality single-center randomized trial of three approaches to ESIs. In this trial, 90 patients with lumbosacral radicular pain and clinical and radiologic correlates for nerve root compression were randomized to receive 40 mg triamcinolone with bupivacaine and lidocaine delivered by transforaminal, caudal, or interlaminar approach (1:1:1). The investigators did not report on baseline characteristics, other treatments received, or attrition. All groups showed improvement in the mean ODI compared to baseline, but the improvements were statistically significantly greater in the patients who had received transforaminal injections. The crude number of patients requiring repeat injection or proceeding to surgery were similar in all three groups. Adverse events were not reported.

### *Karamouzian et al., 2014*

This is a poor-quality randomized trial comparing caudal and transforaminal ESIs in patients with a history of back surgery. In this trial, 30 patients with a history of previous open lumbar discectomy and recurrent radicular pain that had not responded to six weeks of conservative treatment were randomized to receive 40 mg methylprednisolone with bupivacaine and lidocaine by either a caudal or transforaminal approach. All patients in this trail also received treatment with tizanidine, celecoxib, and nortriptyline. Fluoroscopic guidance was only used for the transforaminal injections. Functional outcomes were assessed using the Prolo index (an instrument only validated to measure back surgery outcomes), and no statistically significant difference was observed between the two groups at two or six months after the treatment.

### *Lee et al., 2016*

This is a poor-quality randomized trial comparing pulsed radiofrequency treatment and transforaminal ESI. In this trial, 44 patients under age 70 with cervical or lumbar radicular pain and imaging findings of a herniated disc who had previously undergone ESI with unsatisfactory results were randomized to receive pulsed radiofrequency treatment or repeat transforaminal ESI with 5 mg dexamethasone and bupivacaine under fluoroscopic guidance. At baseline there were more women in the pulsed radiofrequency group. Both groups showed statistically significant improvement in ODI scores compared to baseline, but there were no statistically significant between-group differences at 2, 4, 8, or 12 weeks after the procedure. One patient in the radiofrequency group reported exacerbation of pain, but there were no other adverse events reported in either arm.

### *Manchikanti et al., 2014*

This is a fair-quality single-center, single-operator randomized trial comparing injection of lidocaine with saline to lidocaine with steroid. In this trial, 120 patients who had chronic low back pain for at least six months with L4-L5 or L5-S1 disc herniation and unilateral radiculitis were randomized to undergo fluoroscopically guided transforaminal injection of either lidocaine with saline or lidocaine with 3 mg betamethasone. At baseline, there were more women, a higher average body mass index, and a higher mean ODI score in the lidocaine with saline group. There was a 25% loss to follow-up at two years. At 3, 6, 12, 18, and 24 month follow-up, both groups showed statistically significant improvement over baseline ODI score, but there was no significant difference between the two groups. Both groups also showed significant reductions in opioid dose at three months and beyond (generally on the order of a 15-30 mg morphine equivalent dose), but there were no differences between the two groups. The authors reported that about 5% of injections resulted in intravascular infiltration, and 1.5% led to nerve root irritation.

### *Manchikanti et al., 2015*

This is a fair-quality single-center, single-operator randomized trial comparing injections with lidocaine alone and lidocaine plus steroid. In this trial, 120 patients over the age of 30 with radiologically documented central spinal stenosis and radicular pain for at least six months despite conservative treatment were randomized to receive fluoroscopically guided interlaminar injection of either lidocaine

or lidocaine and 6 mg betamethasone. At baseline there were more women and a higher mean weight in the lidocaine-only group. At two years of follow-up, the average number of injections was between five and six in both groups. At 3, 6, 12, 18, and 24 months of follow-up, there were statistically significant improvements in the ODI compared to baseline, but no statistically significant difference between the two groups. Both groups also showed significant reductions in opioid dose compared to baseline at three months and beyond (generally on the order of a 15-30 mg morphine equivalent dose), but there were no between-group differences. The authors reported 14 subarachnoid entries out of 644 procedures performed.

### *Ökmen & Ökmen, 2016*

This is a poor-quality single-center randomized trial comparing injection of bupivacaine with saline to bupivacaine with steroid and saline. In this trial, 120 patients with low back pain and radicular symptoms for more than six months and MRI findings of disc bulge not responding to conservative treatment were randomized to undergo fluoroscopically guided interlaminar injection of bupivacaine with saline or bupivacaine with 40 mg methylprednisolone and saline. Methods for adequate randomization, allocation concealment, and blinding were not described. Both groups showed statistically significant improvement over baseline ODI scores at 1, 3, 6, and 12 months. In addition, there was statistically significantly greater improvement in the ODI score in the steroid group at each follow-up point. The magnitude of the difference in the ODI score between groups was 10 to 30 points depending on the follow-up period, and those differences would generally be regarded as clinically significant. The authors did not report on adverse events.

### *Spijker-Huiges et al., 2014*

This is a fair-quality pragmatic randomized trial comparing usual care to usual care plus ESI. In this trial, 73 adults under the age of 60 with a clinical diagnosis of lumbosacral radicular back pain of greater than two but less than four weeks duration were randomized to receive care as usual or care as usual plus non-imaging guided lumbar interlaminar injection of 80 mg triamcinolone with saline. There were baseline differences between groups, including differences in the severity of symptoms, which were adjusted for in covariate analysis. Both groups experienced significant improvement in function as measured by the RMDQ score at any endpoint through one year of follow-up; the ESI group showed a statistically significantly greater improvement in RMDQ score, although that difference did not rise to the pre-established minimal clinically important difference of greater than 30% improvement. Patients in the ESI group were statistically significantly more likely to express satisfaction with their treatment.

### *Staats et al., 2016*

This is a poor-quality randomized trial comparing minimally invasive lumber decompression (MILD) to ESI. In this trial, 302 Medicare patients over the age of 65 with neurogenic claudication for more than three months in spite of physical therapy and analgesics and radiologically demonstrated spinal stenosis due to ligamentum flavum hypertrophy were randomized to undergo MILD or fluoroscopically guided interlaminar injection with 40 or 80 mg of triamcinolone or methylprednisolone (up to four treatments per year). At baseline, there were more women and more people with facet arthropathy in the ESI

group. During the trial, more patients in the ESI group also received aquatic therapy. The primary functional outcome of greater than 10-point improvement in ODI at six months was achieved in 62% of patients undergoing MILD and 36% of patients receiving ESI. Procedure-related adverse events were 1.3% in both groups, and there were no serious adverse events in either group.

## Summary of additional studies

In general, the evidence from the additional studies would not be likely to substantially alter the conclusions from the AHRQ review. Most of the additional studies demonstrated functional improvements compared to baseline, but the use of corticosteroids in particular does not offer additional clinically important benefit beyond that of active controls in most studies.

## Effectiveness of epidural steroid injections for reducing pain—low back pain with radiculopathy caused by herniated discs or foraminal stenosis

Based on public testimony, the subcommittee requested information on the effectiveness of ESIs for reducing pain in patients with low back pain and radiculopathy caused by herniated discs or foraminal stenosis. The following section summarizes the evidence on pain outcomes that were reported in the sources used in the Evidence Review above.

### *Chou et al., 2015*

There was moderate-quality evidence from six trials that ESI was associated with greater improvement in immediate-term pain scores compared to placebo in patients with low back pain and radiculopathy (WMD -7.55 [0 to 100 scale], 95% CI -11.4 to -3.74), however, this did not meet the predefined threshold for a minimum clinically important difference. There was low- to moderate-quality evidence of no statistically significant differences between the groups for mean pain improvement at short-, intermediate-, or long-term follow-up.

For categorical pain outcomes, there was low- to moderate-quality evidence of no difference in the likelihood of a successful pain outcome at short-, intermediate-, or long-term follow-up.

### *Cohen et al., 2015*

This trial randomized patients with lumbosacral radicular pain and MRI-demonstrated HNP or spinal stenosis to receive either image-guided ESI and placebo pills or a sham injection and gabapentin. For the outcomes of average pain score at one and three months, there were no statistically significant differences between the two groups. For the secondary outcomes, the ESI group reported lower worst leg pain scores at one month, but there were no differences between the groups at three months. More patients in the ESI group (66%) reported a positive composite outcome (defined as >2 point decrease in average leg pain on a 10-point scale and positive perceived global effect) at one month compared to the gabapentin group (46%) (p=0.02). There were no statistically significant differences in the positive composite outcome at three months.

### *Ghai et al., 2015*

This trial randomized patients with lumbosacral radicular pain with MRI-demonstrated HNP to receive an image-guided interlaminar epidural injection of lidocaine or lidocaine and methylprednisolone. For the primary outcome of effective pain relief (defined as >50% reduction from baseline pain score) at three months, a significantly greater percentage of patients in the steroid with local anesthetic group attained that result compared to the local anesthetic-only group (86% vs. 50%, p=0.002). Those differences were maintained through 12 months of follow-up.

### *Lee et al., 2016*

This trial randomized patients with lumbar radicular pain with imaging findings of intervertebral disc pathology who had not attained satisfactory relief from a first transforaminal ESI to receive repeat image-guided ESI or pulsed radiofrequency treatment of the dorsal root ganglion. Pain scores, as measured by the visual analogue scale (VAS), showed significant decreases compared to baseline in both groups at 2 to 12 weeks of follow-up, but there were no between-group differences.

### *Manchikanti et al., 2014*

This trial randomized patients with lumbosacral radicular pain of at least six months duration and imaging findings of HNP at L4-L5 or L5-S1 to receive an imaging-guided transforaminal epidural injection of lidocaine with saline or lidocaine with betamethasone. For the outcome of mean pain score as reported by the Numeric Rating Scale (NRS), both groups showed significant improvement compared to baseline scores at 3 to 24 months of follow-up, but there were no statistically significant differences between the two groups. The proportion of patients reporting significant pain relief (>50% improvement in NRS from baseline) was higher in the lidocaine with saline group at 3 to 24 months of follow-up, but between-group tests of statistical significance were not reported for this outcome.

### *Ökmen & Ökmen, 2016*

This trial randomized patients with low back pain and radiculitis with MRI-demonstrated disc pathology to receive an imaging-guided interlaminar epidural injection of bupivacaine and saline or bupivacaine and methylprednisolone. For the outcome of mean pain score as measured by the VAS, there were significantly greater improvements for patients in the steroid group at 1 to 12 months of follow-up (mean between-group differences in VAS ranged from 0.9 to 2 [10-point scale] at various follow-up times, p<0.05 for all between-group comparisons).

### *Spijker-Huiges et al., 2014*

This pragmatic trial randomized patients with clinically diagnosed lumbosacral radicular pain to receive care as usual (CAU) or CAU with a non-imaging-guided interlaminar injection of triamcinolone and saline. In the mixed-model analysis that accounts for between-group differences at various time points during 52 weeks of follow-up, there was a statistically significant improvement in the NRS back pain score (estimated mean difference 1.12 [10-point scale], 95% CI 0.26 to 1.98, p=0.01) favoring the patients who received ESI; there were no statistically significant between-group differences with respect to the NRS leg pain score or the NRS total pain score.

### *Summary of findings on pain outcomes*

Based on the AHRQ review, there is moderate-quality evidence of a small but statistically significant improvement in immediate-term pain for patients with lumbosacral radicular pain who receive ESI; however, those improvements were not maintained at a later follow-up period and did not meet the pre-specified threshold for minimal clinically important difference.

The additional RCTs comparing ESI with various control treatments for lumbosacral radicular pain reached mixed conclusions. However, the most methodologically and technically rigorous of these subsequent trials found no significant differences in pain outcomes between patients who received ESI and those who received sham injections plus gabapentin (Cohen et al., 2015) or local anesthetic injections alone (Manchikanti et al., 2014).

## EVIDENCE SUMMARY

Overall, low- to moderate-strength evidence demonstrates no difference in short- or long-term function for patients treated with epidural steroid injections, facet joint steroid injections, or medial branch steroid injections when compared to control treatments. For patients with radiculopathy, epidural steroid injections have been shown to produce immediate-term improvements in pain (moderate confidence) and function (low confidence) compared to control treatments, but the magnitude of those improvements does not rise to pre-specified thresholds of clinical significance. Epidural steroid injections in patients with radiculopathy may reduce the risk of undergoing surgery in the short-term, but the evidence does not support any difference in the long-term risk of surgery compared to control treatments. There was insufficient evidence to draw conclusions about the effectiveness of sacroiliac joint steroid injections. Harms and serious adverse events associated with these procedures are inconsistently reported in the trials, but appear to be rare.

## OTHER DECISION FACTORS

### Resource allocation

The actual prices of the various corticosteroid injections are highly variable depending on the setting and plan. Prices appear to range from hundreds to thousands of dollars. If these injections were effective, then they could potentially be comparable to an extended course of conservative therapy, and some patients would prefer more rapid relief of their symptoms. If these injections decreased future risk of surgery, they would likely be cost saving. However, there is insufficient evidence supporting a decreased use of conservative treatments, and there is moderate confidence that ESIs are ineffective at reducing the risk of surgery for radiculopathic pain. Given the lack of proven benefit on the predefined outcomes, various corticosteroid injections for back pain are unlikely to be cost-effective.

### Values and preferences

Patients with back pain would highly value having effective treatments to improve their symptoms, and would likely prefer interventions that are less invasive, less time consuming, less risky, and less

demanding on the patient. Given the variety of frequently used interventions for low back pain, patient preferences appear to be highly variable.

## Other considerations

There are many proven evidence-based treatments for low back pain that are widely available to patients through most insurers.

# POLICY LANDSCAPE

## Quality measures

A search of the National Quality Measures Clearinghouse did not identify any measures directly related to the use of ESI. The National Quality Measures Clearinghouse does include a number of quality measures that address assessment and collaborative decision-making regarding low back pain. For example, one quality measure is "Percentage of patients with non-specific low back pain diagnosis who have had collaborative decision-making with regards to referral to a specialist" (Institute for Clinical Systems Improvement, 2012).

## Payer coverage policies

### Private payers

#### *Coverage policy for ESIs*

Coverage policies were assessed for Aetna, Cigna, Moda, and Regence. Aetna, Cigna, and Moda provide coverage for ESIs when considered medically necessary according to set criteria. No coverage policy regarding ESIs for low back pain was identified for Regence. The criteria included in Aetna, Cigna, and Moda coverage policies for the treatment of low back pain with ESIs is described below.

##### *Criteria for ESI diagnosis and origin of pain*

Moda covers ESIs for patients with spinal pain (i.e., cervical, thoracic, or lumbar) who have physical examination findings consistent with radicular pain. Aetna and Cigna cover ESIs for patients with radiculopathy. Cigna additionally covers ESIs for certain patients with radiculitis or radicular pain and certain patients with evidence of symptomatic spinal stenosis as an initial trial. Moda and Cigna may require physical exam findings consistent with radicular pain, such as a positive leg raising test. All three of these payers require a failed response to a reasonable course of conservative therapy (e.g., physical therapy, chiropractic care, rest, systemic analgesics) prior to treatment with ESIs. Furthermore, all three payers include criteria for the origin of the pain. Aetna and Moda explicitly exclude patients with non-specific back pain or failed back syndrome.

##### *Criteria for administration of ESI treatment*

Aetna and Moda do not cover ultrasound guidance for administration of ESIs for any indication. Cigna states that ESIs should be administered under fluoroscopic guidance, with few exceptions. Cigna does not cover caudal ESIs because this injection route is not target specific. Cigna only covers ESIs as part of a comprehensive approach to pain, stating "based on the limited long-term benefit of performing an ESI

as an isolated intervention with regard to pain and improved function, all ESIs should be performed in conjunction with active rehabilitative care/therapeutic exercise." Aetna requires that ESIs are provided as part of a comprehensive pain management program following the first set of three injections.

#### *Criteria for repeated use of ESIs*

All three private payers set criteria for continued use of ESIs. Aetna states that it is not medically necessary to employ ESIs more frequently than every seven days, and that it is rarely medically necessary more than every two months following an established therapeutic effect of the treatment. Treatment exceeding 12 months may be reviewed by Aetna for continued medical necessity. Cigna permits repeated use of ESIs given 50% pain relief, an increase in function, or a reduction in utilization of medication or additional medical services. Cigna further specifies that administration of ESIs should be limited to three per episode of pain and four per region in a year. Moda covers up to four injections in a 12-month period if the preceding injection resulted in 50% pain relief for at least six weeks.

### *Coverage policy for facet joint injections*

Aetna and Cigna do not cover therapeutic facet joint injections for the treatment of low back pain. Moda covers therapeutic joint injections for certain patients with back pain when facet joint syndrome is suspected and the patient has tried and failed three months of conservative treatment. No coverage policy regarding facet joint injections for the treatment of low back pain was identified for Regence.

### *Coverage policy for sacroiliac joint injections*

Aetna, Moda, and Cigna cover therapeutic sacroiliac joint injections for certain patients with back pain. No coverage policy regarding the therapeutic use of sacroiliac joint injections was identified for Regence. Both Aetna and Moda require that the patient has chronic low back pain for a period of at least three months prior to treatment. Aetna and Cigna only permit sacroiliac joint injections as part of a comprehensive pain management program. Moda and Cigna only cover sacroiliac joint injections for patients who have been nonresponsive to a reasonable course of conservative treatment.

## Medicaid

The Washington Medicaid program covers ESIs in the cervical, thoracic, or lumbar spine for the treatment of patients with chronic radicular pain who have failed to respond to at least six weeks of conservative therapy or for patients with radiculopathy who have failed to respond to at least two weeks of conservative therapy. Fluoroscopic, CT, or ultrasound guidance must be used in the administration of ESIs. Additionally, Washington Medicaid requires documentation of the patient's baseline level of function.

The Washington Medicaid program also covers sacroiliac joint injections when completed with fluoroscopic or CT guidance for patients with chronic sacroiliac joint pain who have not shown sufficient improvement in response to at least six weeks of conservative therapy. Washington Medicaid states there must be no more than one injection without medical record documentation of at least 30% improvement in function and pain, when compared to the baseline documented before the injections started. Washington Medicaid requires clinical review of requests for more than two injections.

## Medicare

No National Coverage Determination was identified for ESIs for low back pain. Three Medicare Local Coverage Determinations (LCDs) were identified for the treatment of low back pain with ESIs. The LCD for South Carolina, Virginia, West Virginia, and North Carolina (effective 3/17/2016) and the LCD for Kentucky and Ohio (effective 10/01/2015) cover ESIs for patients with suspected radicular pain, neurogenic claudication, post laminectomy syndrome, or low back pain with substantial imaging abnormalities, or a documented Visual Analog scale or Numeric Pain Rating Scale indicating moderate to severe pain with functional impairment in daily living activities. These LCDs require a failed response to at least four weeks of non-surgical, non-injection care. The LCD for Delaware, District of Columbia, Maryland, New Jersey, and Pennsylvania (effective 10/01/2016) states that the therapeutic use of transforaminal epidural injections performed under imaging guidance may be appropriate for certain patients when other therapeutic measures are ineffective or contraindicated and when the low back pain is not associated with myofascial pain syndrome.

No National Coverage Determination was identified for facet joint injections for low back pain. Ten Medicare LCDs were identified for the treatment of low back pain with facet joint injections for certain patients. All 10 LCDs only cover facet joint injections for patients with low back pain that has persisted for at least three months. Additionally, all 10 LCDs state that facet joint injections must be performed with imaging guidance (e.g., fluoroscopy, CT). All 10 LCDs set criteria for continued treatment with facet joint injections. One LCD states that if the first set of injections fails to produce the desired effect, the provider should proceed to the next indicated treatment option. A second LCD states that long-term multiple facet joint injections are not an effective method for chronic pain management and recommends limiting injections to four per region, per year. The remaining eight LCDs state that facet joint injections of corticosteroids are associated with adverse health events, and thus "ongoing coverage requires outcomes reporting as described in this LCD to allow future analysis of clinical efficacy."

No National Coverage Determination was identified for sacroiliac joint injections for low back pain. Two Medicare LCDs were identified for the treatment of low back pain with sacroiliac joint injections. Both the LCDs for Delaware, District of Columbia, Maryland, New Jersey, and Pennsylvania (effective 10/01/2016) and the LCDs for Florida, Puerto Rico, and Virgin Islands (effective 10/01/2015) state that therapeutic sacroiliac injections of steroids may be used to treat low back pain and recommend the use of imaging guidance to ensure the success of this procedure.

# Professional society guidelines

Each of the guidelines summarized below addresses the treatment of low back pain and recommends ESIs for specific patient populations.

- The Toward Optimized Practice (TOP) 2015 clinical practice guideline, *Evidence-informed primary care management of low back pain*, states that there is inconclusive evidence to recommend for or against ESIs in the presence of radiculopathy and recommends "do not use epidural steroid injections for acute low back pain in the absence of radiculopathy" (Toward Optimized Practice, 2015).

- The North American Spine's Society's (NASS) 2014 guideline, *An evidence-based clinical guideline for the diagnosis and treatment of lumbar disc herniation with radiculopathy*, recommends transforaminal ESI to provide short-term pain relief in some patients with lumbar disc herniation with radiculopathy. The guideline additionally recommends contrast-enhanced fluoroscopy to guide ESIs in order to improve accuracy. However, the guideline concludes that there is insufficient evidence to recommend for or against the 12-month efficacy of transforaminal ESI to treat this patient population. Moreover, there is insufficient evidence to recommend for or against one injection approach over another in administering ESIs to this patient population (Kreiner et al., 2014).
- The American Society of Interventional Pain 2013 guideline*, An update of comprehensive evidence-based guidelines for intervention techniques in chronic spinal pain*, recommends caudal, interlaminar, and transforaminal epidural injections for disc herniation and for spinal stenosis, as well as caudal or interlaminar epidural injections for axial or discogenic pain without disc herniation, radiculitis, or facet joint pain (Manchikanti et al., 2013).
- The Canadian Pain Society Task Force 2012 guideline, *Evidence-based guideline for neuropathic pain intervention treatments: Spinal cord stimulation, intravenous infusions, epidural injections, and nerve blocks*, recommends that clinicians consider a trial of ESI for patients with lumbar radiculopathy or with neuropathic pain arising from the cervical spine who failed to respond adequately to conservative treatment. However, the guideline states there is insufficient, limited, or conflicting data to support the use of ESIs to treat spinal stenosis, failed back surgery syndrome, complex regional pain syndrome type I, and postherpetic neuralgia (Mailis and Taenzer, 2012).

The following guideline addresses facet joint injections:

- The American Society of Interventional Pain 2013 guideline*, An update of comprehensive evidence-based guidelines for intervention techniques in chronic spinal pain*, states that the evidence is limited for therapeutic lumbar intraarticular facet joint injections and fair to good for lumbar facet joint nerve blocks (Manchikanti et al., 2013).

The following guidelines address sacroiliac joint injections:

- The Toward Optimized Practice (TOP) 2015 clinical practice guideline, *Evidence-informed primary care management of low back pain*, states that there is inconclusive evidence to recommend for or against intra-articular sacroiliac injections (Toward Optimized Practice, 2015).
- The American Society of Interventional Pain 2013 guideline*, An update of comprehensive evidence-based guidelines for intervention techniques in chronic spinal pain*, states that the evidence is limited for therapeutic sacroiliac joint injections (Manchikanti et al., 2013).

## Food and Drug Administration safety announcement

The injection of corticosteroids into the epidural space of the spine is a widespread medical practice. However, this use of injectable steroids is not currently approved by the FDA because its effectiveness and safety has not been established. In response to concerns of medical professionals regarding the risk

of severe neurological adverse events associated with the use of ESIs for back pain, the FDA initiated an ongoing investigation of the safety issue and has acted to raise awareness of the risks. In 2014, the FDA released a safety announcement regarding the use of ESIs:

> "The U.S. Food and Drug Administration (FDA) is warning that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. The injections are given to treat neck and back pain, and radiating pain in the arms and legs. We are requiring the addition of a *Warning* to the drug labels of injectable corticosteroids to describe these risks. Patients should discuss the benefits and risks of epidural corticosteroid injections with their health care professionals, along with the benefits and risks associated with other possible treatments" (FDA, 2014).

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

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

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# APPENDIX A. GRADE INFORMED FRAMEWORK – ELEMENT DESCRIPTIONS

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

## Strong recommendation

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

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

## Weak recommendation

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

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

## Confidence in estimate rating across studies for the intervention/outcome[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.

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

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

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

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

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

# APPENDIX B. GRADE EVIDENCE PROFILES

| Quality Assessment (Confidence in Estimate of Effect) – Epidural steroids for radiculopathy | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No. of Studies** | **Study Design(s)** | **Risk of Bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Factors** | **Quality** |
| **Long-term Function (Critical)** | | | | | | | |
| 8 (n=950) | RCTs | Moderate | Inconsistent | Direct | Precise | | Low confidence in estimate of effect ●●○○ |
| **Long-term Risk of Surgery (Critical)** | | | | | | | |
| 14 (n=1208) | RCTs | Moderate | Consistent | Direct | Precise | | Moderate confidence in estimate of effect ●●●○ |
| **Short-term Function (Important)** | | | | | | | |
| 11 (n=1226) | RCTs | Moderate | Inconsistent | Direct | Precise | | Moderate confidence in estimate of effect ●●●○ |
| **Change in Utilization of Comparators (Important)** | | | | | | | |
| 8 (n=845) | RCTs | Moderate | Inconsistent | Direct | Precise | | Low confidence in estimate of effect ●●○○ |
| **Harms (Important)** | | | | | | | |
| 29 (n=2792) | RCTs | High | Consistent | Direct | Precise | | Moderate confidence in estimate of effect ●●●○ |

| Quality Assessment (Confidence in Estimate of Effect) – Epidural steroids for spinal stenosis | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No. of Studies** | **Study Design(s)** | **Risk of Bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Factors** | **Quality** |
| **Long-term Function (Critical)** | | | | | | | |
| 2 (n=160) | RCTs | Moderate | Consistent | Direct | Imprecise | | Low confidence in estimate of effect ●●○○ |
| **Long-term Risk of Surgery (Critical)** | | | | | | | |
| 1 (n=30) | RCT | Moderate | Cannot determine | Direct | Imprecise | | Low confidence in estimate of effect ●●○○ |
| **Short-term Function (Important)** | | | | | | | |
| 5 (n=615) | RCTs | Moderate | Consistent | Direct | Precise | | Moderate confidence in estimate of effect ●●●○ |
| **Change in Utilization of Comparators (Important)** | | | | | | | |
| | | | | | | | Insufficient Data ○○○○ |
| **Harms (Important)** | | | | | | | |
| 8 (n=821) | RCTs | High | Consistent | Direct | Precise | | Low confidence in estimate of effect ●●○○ |

| Quality Assessment (Confidence in Estimate of Effect) – Epidural steroids for non-radicular pain | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No. of Studies** | **Study Design(s)** | **Risk of Bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Factors** | **Quality** |
| **Long-term Function (Critical)** | | | | | | | |
| 2 (n=240) | RCTs | Moderate | Consistent | Direct | Imprecise | | Low confidence in estimate of effect ●●○○ |
| **Long-term Risk of Surgery (Critical)** | | | | | | | |
| | | | | | | | Insufficient Data ○○○○ |
| **Short-term Function (Important)** | | | | | | | |
| 2 (n=240) | RCTs | Moderate | Consistent | Direct | Imprecise | | Low confidence in estimate of effect ●●○○ |
| **Change in Utilization of Comparators (Important)** | | | | | | | |
| 2 (n=240) | RCTs | Moderate | Consistent | Direct | Imprecise | | Low confidence in estimate of effect ●●○○ |
| **Harms (Important)** | | | | | | | |
| 2 (n=240) | RCTs | High | Consistent | Direct | Imprecise | | Low confidence in estimate of effect ●●○○ |

| Quality Assessment (Confidence in Estimate of Effect) – Facet joint injections | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No. of Studies** | **Study Design(s)** | **Risk of Bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Factors** | **Quality** |
| **Long-term Function (Critical)** | | | | | | | |
| 2 (n=204) | RCTs | Moderate | Consistent | Direct | Imprecise | | Low confidence in estimate of effect ●●○○ |
| **Long-term Risk of Surgery (Critical)** | | | | | | | |
| | | | | | | | Insufficient Data ○○○○ |
| **Short-term Function (Important)** | | | | | | | |
| 2 (n=171) | RCTs | Moderate | Consistent | Direct | Imprecise | | Low confidence in estimate of effect ●●○○ |
| **Change in Utilization of Comparators (Important)** | | | | | | | |
| 2 (n=204) | RCTs | Moderate | Consistent | Direct | Imprecise | | Low confidence in estimate of effect ●●○○ |
| **Harms (Important)** | | | | | | | |
| 10 (n=823) | RCTs | High | Consistent | Direct | Imprecise | | Low confidence in estimate of effect ●●○○ |

| Quality Assessment (Confidence in Estimate of Effect) – Sacroiliac joint injections | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No. of Studies** | **Study Design(s)** | **Risk of Bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Factors** | **Quality** |
| **Long-term Function (Critical)** | | | | | | | |
| | | | | | | | Insufficient Data ○○○○ |
| **Long-term Risk of Surgery (Critical)** | | | | | | | |
| | | | | | | | Insufficient Data ○○○○ |
| **Short-term Function (Important)** | | | | | | | |
| | | | | | | | Insufficient Data ○○○○ |
| **Change in Utilization of Comparators (Important)** | | | | | | | |
| | | | | | | | Insufficient Data ○○○○ |
| **Harms (Important)** | | | | | | | |
| | | | | | | | Insufficient Data ○○○○ |

# APPENDIX C. METHODS

## Scope Statement

### *Populations*

Adults with acute, subacute, or chronic low back pain with or without radiculopathy

*Population scoping notes: None*

### *Interventions*

Epidural, facet joint, or sacroiliac corticosteroid injections

*Intervention exclusions: None*

### *Comparators*

Other injection therapies (e.g., local anesthetics, hyaluronic acid, or saline), physical therapy, home exercise programs, medications (e.g., oral corticosteroids, opioids, nonsteroidal anti-inflammatory drugs), complementary and alternative therapies (e.g., acupuncture, yoga, chiropractic therapy, Alexander technique), soft tissue injections, ablative interventions, surgery, no treatment

### *Outcomes*

Critical: Long-term function, long-term risk of undergoing surgery

Important: Short-term function, adverse events, change in utilization of comparators (e.g., opioids, surgery)

*Considered but not selected for the GRADE table: intermediate-, short- and long-term pain, immediate-term function*

### *Key Questions*

KQ1: What is the comparative effectiveness of corticosteroid injection therapies for low back pain?

KQ2: Does the effectiveness of corticosteroid injection therapies for low back pain vary based on:

a. Duration of back pain
b. Etiology of back or radicular pain (e.g., stenosis, disc herniation)
c. Choice of corticosteroid, dose, or frequency
d. Anatomic approach
e. Use of imaging guidance
f. Previous back surgery
g. Response to previous diagnostic injections
h. Response to previous injection therapies

KQ 3: What are the harms of corticosteroid injection therapies for low back pain?

*Contextual Questions*

1. Does the use of these therapies influence subsequent utilization of health care resources (e.g., chiropractic, opioids, acupuncture, physical therapy)?

2. Does the effectiveness of these interventions depend on prior treatments the patient has received?

## Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, technology assessments, and clinical practice guidelines using the terms (epidural OR spine OR spinal OR sacroiliac OR medial branch OR radiculopathy) AND (inject* OR steroid* OR corticosteroid). Searches of core sources were limited to citations published after 2011.

The core sources searched included:

Agency for Healthcare Research and Quality (AHRQ)
Blue Cross/Blue Shield Health Technology Assessment (HTA) program
BMJ Clinical Evidence
Canadian Agency for Drugs and Technologies in Health (CADTH)
Cochrane Library (Wiley Interscience)
Hayes, Inc.
Institute for Clinical and Economic Review (ICER)
Medicaid Evidence-based Decisions Project (MED)
National Institute for Health and Care Excellence (NICE)
Tufts Cost-effectiveness Analysis Registry
Veterans Administration Evidence-based Synthesis Program (ESP)
Washington State Health Technology Assessment Program

A MEDLINE® search was then conducted to identify systematic reviews, meta-analyses, and technology assessments. In addition, a MEDLINE® search was conducted for randomized controlled trials published after the search dates of the AHRQ systematic review (Chou et al., 2015). The search was limited to publications in English published after October 2014 (the end search date for the AHRQ systematic review, which was judged to be the most comprehensive review on this topic).

Searches for clinical practice guidelines were limited to those published since 2011. A search for relevant clinical practice guidelines was also conducted, using the following sources:

Australian Government National Health and Medical Research Council (NHMRC)
Centers for Disease Control and Prevention (CDC) – Community Preventive Services
Choosing Wisely
Institute for Clinical Systems Improvement (ICSI)
National Guidelines Clearinghouse
New Zealand Guidelines Group
NICE
Scottish Intercollegiate Guidelines Network (SIGN)
United States Preventive Services Task Force (USPSTF)

Veterans Administration/Department of Defense (VA/DOD)

### *Inclusion/Exclusion Criteria*

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, or clinical practice guidelines. Additionally, studies that reported only on data that had been previously published were excluded.

# APPENDIX D. APPLICABLE CODES

| CODES | DESCRIPTION |
|---|---|
| **CPT Codes** | |
| Paravertebral facet with ultrasound guidance | |
| 0216T | Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; single level |
| 0217T | … lumbar or sacral; second level (List separately in addition to code for primary procedure) |
| 0218T | … lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure) |
| 0230T | Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; single level |
| 0231T | …lumbar or sacral; each additional level (List separately in addition to code for primary procedure) |
| Sacroiliac | |
| 27096 | Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed |
| 76942 | Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation |
| G0260 | Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography |
| Epidural or subarachnoid space, fluoroscopy or CT guidance (interlaminar or transforaminal) | |
| ~~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)~~ |
| ~~62320~~ | ~~Injection(s), of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance~~ |
| 62322 | Injection(s), of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance |
| 62323 | … lumbar or sacral (caudal); with imaging guidance |
| 64483 | Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single level |
| 64484 | … lumbar or sacral, each additional level |

| Paravertebral facet with fluoroscopy or CT guidance | |
|---|---|
| 64493 | Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level |
| 64494 | … lumbar or sacral; second level (List separately in addition to code for primary procedure) |
| 64495 | … lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure) |

Note: Inclusion on this list does not guarantee coverage

# CG -Corticosteroid injections for low back pain

Question: How should the draft Coverage Guidance **Corticosteroid injections for low back pain** be applied to the Prioritized List?

Question source: HERC Staff, EbGS

Issue:
The EbGS approved the following draft "box language:"

Epidural corticosteroid injections are not recommended for coverage for the treatment of low back pain with radiculopathy *(weak recommendation).*

Epidural corticosteroid injections are not recommended for coverage for the treatment of low back pain without radiculopathy (e.g., spinal stenosis, non-radicular pain) *(strong recommendation).*

Corticosteroid injections (including facet joint, medial branch, and sacroiliac joint) are not recommended for coverage for the treatment of low back pain *(strong recommendation).*

Prioritized List Status:

| CODES | DESCRIPTION | |
|---|---|---|
| **CPT Codes** | | |
| Paravertebral facet with ultrasound guidance | | |
| 0216T | Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; single level | Category 2/3 codes not covered |
| 0217T | … lumbar or sacral; second level (List separately in addition to code for primary procedure) | |
| 0218T | … lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure) | |
| 0230T | Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; single level | |
| 0231T | …lumbar or sacral; each additional level (List separately in addition to code for primary procedure) | |
| Sacroiliac | | |
| 27096 | Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed | On 532 but only for diagnostic in relation to SI joint fusion |

| | | |
|---|---|---|
| 76942 | Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation | Diagnostic |
| G0260 | Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography | Diagnostic |
| Epidural or subarachnoid space, fluoroscopy or CT guidance (interlaminar or transforaminal) | | |
| 62322 | Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); *without imaging guidance* | 75 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES<br><br>297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS |
| 62323 | Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); *with imaging guidance* (ie, fluoroscopy or CT) | |
| 64483 | Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, *single level* | SRNC |
| 64484 | Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, *each additional level* (List separately in addition to code for primary procedure) | |
| Paravertebral facet with fluoroscopy or CT guidance | | |
| 64493 | Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; *single level* | SRNC |
| 64494 | … lumbar or sacral; *second level* (List separately in addition to code for primary procedure) | |
| 64495 | … lumbar or sacral; *third and any additional level(s)* (List separately in addition to code for primary procedure) | |

Relevant Prioritized List lines and guidelines

**Line 500**

CONDITION: CONDITIONS FOR WHICH CERTAIN TREATMENTS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS
TREATMENT: MEDICAL AND SURGICAL TREATMENT

GUIDELINE NOTE AAA, TREATMENTS WITH MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS FOR CERTAIN CONDITIONS

The following treatments are prioritized on Line 500 for the conditions listed here:

| CONDITION | TREATMENT |
|---|---|

**Line: 532**

Condition: CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS (See Guideline Notes 37,60,64,65,100,101,161)

Treatment: SURGICAL THERAPY

ICD-10: G95.0,M40.00-M40.15,M40.202-M40.57,M42.00-M42.9,M43.00-M43.28, M43.8X1-M43.8X9,M45.0-M45.9,M46.1,M46.40-M46.99,M47.20-M47.28, M47.811-M47.9,M48.00-M48.19,M48.30-M48.38,M48.8X1-M48.9,M49.80-M49.89,M50.10-M50.11,M50.120-M50.93,M51.14-M51.9,M53.80-M53.9, M54.10-M54.18,M96.1-M96.4,M99.20-M99.79,Q06.0-Q06.3,Q06.8-Q06.9, Q76.0-Q76.2,Q76.411-Q76.49,S13.0XXA-S13.0XXD,S23.0XXA-S23.0XXD, S23.100A-S23.100D,S23.110A-S23.110D,S23.120A-S23.120D,S23.122A-S23.122D,S23.130A-S23.130D,S23.132A-S23.132D,S23.140A-S23.140D, S23.142A-S23.142D,S23.150A-S23.150D,S23.152A-S23.152D,S23.160A-S23.160D,S23.162A-S23.162D,S23.170A-S23.170D,S33.0XXA-S33.0XXD, S33.100A-S33.100D,S33.110A-S33.110D,S33.120A-S33.120D,S33.130A-S33.130D,S33.140A-S33.140D,S34.3XXA-S34.3XXD

CPT: 20610,20660-20665,20930-20938,21720,21725,22206-22226,22532-22865, 27035,27096,27279,29000-29046,29710,29720,62287,63001-63091,63170, 63180-63200,63270-63273,63295-63610,63650,63655,63685,96150-96155, 97110-97124,97140-97168,97530,97535,98966-98969,99051,99060,99070, 99078,99184,99201-99239,99281-99285,99291-99337,99354-99357, 99401-99404,99408-99412,99441-99449,99468-99480,99605-99607

HCPCS: G0157-G0160,G0396,G0397,G0406-G0408,G0425-G0427,G0463-G0467, G0508,G0509,S2350,S2351

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

*Lines 351,532*

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. Decompression and fusion surgeries are both included on these lines for spondylolisthesis.

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. Neurologic impairment is defined as objective evidence of one or more of the following:
    a. Markedly abnormal reflexes
    b. Segmental muscle weakness
    c. Segmental sensory loss
    d. EMG or NCV evidence of nerve root impingement
    e. Cauda equina syndrome
    f. Neurogenic bowel or bladder
    g. Long tract abnormalities

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

1) the spinal stenosis is in the cervical spine OR
2) spondylolisthesis is present as above OR
3) there is pre-existing or expected post-surgical spinal instability (e.g. degenerative scoliosis >10 deg, >50% of foraminal joints expected to be resected)

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

- 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

**GUIDELINE NOTE 161, SACROILIAC JOINT FUSION**

*Line 532*

Sacroiliac (SI) joint fusion (CPT 27279) is included on this line for patients who have all of the following:

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

At least 75 percent reduction of pain for the expected duration of two anesthetics (on separate visits each with a different duration of action), and the ability to perform

previously painful maneuvers, following an image-guided, contrast-enhanced intra-articular SI joint injection.SI joint injections (CPT 20610 and 27096) are included on this line for diagnostic SI joint injections with anesthetic only, but not for therapeutic injections or corticosteroid injections. Injections are only included on this line for patients for whom SI joint fusion surgery is being considered.

History of placement of diagnostic/therapeutic codes on dysfunction lines.

From consent agenda 8/14/14

> DMAP requests that 62311 pair with 343.9 (Unspecified infantile cerebral palsy). 62311 was Ancillary until January, 2013 when it was moved to line 400 only as part of the review for percutaneous interventions for low back pain. This code appears to be used for baclofen trails before pump insertion. 62310 (cervical or thoracic level injections) remains Ancillary.

On 8/14/14 63211 was added to lines 78/75 and 318/297
On 5/7/15 63210 (cervical) was added to dysfunction lines in 5/7/2015 VbBS meeting to match pairing of 63211.

Use of 62320-62323 shows they are used almost exclusively for back diagnoses.

**Staff Summary**

Most of these injections are currently on the Services Recommended for Non-Coverage table (SRNC). HERC is attempting to get rid of the SRNC table and instead place codes on existing lines, or the two new marginal benefit lines, and create a separate experimental group. Therefore, moving the epidural steroid injections from the SRNC to line 532 (the unfunded back line) is the staff recommendation.

**HERC Staff Recommendations:**

1. **Add corticosteroid epidural injections (62322-62323, 64483-64484), facet joint injections, and medial branch blocks (64493-64495), and SI joint injection (G0260) to Line 532** CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
    a. **Remove G0260 from Diagnostic File**
    b. **Keep 62322- 62323 on Dysfunction lines with a coding specification (see below)**
    c. **Remove 64483-64484, and 64493-64495 from the SRNC**

2. **Add a coding specification for lines 75 and 297:**
    CPT codes 62320-3 are only included on lines 75 and 297 for trials of antispasmodics in preparation for placement of a baclofen pump.

**3. Modify Guideline Note 161 to include additional HCPCS code for SI injections**
**GUIDELINE NOTE 161, SACROILIAC JOINT FUSION**

*Line 532*

Sacroiliac (SI) joint fusion (CPT 27279) is included on this line for patients who have all of the following:

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

At least 75 percent reduction of pain for the expected duration of two anesthetics (on separate visits each with a different duration of action), and the ability to perform previously painful maneuvers, following an image-guided,

contrast-enhanced intra-articular SI joint injection. SI joint injections (CPT 20610 and 27096, and HCPCS G0260) are included on this line for diagnostic SI joint injections with anesthetic only, but not for therapeutic injections or corticosteroid injections. Injections are only included on this line for patients for whom SI joint fusion surgery is being considered.

4. Modify Guideline Note 37 as follows

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

*Lines 351,532*

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. Decompression and fusion surgeries are both included on these lines for spondylolisthesis.

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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. Neurologic impairment is defined as objective evidence of one or more of the following:
    a. Markedly abnormal reflexes
    b. Segmental muscle weakness
    c. Segmental sensory loss
    d. EMG or NCV evidence of nerve root impingement
    e. Cauda equina syndrome
    f. Neurogenic bowel or bladder
    g. Long tract abnormalities

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

1) the spinal stenosis is in the cervical spine OR
2) spondylolisthesis is present as above OR
3) there is pre-existing or expected post-surgical spinal instability (e.g. degenerative scoliosis >10 deg, >50% of foraminal joints expected to be resected)

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

- ~~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~~

- corticosteroid injections for cervical pain

Corticosteroid injections for low back pain are only included on Line 532.

The development of this guideline note was informed by a HERC coverage guidance. See WEBSITE/CORTICOSTEROID INJECTIONS.

# HERC Coverage Guidance: Low Back Pain - Corticosteroid Injections
# Disposition of Public Comments

## Table of Contents



## Discussion Table

| IDs/#s | Summary of Issue | Subcommittee response |
|---|---|---|
| B1, C1, E1, G1, J1, J2, L1, L3, N1, AA1, EE1, GG2, KK1, QQQ1 | Steroid injection therapies reduce the use of opioid and non-opioid analgesics and delay or prevent surgery. | *The evidence review did not show that steroid injection therapies reduce the use of opioid pain medications (evidence was either insufficient or showed no difference in opioid use) or the long-term likelihood that a patient will undergo surgery to treat back pain.* |
| C2, J3, QQQ1 | The AHRQ report includes trials that lacked rigorous patient selection criteria. | *Many of the trials included in the AHRQ report relied on rigorous patient selection criteria. The authors of the AHRQ report also considered whether patient characteristics influence the likelihood of a successful injection; they concluded that there was "insufficient evidence to determine whether the cause of radicular symptoms, duration of symptoms, imaging findings, or other patient factors" influenced patient outcomes from injection therapies.* |
| J3, MMMM2 | The use of continuous (as opposed to categorical) outcomes in the meta-analysis does not allow discernment of treatment responders from non-responders. | *With respect to the use of categorical as opposed to continuous outcomes, the authors of the AHRQ review noted* |

| IDs/#s | Summary of Issue | Subcommittee response |
|---|---|---|
| | | *that "[A]s presented in the results, analyses on both continuous and dichotomous outcomes were presented. If anything, results using dichotomous outcomes (likelihood of experiencing a clinically meaningful benefit) showed less evidence of effectiveness than analyses based on continuous outcomes (mean change in pain or function scores)." Furthermore, the use of composite categorical outcomes that include a mix of pain relief and functional outcomes would be beyond the scope of the outcomes selected for this coverage guidance.* |
| D2, EE1 | It was inappropriate to convert active control trials to placebo for the purpose of examining the effects of corticosteroid injections. | *The purpose of this evidence review was to determine whether injection of corticosteroids into the lumbar epidural space, the facet joint, or the SI joint improved the outcomes listed in the scope statement. Indeed, injection of local anesthetics (and other substances) are included as comparators in the scope statement. Trials comparing local anesthetics to local anesthetics plus corticosteroids are thus helpful in determining the comparative effectiveness of corticosteroid injections. The authors of the AHRQ report have previously responded to this criticism: "[A]s described in the Results, there were no clear differences between local anesthetic injection, saline injection, or non-epidural injection as control interventions; therefore we think it is appropriate to classify all of these as placebo interventions."* |
| Y2, QQQ1 | The investigators for AHRQ report were biased and/or funding from AHRQ influenced the findings of the investigators. | *The evidence review that informs this coverage guidance was funded by AHRQ. The research was conducted by experienced systematic reviewers and was subject to both technical expert* |

| IDs/#s | Summary of Issue | Subcommittee response |
|---|---|---|
| | | *and peer review. The investigators disclosed no affiliations or financial involvement that conflicts with the material presented in the report. The assertion of intellectual bias or conflict of interest rests on an assumption that AHRQ had a pre-supposed conclusion about the effectiveness of injection therapies for low back pain that resulted in pressure to reach certain conclusions. We find no basis to support such a claim.* |
| QQQ1, MMMM2 | The evidence review fails to account for the use of imaging guidance, various anatomic approaches, or other procedural characteristics that may influence effectiveness. | *As part of the pre-specified scope and key questions of the AHRQ review, the authors considered whether specific diagnoses, imaging guidance, or the use of certain approaches or access methods influenced the effectiveness of these procedures. Those analyses are summarized in the coverage guidance.* |

## Commenters

| Identification | Stakeholder |
|---|---|
| A | Kevin Cuccaro, DO *[Submitted November 11, 2016]* |
| B | Ariel Majjhoo, MD *[Submitted November 11, 2016]* |
| C | Eric Shoemaker, DO *[Submitted November 11, 2016]* |
| D | Daniel R. Faber, MD *[Submitted November 11, 2016]* |
| E | Deepak Sreedharan, MD *[Submitted November 11, 2016]* |
| F | Beth Jackson, PA-C *[Submitted November 11, 2016]* |
| G | Michael Horner *[Submitted November 11, 2016]* |
| H | Alok Gopal, MD, DABMA *[Submitted November 12, 2016]* |
| I | Craig Carmichael MD *[Submitted November 13, 2016]* |

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|---|---|
| J | Douglas P. Beall, MD *[Submitted November 13, 2016]* |
| K | Vipul Mangal, MD and Ketan Patel, MD *[Submitted November 15, 2016]* |
| L | Gaurav Bhatia, MD *[Submitted November 15, 2016]* |
| M | Ahsan Usmani, MD *[Submitted November 15, 2016]* |
| N | Costa G. Soteropoulos, MD *[Submitted November 17, 2016]* |
| O | Bennett Garner, MD, MSHA, on behalf of FamilyCare *[Submitted November 17, 2016]* |
| P | Virgil Balint, MD *[Submitted November 20, 2016]* |
| Q | Daniel Albrecht, MD, FABPMR, FABEM *[Submitted November 23, 2016]* |
| R | Kim Evans-Allen *[Submitted November 27, 2016]* |
| S | Gary Bennett, MD, on behalf of Chapman Global Medical Center *[Submitted November 27, 2016]* |
| T | Jeffrey A. Katz, MD *[Submitted November 28, 2016]* |
| U | Jeffrey Rosenberg, MD, PhD and Fawad Rizvi, DO, on behalf of Prizm Pain Specialists *[Submitted November 29, 2016]* |
| V | Shawn M. Sills, MD *[Submitted November 29, 2016]* |
| W | YiJia Chu, MD *[Submitted November 30, 2016]* |
| X | Rudy Malayil, MD, on behalf of St. Marys Pain Relief Center *[Submitted November 30, 2016]* |
| Y | Joseph E. Mouhanna, MD, on behalf of the American Society of Interventional Pain Physicians *[Submitted December 3, 2016]* |
| Z | Joseph F. Jasper, MD *[Submitted December 4, 2016]* |
| AA | T. Kindl, MD *[Submitted December 5, 2016]* |
| BB | Premier Pain Centers: similar letters submitted by Sean Li, MD, Michael O'Hara, DO, Carmen M. Quiñones, MD, Peter S. Staats, MD, and Kulbir S. Walia, MD *[Submitted December 5, 2016]* |
| CC | Theodore A. Manos, MD *[Submitted December 5, 2016]* |
| DD | Ajit Shrestha, MD *[Submitted December 5, 2016]* |
| EE | Ashley Walton, JD, on behalf of the American Society of Anesthesiologists, American Society of Regional Anesthesia and Pain Medicine, and Oregon Society of Anesthesiologists *[Submitted December 5, 2016]* |
| FF | David A. Williams, PhD, on behalf of the American Pain Society *[Submitted December 6, 2016]* |
| GG | Robert D. Heros, MD, and Jason G. Anderson, DO *[Submitted December 6, 2016]* |
| HH | Laura Pinault, MD *[Submitted December 7, 2016]* |

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|---|---|
| II | Jennifer McNelis Pusey, RN *[Submitted December 7, 2016]* |
| JJ | Tiffany S. Kon, on behalf of Oregon Health & Science University Comprehensive Pain Management Center *[Submitted December 7, 2016]* |
| KK | Tanith Graham, MD *[Submitted December 7, 2016]* |
| LL | Tina Foss, MHA *[Submitted December 7, 2016]* |
| MM | Lisa Whitmore RN, NP-BC *[Submitted December 7, 2016]* |
| NN | Tammy Carpenter, MD *[Submitted December 7, 2016]* |
| OO | Tom Kern, PhD *[Submitted December 7, 2016]* |
| PP | Jeremy Hansen, MD *[Submitted December 7, 2016]* |
| QQ | Jaimy Patton, MD *[Submitted December 7, 2016]* |
| RR | R. Paul Tostenrud, MD *[Submitted December 7, 2016]* |
| SS | Bryant Santos MD *[Submitted December 7, 2016]* |
| TT | Brian Marlowe *[Submitted December 7, 2016]* |
| UU | Jeffrey F Croy, MD *[Submitted December 7, 2016]* |
| VV | Jennifer Hessick, LMT *[Submitted December 7, 2016]* |
| WW | Brett R. Stacey, MD *[Submitted December 7, 2016]* |
| XX | Catriona Buist, PsyD *[Submitted December 7, 2016]* |
| YY | Mandi Rae Bryson, RMA *[Submitted December 7, 2016]* |
| ZZ | Charlene Carney, RT *[Submitted December 7, 2016]* |
| AAA | Jack E. Berndt, MD *[Submitted December 7, 2016]* |
| BBB | J. Brian Liddy, MD *[Submitted December 7, 2016]* |
| CCC | Julio A. Gonzalez-Sotomayor, MD *[Submitted December 7, 2016]* |
| DDD | Winston Chang, MD, PhD *[Submitted December 7, 2016]* |
| EEE | Paul Greaves, MD *[Submitted December 7, 2016]* |
| FFF | Carmen L. Maymi, MD *[Submitted December 7, 2016]* |
| GGG | Remigio A. Roque, MD *[Submitted December 7, 2016]* |

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|---|---|
| HHH | Ramon Larios, MD *[Submitted December 7, 2016]* |
| III | Dean Laochamroonvorapongse, MD, MPH *[Submitted December 7, 2016]* |
| JJJ | Brandi Hanson *[Submitted December 7, 2016]* |
| KKK | Anabel Lara, CMA *[Submitted December 7, 2016]* |
| LLL | Wendy Young *[Submitted December 7, 2016]* |
| MMM | Jessica Smith *[Submitted December 7, 2016]* |
| NNN | Jim Carson, PhD *[Submitted December 7, 2016]* |
| OOO | Norman A. Cohen, MD *[Submitted December 7, 2016]* |
| PPP | Andrea Johnson, DO *[Submitted December 7, 2016]* |
| QQQ | Belinda Duszynski, on behalf of American Academy of Pain Medicine, American Academy of Physical Medicine and Rehabilitation, American College of Radiology, American Society of Anesthesiologists, American Society of Neuroradiology, American Society of Regional Anesthesia and Pain Medicine, American Society of Spine Radiology, North American Neuromodulation Society, North American Spine Society, Society of Interventional Radiology, Spine Intervention Society *[Submitted December 8, 2016]* |
| RRR | Laxmaiah Manchikanti, MD, on behalf of the American Society of Interventional Pain Physicians, Oregon Society of Interventional Pain Physicians, and the other 50 state and Puerto Rico interventional pain physician societies *[Submitted December 8, 2016]* |
| SSS | Yunlong Ong, MSN, ACNP-BC *[Submitted December 8, 2016]* |
| TTT | Jordan Johnson, MD *[Submitted December 8, 2016]* |
| UUU | Ramay Lewis-Dansby *[Submitted December 8, 2016]* |
| VVV | Bart Bruns, MD *[Submitted December 8, 2016]* |
| WWW | Chris D. Skagen, JD, MELP, on behalf of the Oregon Ambulatory Surgery Association *[Submitted December 8, 2016]* |
| XXX | Kate Ropp, MD *[Submitted December 8, 2016]* |
| YYY | Jeffrey R. Kirsch, MD *[Submitted December 8, 2016]* |
| ZZZ | James S. Hicks, MD, MMM *[Submitted December 8, 2016]* |
| AAAA | Mark Gilbert, MD *[Submitted December 8, 2016]* |
| BBBB | Joanne Jene, MD *[Submitted December 8, 2016]* |
| CCCC | Kim Mauer, MD *[Submitted December 8, 2016]* |
| DDDD | Jennifer Gonzalez Birk *[Submitted December 8, 2016]* |

| | |
|---|---|
| EEEE | Sandy Christiansen, MD *[Submitted December 8, 2016]* |
| FFFF | Margaret Allen, MD *[Submitted December 8, 2016]* |
| GGGG | Amanda R. St. John, DNP, FNP-C *[Submitted December 8, 2016]* |
| HHHH | Brian Mitchell, MD *[Submitted December 8, 2016]* |
| IIII | Chidi Ani, MD *[Submitted December 8, 2016]* |
| JJJJ | Carla De Martino *[Submitted December 8, 2016]* |
| KKKK | Christopher E. Swide, MD *[Submitted December 8, 2016]* |
| LLLL | Jordan Graeme MS DC *[Submitted December 8, 2016]* |
| MMMM | Deven Karvelas, MD, Jerod Cottrill, DO, John Kafrouni, MD, and Matt Gambee, MD *[Submitted December 9, 2016]* |
| NNNN | Michael Su, MD *[Submitted December 9, 2016]* |

## Public Comments

| ID/# | Comment | Disposition |
|---|---|---|
| A1 | As a fellowship trained interventional pain physician, I applaud OHA's draft coverage guidance to eliminate coverage for epidural, facet joint, medial branch, and sacroiliac joint injections.<br><br>The “experiment” that was “interventional pain medicine” has run its course and demonstrated NO sustained functional or subjective improvements for our patients.<br><br>Instead, we've found a proliferation of highly-reimbursed specialists profiteering by continuing and advocating for failed therapies.<br><br>In addition, we as pain specialists, continue to push risky interventional modalities that subject our patients to both direct and indirect harms.<br><br>It's time that these harmful therapies are NOT reimbursed by third-party payors and funds redirected towards therapies that do not promote organic pain beliefs (associated with worse outcomes), passive coping style (associated with worse outcomes) and lowered patient pain self-efficacy (associated with worst | *Thank you for your comments.* |

| ID/# | Comment | Disposition |
|---|---|---|
| | outcomes) as interventional modalities do.<br><br>Please stand firm in your decision even in the face of what will likely be a well-funded campaign to promote profits over patient well-being. | |
| B1 | I just received an email from SIS stating that HERC is recommending stopping coverage for many of the minimally invasive spinal injections we perform. I find this very disturbing. My practice's platform are ESIs, facet/RFA, SI, etc. based on individual patient's etiology. These are not for everyone but many patients find them extremely helpful in reducing pain. Countless patients say physical therapy makes the pain worse, Motrin doesn't do anything (or can't take BC of heart issues or GI issues) and procedures are the only thing that keeps them going allowing them to stay active and improving their quality of life. Countless patients.<br><br>I'm not a believer in lots of opioids, and in today's society we are looked at badly when prescribing any ways. Many patients themselves don't want to take opioids BC of the fear of addiction.<br><br>So how am supposed to treat their pain? Surgery? Of course you should know that is more costly and many times not helpful or makes things worse. Spinal cord stimulation? I don't mind doing that and I usually bring it up in conversation with patients especially for those that are getting procedures 3-4 times per but if you are getting an epidural once per year or like a patient I had this week whose first and only ESI was 4/2014, and just returned for a second it's hard to justify a SCS implant.<br><br>I think definitely there are bad doctors out there that over bill and over perform these procedures for patients and that may also lead to poor outcomes.<br><br>I think what you should first recommend is that you will get a reduced reimbursement and then eventually no reimbursement if doctors are not board certified in pain management or a step further if you did complete an ACGME | *Thank you for your comments.*<br><br>*The evidence review did not show that steroid injection therapies reduce the use of opioid pain medications or the long-term likelihood that a patient will undergo surgery to treat back pain.*<br><br>*Other interventions for the treatment of low back pain have been reviewed separately in other coverage guidances.* |

| ID/# | Comment | Disposition |
|---|---|---|
| | accredited pain management fellowship. A lot of the "shady" behaviors and poor outcomes are coming from these doctors who have no business practicing pain management. | |
| C1 | I am writing to express my grave disappointment in the decision by the Oregon Health Authority to eliminate coverage for steroid injections for spine pain. I see these procedures help people every day to relieve their pain and facilitate and engage them in active rehabilitation. If this coverage is eliminated more and more people will be left to stagnate on opiate pain medication, resulting in decreased productivity and increased opiate dependence. | *Thank you for your comments.*<br>*The evidence review did not show that steroid injection therapies reduce the use of opioid pain medications.* |
| C2 | I recognize there are studies out there that seem to demonstrate that these procedures are not helpful. This is because these studies fail to select patients who have the correct diagnosis and pathology to support the studied procedure. Nonspecific study designs yield nonspecific and often negative results. Quality studies have been done and show clear efficacy. | *Many of the trials included in the AHRQ report relied on rigorous patient selection criteria. The authors of the AHRQ report also considered whether patient characteristics influence the likelihood of a successful injection; they concluded that there was "insufficient evidence to determine whether the cause of radicular symptoms, duration of symptoms, imaging findings, or other patient factors" influenced patient outcomes from injection therapies.* |
| C3 | The people who want to save money push forward the negative studies as justification. Do not be fooled. This will be very bad for patients and the healthcare system. I am asking you to consider resuming coverage for epidural, facet joint and sacroiliac corticosteroid injections. | *Thank you for your comments.* |
| D1 | I have reviewed the draft coverage guidelines proposed for certain steroid injections. I am a full-time interventional pain practitioner for 20 years, and have developed a firm understanding of many interventions. Experience with many thousands of patients has taught me: | *Thank you for your comments. The use of diagnostic injections or other procedures (SI joint fusion, radiofrequency denervation) are beyond the scope of this coverage guidance.* |

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| | 1. All of these interventions can benefit some patients for extended periods of time, although there is not always a large number of patients who benefit.<br>2. Sacroiliac joint steroid injections do not benefit a large number of patients. A few do really well with them. Those who don't can benefit from new fusion techniques. Local anesthetic injections should still be covered as a diagnostic procedure.<br>3. Medial branch block steroid injections do not benefit a large number of patients. If used in conjunction with radiofrequency, medial branch local anesthetic blocks DO result in a high rate of excellent patient benefit.<br>4. Epidural steroid injections for radicular pain DO result in a large benefit for patients. I have now hundreds of patients who maintain their overall function by receiving these injections 2-3 times per year. These patients do so well that they threaten me that I should not retire until they are dead. | |
| D2 | I am surprised that the draft makes a STRONG recommendation based on WEAK to MODERATE published evidence.<br><br>Bad Science:<br><br>Many of the studies were done by people using inadequate techniques. For example, some studies use lidocaine without steroids and then claim that this is a placebo. This is simply wrong. Lidocaine has known anti-inflammatory properties. There is evidence that simply irrigating the epidural space with any liquid also provides significant benefit, so no injection that actually puts liquid in the epidural space can be considered a true placebo treatment. Not only is the published evidence of weak or moderate level, the actual studies are often simply bad science. For your purposes, the real evidence needs to come from a study that compares epidural steroid injections with the other treatments that the draft | *The evidence review acknowledges that the evidence for the included outcomes ranges from insufficient to moderate confidence; the strength of recommendation is based not only on the confidence in the evidence, but also on resource allocation, values and preferences, and other considerations.*<br>*The purpose of this evidence review was to determine whether injection of corticosteroids into the lumbar epidural space, the facet joint, or the SI joint improved the outcomes listed in the scope statement. Indeed, injection of local anesthetics (and other substances) are included comparators in the scope statement. Trials comparing local anesthetics to local anesthetics plus corticosteroids* |

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| | claims are available, not a pretended sham injection that has real medical benefit all by itself. | *are thus helpful in determining the comparative effectiveness of corticosteroid injections. The authors of the AHRQ report have previously responded to this criticism: "[A]s described in the Results, there were no clear differences between local anesthetic injection, saline injection, or non-epidural injection as control interventions; therefore we think it is appropriate to classify all of these as placebo interventions."* |
| D3 | I am sympathetic to the cost involved with these procedures. I would propose that Oregon can save much more money looking at the evidence (or lack thereof) for chronic opioid use in pain patients. That's where bigger utilization costs are. | *Thank you for your comments.* |
| E1 | I think it is heartless to deny patients access to one of the few therapeutic options we have available as clinicians to alleviate pain and help patients recover from injury. When a patient has chronic pain the best remedy is exercise, pacing and coping with the pain. However, for most patients it is nearly impossible to initiate an exercise program when they are in pain. In the least, Oregon should allow access to steroid injections to facilitate the early adoption of exercise. Without this, patients will only fall back on opioid consumption obtained through legal or illegal means. | *Thank you for your comments.*<br>*The evidence review did not show that steroid injection therapies reduce the use of opioid pain medications.* |
| F1 | I am writing as a health care provider to urge you to reconsider your recommendations regarding "epidural, facet joint, medial branch, and sacroiliac joint corticosteroid injections." As a provider in the field of comprehensive spine care, these injections serve a vital role in our treatment of low back pain. While most diagnosis treated with an epidural injection are well treated with surgery, the diagnosis treated by facet injections, medial branch blocks, sacroiliac joint injections are not as well treated with surgery. Limiting coverage will leave patients with very few options to treat their low back pain. Several injections listed above provide diagnostic value and aid our clinical decision making. Also, surgical | *Thank you for your comments.*<br>*Diagnostic injections with local anesthetics are outside the scope of this evidence review and coverage guidance.* |

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| | interventions for several causes of low back pain are not very successful therefore a nonsurgical option is a great option for the patient.<br><br>By limiting our ability to offer safe alternatives to our patients, you are leaving us with very few treatment options. Please reconsider your recommendation on "epidural, facet joint, medial branch, and sacroiliac joint corticosteroid injections." | |
| G1 | It troubles me greatly as both a physician and a patient that the Health Evidence Review Commission (HERC) would propose such a drastic recommendation to no longer cover spinal injections. These are a necessary and invaluable tool to control all types of spine related pain. Often these are the one thing keeping people from more invasive surgical interventions, being gainfully employed, and off of or limited chronic opioid medications. Would HERC prefer the later? More surgery, more missed work, and more opioids? Please strongly consider the very real negative ramifications of following through with such an all encompassing and devastating proposal for patients. | *Thank you for your comments.*<br><br>*The evidence review did not show that steroid injection therapies improve long-term function or reduce the use of opioid pain medications or the long-term likelihood that a patient will undergo surgery to treat back pain.* |
| H1 | Having practiced medicine for 15 years -- I have been able to save thousands of dollars and patients from the surgical options --<br><br>What is not understood is saying PT does not cure low back pain -- there is no study to confirm that PT will cure back pain -- but no one mentions to ban this -- AS IT IS A MULTIMODAL approach to get rid of pain -- doing injections lets patients get back to doing PT/exercises and this is the role we as intervention physicians play.<br><br>You can achieve this with chiropractor treatments for 4 - 6 months /acupuncture session ( I am also board certified in acupuncture) -- which would take at least 10-15 sessions -- rather than 2-3 injections to get rid of the pain to get them to PT.<br><br>Also steroids may help with SI disease -- yes I agree for facets we only use as diagnostic purpose -- so we should be allowed diagnostic local anesthetic injection | *Thank you for your comments.* |

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| | on facet followed by RF ablation as there may no need for steroid in facets.<br><br>Thanking you in anticipation.<br><br>Hope you can save money for your state and the country by not restricting the correct care. | |
| I1 | I am a Mayo-trained interventional spine physician who has been in private practice for 16 years. I chose to train in interventional spine injections because as a rehab physician at Mayo Clinic I found that the other treatments such as physical therapy that I was prescribing were not satisfying the patients, but when they returned from spine injections they were very happy with their injections and did well over the short and long-term. It was after that realization that I elected to train in interventional spine procedures, and have had a very successful 16 years in helping patients recover and avoid surgery. Every day I see patients in severe pain whose pain is dramatically improved or eliminated through the use of steroid spine injections. Over the long-term, patients do better if they can recover with just spine injections as compared to their long-term outlook with surgery.<br><br>There are no other good alternative treatments. There is no research that shows that physical therapy is very helpful for back pain or radiculopathy and in my clinical experience I find it very expensive and low yield. The same can be said for chiropractic care and oral medications. Oral medications, particularly opioid-narcotics have serious side effects. I have no doubt that the elimination of steroid spine injections will cause immeasurable suffering.<br><br>Please reconsider your position on coverage of corticosteroid spine injections. If you are treating these patients on a daily basis as I do then there would be no question in your mind as to their importance and effectiveness. | *Thank you for your comments.*<br><br>*The evidence review did not show that steroid injection therapies improve long-term function or reduce the use of opioid pain medications or the long-term likelihood that a patient will undergo surgery to treat back pain.* |
| J1 | On November 8, 2016, your HERC issued draft coverage recommendations strongly recommending against coverage for epidural, facet joint, medial branch, | *Thank you for your comments.* |

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| | and sacroiliac joint corticosteroid injections for low back pain regardless of etiology. This flies in the face of the demonstrated effectiveness of these injection and is not good for patient care. Below is a summary of the safety and effectiveness of epidural steroid injections written by experts to illustrate the utility of these injections. In consideration of this effectiveness the OHA should reconsider their provisional decision as this has the potential to have a significant and adverse impact on those patients suffering from low back discomfort. | |
| J2 | **Safety of Epidural Steroid Injections**<br><br>While complications with epidural steroid injections (ESIs) have been reported, and are likely underreported, serious complications are limited to isolated case reports. This is despite the large number of injections performed annually.[1] No serious neurological complications have ever been reported in any prospective study of ESIs, regardless of approach or technique used, or anatomical area injected. A recently completed multi-institutional cohort of over 16,000 consecutive ESI procedures at all spine segments also reported no major complications.[2,3,4]<br><br>*Particulate and Non-Particulate Steroids*<br><br>Though rare, neurological complications are catastrophic and include stroke, blindness, paralysis, and death. These adverse events likely result from inadvertent injection of a radicular or vertebral artery that perfuses the spinal cord and brain. In all reported cases, particulate steroids have been used, and the mechanism of injury is presumed to be embolism of these particulates resulting in infarction. Light microscopy studies have demonstrated that the particles in these steroid preparations are either larger than red blood cells or form aggregates larger than red blood cells.[5] Additionally, animal studies have shown central nervous system infarction with intra-arterial injection of particulate steroids.[6] | *The evidence review concluded that corticosteroid injection therapies are associated with few harms or serious adverse events, but also noted that reporting of harms was sparse and inconsistent in the trials.*<br><br>*With respect to the type of steroid used, the authors of the AHRQ review stated, "four trials that directly compared epidural corticosteroid injections for radiculopathy with different corticosteroids found few differences in outcomes including pain and function, but conclusions were limited by differences in the corticosteroids compared, doses, and some inconsistency."*<br><br>*The evidence review did not show that steroid injection therapies improve long-term function or reduce the use of opioid or other analgesic medications or the long-term likelihood that a patient will undergo surgery to treat back pain.* |

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| | This is in contrast to dexamethasone, which has particles 5 to 10 times smaller than red blood cells on microscopic evaluation, and is effectively non-particulate in this context. Dexamethasone has been shown to have no adverse sequelae with direct injection into the arterial supply of the neuroaxis in animals.[5,6] Non-particulate steroids have been routinely administered via the transforaminal epidural technical approach without a single report of a serious neurologic adverse event to date. It is logical to conclude that increased utilization of this medication will lead to decreased complication rates associated with these procedures. However, use of dexamethasone has not been universally adopted due to the fact that most published studies demonstrating the effectiveness of transforaminal injection of steroid (TFIS) have utilized particulate steroids. However, recent high quality studies have demonstrated the non-inferiority of dexamethasone to the most commonly injected particulate corticosteroid, triamcinolone acetate,[7,8] which should further increase its utilization. Given that the risk of neurologic injury may be eliminated with the use of a non-particulate steroid, dexamethasone should be considered the preferred first-line medication option. This recommendation is consistent with the FDA Safe Use Initiative's recommendations for safe injection practices which have been submitted for publication. Based on these data, and further supported by the consensus of experts representing fourteen different specialty societies, we feel non-particulate steroids should be excluded from any FDA action as they have a robust safety profile.<br><br>*Comparison to Alternative Treatments for Back Pain*<br><br>For further comparison, the rates of serious complications from alternative treatments for spine pathology are significantly higher. There are over 100 opioid related deaths in the United States every day (>35,000 per year).[9] More than 103,000 individuals are hospitalized annually in the United States for NSAID-related serious GI complications, with 16,500 NSAID-related deaths occurring each | |

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| | year in the United States among patients with rheumatoid arthritis and osteoarthritis.[10] Significantly, spinal surgery has been shown to have a much higher incidence of complications than any type of epidural injection, regardless of steroid utilized.[11] Based on these data, we request that the FDA warning be modified to reflect the extremely low risk involved with lumbar ESI in comparison to significantly higher risks of alternative treatment option such as opioids and NSAIDs. | |
| J3 | **Effectiveness of Epidural Steroid Injections**<br><br>The second area of concern with the FDA statement is the misleading sentiment that the effectiveness of ESIs has not been determined. While there is always room for more research, there is ample evidence demonstrating the effectiveness of ESIs in reducing and eliminating pain, improving function, decreasing reliance on opioids, and eliminating the need for surgery for many patients.[12]<br><br>*Particulate and Non-Particulate Steroids*<br><br>Multiple high quality studies have demonstrated efficacy of ESIs when performed on patients with appropriate indications. A double blind randomized controlled trial (RCT) by Riew et al. investigated the effect of TFIS on avoidance of surgery for lumbar radicular pain.[13] Only 29% of patients who were treated with transforaminal injection of betamethasone and bupivacaine required surgery during the 13-28 month post-procedure follow-up time period compared with 66% of those who received transforaminal injection of bupivacaine alone ($P < 0.004$). Another RCT found that after an average follow-up period of 1.4 years, the patients receiving TFIS had an 84% success rate compared to only 48% for the group receiving deep lumbar paraspinal muscle injection with saline ($P < 0.005$).[14] The most scientifically rigorous double blind RCT compared the efficacy of TFIS with transforaminal injection of local anaesthetic, transforaminal injection of | *With respect to the type of steroid used, the authors of the AHRQ review stated, "four trials that directly compared epidural corticosteroid injections for radiculopathy with different corticosteroids found few differences in outcomes including pain and function, but conclusions were limited by differences in the corticosteroids compared, doses, and some inconsistency."*<br><br>*Many of the trials included in the AHRQ report relied on rigorous patient selection criteria. The authors of the AHRQ report also considered whether patient characteristics influence the likelihood of a successful injection; they concluded that there was "insufficient evidence to determine whether the cause of radicular symptoms, duration of symptoms, imaging findings, or other patient factors" influenced patient outcomes from injection therapies.*<br><br>*The authors of the AHRQ review noted that there were no trials that directly compared image-guided epidural steroid injections to non-image-guided injections. They* |

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| | saline, intramuscular steroids, or intramuscular saline for the treatment of lumbar radicular pain.[15] The authors found that success rates for providing at least 50% pain relief from the various control treatments were statistically indistinguishable at 15% (95% CI +/- 7%) while 54% (+/- 18%) of patients who received TFIS achieved a successful outcome both at 1- month and at 12- month follow-up. Collectively these studies have led to recent systematic reviews[16,17] with meta-analyses that have summarized the large volume of research on this topic. Up to 70% of patients achieve 50% pain relief for 1-2 months; 30% achieve complete pain relief.[17] For patients with disc herniations, up to 70% may achieve 50% pain relief for six months.[7] Pain relief is accompanied by functional recovery and reduced reliance on other health care resources.[7,17,18] *(Comment truncated because it exceeded the 1,000 word limit)* | *concluded that there is insufficient evidence that imaging guidance influences the effectiveness of these procedures.*<br><br>*With respect to the use of categorical as opposed to continuous outcomes, the authors of the AHRQ review stated that, "[A]s presented in the results, analyses on both continuous and dichotomous outcomes were presented. If anything, results using dichotomous outcomes (likelihood of experiencing a clinically meaningful benefit) showed less evidence of effectiveness than analyses based on continuous outcomes (mean change in pain or function scores)." Furthermore, the use of composite categorical outcomes that include a mix of pain relief and functional outcomes would be beyond the scope of the outcomes selected for this coverage guidance.* |
| K1 | We would like to comment on the actions made by Oregon Health Authority in eliminating coverage for epidural steroid, facet, and sacroiliac injections. We at the society feel that it is unjust and see the potential devastating consequences. We treat epidural steroid injections as an adjunct and as part of a multimodal therapy to treat our patients. | *Thank you for your comments.* |
| K2 | There is significant amount of evidence that an epidural steroid injection can help radicular pain and that in combination of physical therapy, can be just as effective as certain spine surgeries. The literature review that was performed was unfortunately limited by the fundamental flaw of meta-analysis. That is that the power of the included studies does not allow for any reasonable conclusion to be made. | *Thank you for your comments. We believe that meta-analysis was appropriate and that the limitations of the individual studies are reflected in the authors' assessment of the strength of evidence.* |

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| K3 | It strikes it as draconian to cut the coverage of many of these procedures that allow individuals to return to work earlier and have improved functionality. Eliminating epidural steroid injections will potentially significantly increase the amount of NSAID and oral opioid consumption, and spine surgeries patients will be subject to and most likely will cause undue burden of patient. This is a particular and important concern given the current considerations regarding opioids. Let us make it clear that you will definitively see a rise in the amount of opioids and the amount of spine surgeries performed as the reality is that most citizens of this country are not patient individuals.<br><br>We do recommend clear documentation of benefits from injections for a patient and having them performed on appropriate patients. Denying them all together seems very inappropriate. Oral opioid consumption is a major epidemic in our country, and this will most likely make the situation worse. Rather than have some absurd recommendations, it is our request that any draconian cuts are postponed until further data proving the safety and efficacy of the procedures can be performed. However, let us be clear, by eliminating these procedures, you will not only prevent your citizens from having appropriate care, but further worsen the situation by driving them towards opioid medications and surgery.<br><br>In behalf of DC, MD, VA Pain society, we urge to repeal the action of the Oregon Health Authority. | *Thank you for your comments.* |
| L1 | I would like to comment on the actions made by Oregon Health Authority in eliminating coverage for epidural steroid, facet, and sacroiliac injections.<br><br>This truly undermines the benefit that thousands of patients receive on daily basis in our country and worldwide who are suffering from an acute episode of low back and neck pain.<br><br>Taking them out of practice will most definitely result in unnecessary surgeries for | *Thank you for your comments.*<br><br>*The evidence review did not show that steroid injection therapies improve long-term function or reduce the use of opioid or other analgesic medications or the long-term likelihood that a patient will undergo surgery to treat back pain.* |

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| | low back and neck, not to mention, more prescribing practice of opioid analgesics to seek comfort.<br><br>In addition, it will also burden society with people missing work and contributing to disability and unemployment. | |
| L2 | Epidural steroid injections is an adjunct and as part of a multimodal therapy to treat our patients. There is significant amount of evidence that an epidural steroid injection can help radicular pain and that in combination of physical therapy, can be just as effective as certain spine surgeries. The literature review that was performed was unfortunately limited by the fundamental flaw of meta-analysis. That is that the power of the included studies does not allow for any reasonable conclusion to be made. | *Thank you for your comments.*<br><br>*We believe that meta-analysis was appropriate and that the limitations of the individual studies are reflected in the authors' assessment of the strength of evidence.* |
| L3 | It strikes it as draconian to cut the coverage of many of these procedures that allow individuals to return to work earlier and have improved functionality. Eliminating epidural steroid injections will potentially significantly increase the amount of NSAID and oral opioid consumption, and spine surgeries patients will be subject to and most likely will cause undue burden of patient. This is a particular and important concern given the current considerations regarding opioids.<br><br>I recommend clear documentation of benefits from injections for a patient and having them performed on appropriate patients. Denying them all together seems very inappropriate. Oral opioid consumption is a major epidemic in our country, and this will most likely make the situation worse. Rather than have some absurd recommendations, it is our request that any draconian cuts are postponed until further data proving the safety and efficacy of the procedures can be performed. However, let us be clear, by eliminating these procedures, you will not only prevent your citizens from having appropriate care, but further worsen the | *Thank you for your comments.*<br><br>*The evidence review did not show that steroid injection therapies improve long-term function or reduce the use of opioid or other analgesic medications or the long-term likelihood that a patient will undergo surgery to treat back pain.* |

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| | situation by driving them towards opioid medications and surgery.<br><br>I strongly urge you to repeal the action of Oregon Health Authority. | |
| M1 | Many patients with chronic neck and lower back pain benefit from epidural steroid and facet injections. They are safe and help patients function better and decrease reliance on pain medications. I strongly urge State of Oregon to reverse their decision on corticosteroid spinal injections. | *Thank you for your comments.* |
| N1 | As an Interventional Pain provider in Virginia now for nearly 7-years I am deeply disturbed about the Oregon Health Authority's decision to eliminate coverage of epidural steroid injections and various other interventional pain techniques. Not only do these procedures provide tremendous relief to millions of patients in both acute and chronic pain worldwide but are an essential adjunctive treatment to holistic pain management. In an age where our country is being ravaged by the worst opioid epidemic we have ever seen how could anyone even consider eliminating coverage for the one tool interventional pain providers have to stave off this horrid epidemic. More patients in Oregon will be needlessly narcotized by excessive opioid prescribing as well as unnecessary spinal surgeries. The cost for interventional pain therapy combined with reasonable opioid and non-opioid management as opposed to opioid management along with unnecessary has been studied extensively in multiple pain and various other medical publications and the results are conclusive that non-surgical (interventional) management along with reasonable opioid support is far more cost effective. I ask you to consider these facts and the devastation you will cause countless pain patients in your state with this short sighted thinking and draconian cuts you are about to make. | *Thank you for your comments.*<br><br>*The evidence review did not show that steroid injection therapies improve long-term function or reduce the use of opioid or other analgesic medications or the long-term likelihood that a patient will undergo surgery to treat back pain.* |
| O1 | FamilyCare's understanding of the evidence regarding the efficacy of epidural steroid injections comports with the HERC's position. We thus continue to support HERC's position and would suggest no change to the current Guideline Note. | *Thank you for your comments.* |

# HERC Coverage Guidance: Low Back Pain - Corticosteroid Injections
## Disposition of Public Comments

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| P1 | I have recently learned about the Oregon state's decision not to cover any spine injections for their residents and I am at a loss understand what prompted this measure. The epidural injections have been in existence since 1901 and they served numerous patients ever since. There are numerous high quality studies that shows that these injections are very effective in preventing back surgeries. As a matter of fact the standard of care is to do epidural injections before recommending any spine surgery. The decision not to cover these injections will push the patients towards expensive surgery and narcotic medications. My impression is that this is just another cost cutting decision that will affect the poorest and less fortunate residents of Oregon. | *Thank you for your comments.*<br><br>*The evidence review did not show that steroid injection therapies decrease the long-term likelihood that a patient will undergo surgery to treat back pain.* |
| Q1 | I am appalled at the review of the literature by HERC resulting in the desire to eliminate coverage for all spinal injection procedures. In terms of the lumbar epidural steroid injections to be done, there are two issues at play. The first is for epidural steroid injections for axial low back pain. The second is epidural steroid injections for lumbar radicular pain, which is pain traveling down one or both legs in a dermatomal pattern. This is a major distinction between indications for epidural steroid injection. Epidural steroid injections for axial low back pain can be controversial. There is anecdotal evidence of certain situations where it can be beneficial. However, with regards to radicular pain, there is a substantial benefit in favor of epidural steroid injection. The main indication for epidural steroid injection is for radicular pain. The decision to eliminate all epidural steroid injections for all reasons should not be done. I understand if there is to be made a distinction between doing the steroid injection for low back pain versus radicular pain. | *Thanks you for your comments. The authors of the AHRQ review performed separate analyses to examine differences in the effectiveness of steroid injections for axial low back pain and lumbar radicular pain. Those groups are discussed individually in the AHRQ review and the summary of the evidence provided to the subcommittee.* |
| Q2 | In terms of an algorithm for treating axial low back pain, it is erroneous to equate intra-articular facet steroid injection with medial branch block followed by radiofrequency neurotomy. There is an apparent lack of understanding by HERC | *Thank you for your comments.*<br><br>*This coverage guidance only pertains to the use of medial branch block as a therapeutic intervention and reflects its* |

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| | when lumping medial branch block and intra-articular facet injection together and looking at long-term outcomes. This is seen on page 12 of the HERC analysis. Medial branch block is not designed to give long-term relief. It is meant to be a diagnostic procedure to determine who would benefit from lumbar radiofrequency neurotomy. Radiofrequency neurotomy is not being discussed in this policy that is open for public comment, so I will save my thoughts for HERC about this procedure for another time. However, briefly, it can result in 100% pain relief and restoration of function for many months, something that no other treatment for chronic low back pain can offer. | *inclusion in the AHRQ review. The use of blocks as diagnostic procedures is beyond the scope of this guidance. Facet joint radiofrequency neurotomy is also beyond the scope of this coverage guidance.* |
| Q3 | Next, I would like to outline how the HERC policy would be a far outlier in terms of standard of care. HERC has summarized other policy coverages for commercial payers, Medicare, and the Washington Medicaid system. All of these other payers allow for various types of injections to be performed. Furthermore, the HERC policy would go against all of the professional society guidelines which they cite. | *Thank you for your comments. The coverage guidance summarizes the policies of select payers along with relevant professional guidelines as a part of the policy landscape, but bases coverage recommendations on the GRADE domains.* |
| Q4 | Lastly, I would like to address the concern regarding the FDA safety announcement. The catastrophic risks associated with epidural steroid injections have only occurred with particulate steroid injections. There have been no adverse events that have occurred with use of non-particulate steroids. It would be quite unfortunate to eliminate all epidural steroid injections from a safety standpoint based on the statement made by the FDA. It would be reasonable to continue to allow epidural steroid injections if not particulate steroids are used. One other category of catastrophic events has to do with infections as a result of epidural steroid injections. A large number of the cases of infections have been as a result of using a compounded steroid that was made in a facility that did not have a sterile environment for making the steroid. It would be reasonable to require the use of steroids from a company who does not compound the steroid formulation. | *Thank you for your comments. The coverage guidance concludes that adverse events with steroid injection therapies are rare, but may be underreported. The inclusion of FDA safety information was deemed pertinent to the deliberations of the committee.* |
| Q5 | If you have any questions or would like to discuss things further, please do not | *Thank you for your comments. A letter from the* |

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| | hesitate to contact me. I am attaching a couple of documents written by one of the societies to which I belong, the Spine Intervention Society, for HERC's review. I am also attaching some journal articles pertaining to epidural steroid injections. Radiofrequency neurotomy should be covered by HERC, but it is outside the scope of the policy being discussed, so I will forego articles about it but I have included a letter by the Spine Intervention Society addressed to Washington. | *Intervention Society to HERC (dated May 11, 2016) and a letter from the International Spine Intervention Society to Washington State Health Technology Committee (dated January 17, 2014) were attached to the submitted comment. With these letters, the submitted comment exceeds the 1,000 word limit. However, the issues highlighted in these letters are addressed elsewhere in this Public Comment Disposition.* |
| R1 | I am concerned about the proposed changes regarding no coverage for steroid injections. First, I am a patient of National Spine & Pain and have received a few steroid injections. It was VERY helpful, and I was completely pain free after the injection. I have Rheumatory Arthritis, Mixed Connective Tissue Disease, and Bursitis in the hip/tail bone. I don't want to take pain medicines. Having these injections that provide quick, extended relief, and not have to take a pain medicine is such a benefit to the patient! I work full time in a very active professional job; therefore the quick recovery is critical.<br><br>Please continue to provide coverage for steroid injections for patients in need! | *Thank you for your comments.* |
| S1 | This letter is written on behalf of the medical staff at Chapman Global Medical Center in Orange, California, in response to the Oregon Health Evidence Review Commission's proposal to eliminate coverage for what appears to be ALL minimally invasive spinal interventional techniques for low back pain. If adopted, this proposal will severely limit access to minimally invasive and cost effective treatments to the millions of patients who suffer with severe disabling pain. | *Thank you for your comments.* |
| S2 | Comment similar to Y2. | *See response to Y2.* |
| T1 | Although I am in full agreement with the letter submitted by the American Society of Interventional Pain Physicians regarding the notable methodological and | *Thank you for your comments.*<br><br>*The subcommittee elected to look at a mix of short- and* |

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| | statistical fallacies in the proposed draft guideline, I do also appreciate Oregon's efforts to curb the overuse of interventional pain procedures in the management of chronic low back pain. Therefore my below comments intend to propose an alternative approach to the challenge of curbing overuse of procedures while maintaining their availability to patients who will benefit.<br><br>First, long term benefits are inappropriate to look at, as the degenerative spine processes being treated continue to worsen regardless of the treatments proposed. Specifically, the draft guidelines note a lack of long term benefit from any of the interventions mentioned but an absence of significant complications. Comparably, opioids used following surgery have demonstrated notable risks (including death), and yet months after the surgery demonstrate no benefit at all. Would the Commission therefore also suggest that patients undergoing surgery receive no opioids postoperatively?<br><br>Second, the draft guidelines incorrectly assume that interventions are a first line treatment and that more conservative options have more data to support them. In fact, conservative options are overwhelmingly used prior to interventions, with interventions appropriately being employed when less invasive approaches (meds, PT, chiropractic) have failed.<br><br>Third, the draft guidelines (and most interventionalists) ignore the diagnostic value of interventions, with the placement of local anesthetic serving to rule in or rule out an anatomic source of pain with subsequent targeted therapy (PT, surgery, etc.).<br><br>Rather than a blanket restriction of all interventions, the Commission should examine those centers/practitioners with high procedure rates relative to the served population. Should evidence be found of clear overuse of procedures and/or a failure to document the diagnostic value of such treatments (e.g., facet rhizotomy performed in the presence of a mere 75% relief from diagnostic blocks, | *long-term outcomes for these procedures.*<br><br>*Although individual trials varied, most only used steroid injection therapies after 4-6 weeks without improvement.*<br><br>*The use of steroid injections as diagnostic procedures is beyond the scope of this coverage guidance.* |

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| | or no PT done prior to interventions, etc.), then those practitioners should no longer be reimbursed by Oregon for performing pain procedures at all. A ban should be imposed on those individuals, as it were. It would encourage proper practice per interventional pain society guidelines, and discourage the indiscriminate (and costly) application of procedures.<br><br>It is time for government agencies to realize that the problems of overuse of treatments in the name of profit rest in a small minority of physicians and practices, and that these individuals should be targeted and not the use of interventional pain procedures as a whole. To do the latter denies patients in pain of effective treatment, and further dooms them to either opioid treatments and addiction or suffering unrelenting pain with no options or hope offered by the state of Oregon. | |
| U1 | On behalf of Prizm Pain Specialists, Drs. Jeffrey Rosenberg and Dr. Fawad Rizvi, we would like to submit our strong opposition to coverage guidance for low back pain, and request that this guidance be withdrawn from consideration immediately to avoid drastic implications regarding access to effective interventional therapies. | *Thank you for your comments.* |
| U2 | Comment similar to Y2. | *See response to Y2.* |
| V1 | I am writing to contest the recommendation to remove coverage for corticosteroid injections for Low Back Pain.<br><br>I believe the recommendation was based largely on the Technology Assessment submitted by Chou, et al. in March 2015. Several key medical societies, including all spine societies that treat low back pain such as Physiatry, Anesthesiology, Neurosurgery, and Radiology submitted a letter on July 29, 2015 outlining the serious flaws on the assessment guiding recommendations to the OHA. As a physician who has been active in critiquing submissions to peer reviewed journals for publication, I feel that the assessment bordered on being unethical. I have | *Thank you for your comments. The letter to the Agency for Healthcare Research and Quality (dated July 29, 2015) was attached to the submitted comment. With the letter, the submitted comment exceeds the 1,000 word limit. However, the Agency for Healthcare Research and Quality addressed this letter's concerns during the public comment phase of the systematic review by Chou and colleagues. The public comment responses from the Chou review have been included in the meeting materials.* |

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| | attached the Multisociety critique letter in this email.<br><br>As an Oregon physician who actively treats spine pain, the removal of corticosteroid injections for Low Back Pain would be a huge disservice to Oregon patients. In a time when we are actively reigning in opiates for treating chronic pain, it is important to have evidenced based medicine backed procedures to offer patients. Societies like the Spine Intervention Society have championed higher quality studies and modern techniques that are effective for our patients. Using modern techniques including image guidance (which was not considered in the Chou Assessment) as well as a categorical approach to data interpretation for assessing appropriate procedures, allow not only therapeutic benefit, but also important diagnostic information for the origin of low back pain. Although important, the other recommended treatments (acupuncture, manipulation, massage, CBT, PT, or even Yoga) have a far less robust literature to support their efficacy often using continuous data interpretation to try to show statistical significance.<br><br>Please don't let reducing costs based on unethical "technology assessments" force our patients with OHP to suffer and go without treatment. I along with many physicians plan to push this issue in the media and bring attention to the terrible consequences of this current recommendation. | |
| W1 | I understand the need for cost containment but I believe this proposal is short-sided and based on extremely flawed and biased data. As we have seen before, the ultimate outcome of eliminating opioid-sparing and surgery-sparing procedures like the ones you are proposing will lead to more patients being on or escalating opioid medications and having unnecessary surgeries, not to mention the increase utilization of emergency rooms for chronic pain patients and worsening of the ongoing opioid epidemic. I strongly urge you reconsider. | *Thank you for your comments.* |

# HERC Coverage Guidance: Low Back Pain - Corticosteroid Injections
## Disposition of Public Comments

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| X1 | On behalf of St. Marys Pain Relief Center, Dr. Rudy Malayil, I would like to submit our strong opposition to coverage guidance for low back pain, and request that this guidance be withdrawn from consideration immediately to avoid drastic implications regarding access to effective interventional therapies.<br><br>I like many other Interventional Pain Specialists see the great benefit that Interventional pain procedures give our patients everyday we are working with our patients. I have patients who travel even three hours just to receive an Interventional treatment to help them live a better quality of life. Your decision in Oregon does not affect me directly but I can't imagine any physician trying to treat a patient's pain conditions without the option of an Interventional modality. Interventions do not help everyone but when an Interventional pain physician evaluates and deems it fit most likely it can help. | *Thank you for your comments.* |
| X2 | Comment similar to Y2. | *See response to Y2.* |
| Y1 | On behalf of the American Society of Interventional Pain Physicians (ASIPP), Oregon Society of Interventional Pain Physicians, and the other 50 state interventional pain physician societies, including Puerto Rico, we would like to submit our strong opposition to coverage guidance for low back pain, and request that this guidance be withdrawn from consideration immediately to avoid drastic implications regarding patients access to effective interventional therapies. | *Thank you for your comments.* |
| Y2 | Consequently, we recommend that the agency withdraw the present recommendation and engage in a proper analysis of the literature, free from intellectual bias or conflict and confluence of interest. This may avoid major issues for patients and the extinction of AHRQ. | *The evidence review that informs this coverage guidance was funded by AHRQ. The research was conducted by experienced systematic reviewers and was subject to both technical expert and peer review. The investigators disclosed no affiliations or financial involvement that conflicts with the material presented in the report. The assertion of intellectual bias or conflict of interest rests on* |

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| | | *an assumption that AHRQ had a pre-supposed conclusion about the effectiveness of injection therapies for low back pain that resulted in pressure to reach certain conclusions. We find no basis to support such a claim.* |
| Z1 | I am deeply concerned that Oregon is about make a serious error in medical coverage for patients with pain by denying coverage of spinal injections. Consider the following:<br>1. There is abundant observational, controlled study, and some meta-analyses demonstrating the efficacy of spinal injection and other interventions for spine related pain problems such as axial and radicular pain.<br>2. The analysis and recommendations of Chou have a significant conflict of interest introduced by funding from the defunct AHRQ.<br>3. The analysis by Chou has some methodology flaws.<br>4. Oregon has previously been ahead of other states in assuring humane treatment of patients in pain. A law suit was successfully filed by an oncology patient denied access to adequate pain management. Death with Dignity via physician assisted suicide was legalized. Medical marijuana was legalized. OHSU has had a pain management fellowship that includes interventional spine techniques.<br>The 1990s saw states passing patient bill of rights laws. You may contact Dr. Manchikanti et al. at ASIPP for detailed analyses and literature to refute Chou.<br>Thus, I think Oregon is making a wrong decision. This is similar to efforts made by Washington state medical directors that has failed twice on the basis of evidence based medicine thereby retaining coverage. Please, reconsider before making a decision that could result in very undesirable consequences and embarrassment | *Thank you for your comments. We believe the AHRQ review offers the most comprehensive and methodologically rigorous analysis available of RCTs of steroid injection therapies. The limitations of the individual studies were assessed, noted, and reflected in the study quality and the overall assessment of the strength of evidence for various outcomes. Observational studies were beyond the scope of the AHRQ review and our coverage guidance process.*<br>*The assertion of intellectual bias or conflict of interest rests on an assumption that AHRQ had a pre-supposed conclusion about the effectiveness of injection therapies for low back pain that resulted in pressure to reach certain conclusions. We find no basis to support such a claim.* |

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| | for Oregon. | |
| AA1 | The termination of interventional pain procedures is unfounded and medically inappropriate.<br><br>There is substantial peer-reviewed review evidence to support the usefulness of the interventional pain modalities for both diagnostic and therapeutic useless.<br><br>A blanket refusal to reimburse any interventional pain modality is a rash decision which shows a complete lack of regard for compassionate patient care especially in light of our nation's opioid epidemic, disregard for a continuum of pain care that would include oral, physical, interventional pain and surgical modalities.<br><br>In short, obliterating interventional pain modalities would leave patients with pain control options inclusive of morphine and back surgery, which is inappropriate.<br><br>Thank you for considering my medical opinion in this matter. | *Thank you for your comments.*<br><br>*The evidence review did not show that steroid injection therapies reliably improve long-term function or reduce the use of opioid or other analgesic medications or the long-term likelihood that a patient will undergo surgery to treat back pain.* |
| BB1 | Comment similar to Y1 and Y2. | *See response to Y2.* |
| CC1 | On behalf of the American Society of Interventional Pain Physicians (ASIPP), Oregon Society of Interventional Pain Physicians, 50 state interventional pain physician societies, including Puerto Rico, and the multitude of pain patients who genuinely benefit from pain injections, I would like to submit strong opposition to coverage guidance for low back pain, and request that this guidance be withdrawn from consideration immediately to avoid drastic implications regarding access to effective interventional therapies. | *Thank you for your comments.* |
| CC2 | Numerous systematic reviews that employed excellent methodologic quality assessment, utilizing appropriate active-control design, have shown positive results, not only for epidural injections, but also for multiple other injection therapies in managing spinal pain.[1-5] These systematic reviews overwhelmingly have demonstrated, based on high quality, randomized, controlled trials, that a | *The authors of the coverage guidance considered other systematic reviews of randomized controlled trials but found that Chou and colleagues provided the most comprehensive and methodologically rigorous review of the evidence and meta-analysis. The scope of this* |

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| | local anesthetic and/or local anesthetic with steroids are effective for pain management in these patients. Similar results have been shown in managing axial low back pain, lumbar post-surgery syndrome, as well as good results for epidural injections in the thoracic and cervical spines. Further, multiple systematic reviews of facet joint injections and sacroiliac joint injections have yielded similar results with diagnostic validity and long-term effectiveness of facet joint and sacroiliac joint injections with or without steroids. | *coverage guidance is limited to the effectiveness of steroid injection therapies. Diagnostic procedures, other injection therapies, and other interventional procedures are thus beyond the scope of this coverage guidance except where they serve as a comparator to steroid injection therapies.* |
| CC3 | Irrational assessments and decisions, specifically in Oregon, may spread to the entire country based on a flawed meta-analysis and intellectual bias. Such a mistake may result in decisions to eliminate coverage of important modalities and to force patients to succumb to unnecessary, expensive therapeutic options, including opioids, other drug therapies, and surgical interventions. In fact, the commission should be aware of the two studies funded by the National Health Services (NHS) showing the effectiveness of epidural injections and also the coverage policies of NHS for epidural, facet joint, and sacroiliac joint interventions.[5,6]<br><br>I suggest that the agency withdraw the present recommendation and engage in a proper analysis of the literature, free from intellectual bias or conflict and confluence of interest. This may avoid major issues for patients and the extinction of AHRQ. | *Thank you for your comments.*<br><br>*The reviews by Lewis and colleagues were out of scope because they only reported on pain intensity and a composite outcome of overall response in leg pain or patient- and physician-perceived global effect.* |
| DD1 | I am a Pain Physician working in Salisbury, MD. I am very concerned about your decision to stop coverage for spinal procedures for chronic back conditions.<br><br>As you are aware, there are limited effective treatment strategies to help suffering from chronic low back pain. I have come across many patients who have tried various modalities of treatment including surgeries to help their pain, without no avail. In many instances they are started on opioid therapy which have limited | *Thank you for your comments.* |

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| | evidence as well. This has caused bigger issues of dependence and addiction as well.<br><br>In this context, many patients are benefitting from spinal injections. Most of these procedures are not great for long term but they do help the patients tide over short periods of weeks or months of aggravated pain without having to take increased narcotics or risky adjuvants. (Adjuvants like NSAIDs are one of the major causes of GI bleed in elderly.)<br><br>I have many patients who are on no or low dose opioid therapy, who routinely call me for spinal injections to help with the pain.<br><br>I don't think it is ethical to take away these interventions quoting lack of long time effects without proposing a better alternative.<br><br>As far as I know, none of the medication management or non-medication management options including spine surgery (except select cases) has any better long term beneficial effects compared to the injections.<br><br>In summary, I request you on behalf of all the suffering patients to continue the coverage for the spine interventions and work on better alternatives as well. | |
| EE1 | The undersigned organizations are fully committed to providing effective care for the millions of individuals with chronic pain, including low back pain, which is the leading cause of worldwide disability. We are also invested in determining which treatments are effective and which are not, and this is dependent on which conditions and patients they are used for, and on preventing misuse and abuse at all levels.<br><br>Epidural steroid injections (ESI) are arguably the most controversial of all medical procedures, which is a function of the dramatic surge in their use. Yet, when one considers the conglomeration of evidence, there is compelling evidence that ESI | *Thank you for your comments.*<br><br>*As noted above, we believe the AHRQ review offers the most comprehensive and methodologically rigorous analysis available of RCTs of steroid injection therapies. The limitations of the individual studies were assessed, noted, and reflected in the study quality and the overall assessment of the strength of evidence for various outcomes.*<br><br>*The evidence review did not show that steroid injection* |

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| | are effective in well-selected candidates, based on literally tens of millions of injections, clinical trials, and observational studies. Even most "negative" studies have shown at least short-term benefit lasting up to 6 weeks from a single injection. In a meta-analysis based on six high-quality randomized trials presented at the FDA panel convened in November 2014 on the effectiveness and safety of ESI, Dr. Steven Cohen found that a single injection loses its "effectiveness" somewhere between six weeks and three months.<br><br>The more injections that are done, the less benefit we observe because it means that people are not being carefully selected. This holds true for medications, alternative therapies, and surgery. Yet, there are many patients who have received dozens of injections with continued relief over years, which has prevented surgery and treatment with opioids, which carry far greater risks and costs than ESI. For opioids in particular, randomized controlled trials have failed to demonstrate benefits lasting more than 12 weeks, or that they are superior to non-opioids for functional benefit. A recent meta-analysis done to determine whether ESI prevent surgery found a small effect at up to one year, but not afterwards. However, these studies were based on randomized trials that, for practical purposes, allowed for only one or two ESI; similar to any other medication, including medications approved for back pain and biological therapies, long-term benefit from pharmacotherapy depends on continued therapy, which must always be monitored for continuing benefit and weighed against risks.<br><br>Currently, there are little funds to perform the types of studies that pharmaceutical firms conduct to get drugs approved for use, which can cost tens or hundreds of millions of dollars. Those government-funded studies carefully select patients without confounding factors such as psychosocial issues and opioid use, and though they may show "efficacy", the results are not readily generalizable to the people who we see in pain treatment centers. Many studies construed as | *therapies improve long-term function or reduce the use of opioid or other analgesic medications or the long-term likelihood that a patient will undergo surgery to treat back pain.*<br><br>*The purpose of this evidence review was to determine whether injection of corticosteroids into the lumbar epidural space, the facet joint, or the SI joint improved the outcomes listed in the scope statement. Indeed, injection of local anesthetics (and other substances) are included comparators in the scope statement. Trials comparing local anesthetics to local anesthetics plus corticosteroids are thus helpful in determining the comparative effectiveness of corticosteroid injections. The authors of the AHRQ report have previously responded to this criticism: "[A]s described in the Results, there were no clear differences between local anesthetic injection, saline injection, or non-epidural injection as control interventions; therefore we think it is appropriate to classify all of these as placebo interventions."* |

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| | "negative" did not include a true placebo group, but rather compared ESI to individuals who received epidural LA or saline. Previous systematic reviews on this topic demonstrated conclusively that epidural LA or saline are not "placebos." Failure to demonstrate benefit under these circumstances cannot be equated with a lack of efficacy. A case in point for these issues is the Friedly et al. study published in the New England Journal of Medicine in 2014, which compared non-standardized ESI to epidural lidocaine in individuals who had long duration of pain, spinal stenosis (which is less responsive than HNP as an indication), had overlying psychosocial issues including secondary gain, and were taking opioids. Even with these limitations, ESI were still found to be superior to epidural local anesthetic at 3 weeks, and nearly at 6 weeks (p=0.07).<br><br>As alluded to above, similar to other medications for chronic pain, one cannot reasonably expect a single ESI or two scheduled ESI to provide long-term benefit, just as one cannot expect a single dose of gabapentin to provide long-term benefit. However, there is a wealth of literature that suggests that performing multiple injections on an 'as needed' basis can enable people to function well (including working) over a long period of time. Unfortunately, one cannot study, for practical and ethical reasons, a series of ESI vs. a series of placebo shots over a long time period.<br><br>The issue of ESI cannot be viewed in a vacuum, and should not be resolved without adequate discussion that includes both patients and responsible doctors who provide the service, preferably without secondary gain. It is unreasonable to remove a minimal risk, beneficial procedure when there are no clear-cut, effective alternatives, particularly in the middle of an opioid epidemic (neither surgery nor opioids have been shown to provide long-term benefit and carry considerably greater risks than injections). The unintended consequences of eliminating payment for ESI are not being considered, and could result in an unregulated | |

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| | "shadow" economy in which only people who could afford to pay for treatment would be able to receive it. Instead of preventing people who have derived (and will in the future derive) pain relief and functional benefit from ESI, what needs to be done is to convene a multispecialty working group to determine which individuals should be treated with this intervention, and to crack down on inappropriate use. | |
| FF1 | The American Pain Society (APS) is a multidisciplinary community that brings together a diverse group of scientists, clinicians and other professionals to increase the knowledge of pain and transform public policy and clinical practice to reduce pain-related suffering. While other pain societies focus largely on practice issues, the emphasis within APS is pain science and the application of that science into evidence-based practice. The essence of our approach is that each patient is unique and should have access to interdisciplinary care that is integrated, cost effective and comprehensive.<br><br>Spinal injections are not the panacea for all spinal conditions. There are conditions best treated conservatively and others best treated surgically. Spinal injections however do have their place as a valuable alternative option for some people particularly when used in the context of a long-term patient-centric pain management plan involving multidisciplinary care.<br><br>Oregon Health Authority has effectively left Oregon Health Plan patients (low-income and disabled individuals), and providers with a reduced set of viable options for pain management. Elimination of coverage contradicts coverage policies implemented by all major health plans and Medicare.<br><br>We hope that you will consider our comments regarding the appropriate context for using corticosteroid injections as they can be effective tools in the treatment of appropriately selected patients. | *Thank you for your comments.* |

# HERC Coverage Guidance: Low Back Pain - Corticosteroid Injections
## Disposition of Public Comments

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| GG1 | Comment similar to Y2. | *See response to Y2.* |
| GG2 | On a more personal note, as two physicians here in Oregon who have dedicated their careers towards the safe and effective treatment of pain, we are extremely concerned about the potential implications of this. The only possible outcome of denying patients access to beneficial spinal interventions will be a huge rise in opiate use and more unnecessary spinal surgery. | *Thank you for your comments.*<br>*The evidence review did not show that steroid injection therapies improve long-term function or reduce the use of opioid or other analgesic medications or the long-term likelihood that a patient will undergo surgery to treat back pain.* |
| HH1 | Comment is substantively similar to KK1. | *See response to KK1.* |
| II1 | I am writing to you today due to the recent information that was presented to me today regarding epidural steroid injections. It was brought to my attention that in Oregon, patients with Medicare are now denied coverage for these injections. I currently work in a free standing surgery center and we perform these injections daily. I see the patients come in with terrible pain & leave with relief. I see PCPs are not prescribing narcotics to patients that have pain because they are afraid of the back lash. The government wants to take narcotics away completely due to the high misuse of them but that leaves the "pain patient" between a rock and a hard place. If you take away the epidural steroid injections and they do not have medication to help, then where does that leave them?? Not only am I a nurse, but I am also one of those "pain patients." If it was not for the injections that I receive, I would not be able to work in a profession that I love or take care of my family. Please reconsider the decision for elimination in coverage for epidural steroid injections. | *Thank you for your comments.* |
| JJ1 | On behalf of the Oregon Health & Science University Comprehensive Pain Management Center and the wide community of patients that we serve, I strongly oppose the proposal to cut insurance coverage for low back pain interventional procedures. | *Thank you for your comments.*<br>*This review was focused on the evidence for the effectiveness of steroid injection therapies; workforce training issues are thus beyond the scope of the evidence* |

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| | I, as a member of the multidisciplinary pain team, welcome guidance from the national academic community in patient selection for interventions and directions for further research. I understand that interventions are far from a cure for low back pain. However, these interventions had been a long standing part of back pain treatment and practiced by all academic pain institutions in the country. Multidisciplinary pain care, including interventions, is the standard of care nationally for our patients. Denying Oregon patients the stand of care is unjust.<br><br>The procedures do not benefit everyone. However, patients who do benefit from these procedures are more active, with less opioid use, and improves their societal function. Being involved in traditional society functions allows for less depression, anxiety, financial distress.<br><br>Eliminating coverage for these procedures will also compromise training of fellows and residents. As the major academic center for the state of Oregon, denying insurance coverage for our patients' procedures will also cripple medical education.<br><br>I additionally have concern that patients will be forced to other options such as opioids and more expensive options such as low back surgery. None of the medical or surgical alternatives covered by insurance satisfy the level of evidence exacted from the HERC. The conflicting evidence for efficacy must be considered by practicing physicians and discussed with patients. However, the final determination of treatment should be left between physician and patients, not the insurance company.<br><br>I recommend further review before these decisions are finalized. | *summary.* |
| KK1 | I write with disappointment and strong opposition to the OHA draft coverage guideline "Corticosteroid injection - Low Back Pain." This proposal removes coverage for a well-established and evidence-based treatment for low back pain. | *Thank you for your comments.*<br><br>*As noted above, we believe the AHRQ review offers the most comprehensive and methodologically rigorous* |

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| | In the absence of access to epidural steroid injections, patient outcomes can include: unnecessary suffering, additional drug dependency, unnecessary surgeries, increased utilization of more expensive therapies, and additional work disability.<br><br>A number of studies support the use of epidural steroid injections to reduce low back pain in patients.[1-6] Impressively, a large meta-analysis has also shown that 33-50% of patients considering surgery who undergo epidural steroid injections can avoid surgery.[7] The OHA should consider the evidence-based reduction in pain and potential decrease in surgery when evaluating ESI coverage.<br><br>It is critical that the OHA evaluate the value of epidural steroid injections with a recognition that we are in the midst of an opioid crisis. Many patients with low back pain are treated with opioid pain medications. The OHA must ensure that new policies do not increase this crisis. Epidural steroid injection can reduce low back pain without the use of opioid pain medications.<br><br>The Oregon Health Authority should evaluate all available evidence before establishing coverage guidelines for epidural steroid injections. Current evidence does not support the removal of epidural steroid injections from coverage. | *analysis available of RCTs of steroid injection therapies. The limitations of the individual studies were assessed, noted, and reflected in the study quality and the overall assessment of the strength of evidence for various outcomes.*<br><br>*Our evidence review did not show that steroid injection therapies improve long-term function or reduce the use of opioid or other analgesic medications or the long-term likelihood that a patient will undergo surgery to treat back pain.*<br><br>*Indeed, the Bicket meta-analysis cited here found that epidural steroid injections provided no statistically significant difference in either the short-term (<1 year) or long-term (>1 year) risk of undergoing surgery.* |
| KK2 | I have worked at Columbia Pain and Spine Institute for two years with two other MDs and two midlevels. We use comprehensive pain techniques to take care of pain patients including those with back pain. When I took the job I was excited to be able to offer techniques to all patients including Medicaid, Family Care, and CareOregon. Many of these patients had not received steady medical care and it was their first time to be seen at a "Pain Clinic."<br><br>I believe we were able to help many of these patients by using Evidence-Based Medicine including PT, Acupuncture, medications, and injections.<br><br>I am sorry I have to tell many of these same patients now that their insurance will | *Thank you for your comments.* |

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| | not cover injections as a part of that therapy. When they ask, "why?", I have no answer. | |
| LL1 | Comment is substantively similar to JJ1. | *See response to comment JJ1.* |
| MM1 | Comment is substantively similar to JJ1. | *See response to comment JJ1.* |
| NN1 | Comment is substantively similar to KK1. | *See response to comment KK1.* |
| OO1 | I am an employee of the Oregon Health & Science University Comprehensive Pain Management Center. On behalf of patients whom we serve, I strongly oppose the proposal to cut insurance coverage for low back pain interventional procedures.<br><br>I am a psychologist with no personal financial interest in pain procedures. I am speaking based upon my 25 years of working with patients with chronic pain. I understand that these interventional procedures are far from a cure for low back pain. However, these interventional procedures are a long-standing part of back pain treatment and are practiced by all academic pain institutions in the country. Multidisciplinary pain care, including interventions, is the standard of care nationally for patients with chronic pain. Denying Oregon patients the standard of care is unjust.<br><br>The procedures do not benefit everyone. However, patients who do benefit from these procedures are more active, with less opioid use, and improved social function. Being more involved in normal functioning allows for less depression, anxiety, and financial distress.<br><br>I also am concerned that patients will be forced to other options such as opioids and more expensive options such as low back surgery. The evidence for efficacy of various treatment options must be considered by practicing physicians and discussed with patients. However, the final determination of treatment should be left between physician and patients, not the insurance company. | *Thank you for your comments.* |

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| | I strongly recommend further review before these decisions are finalized. | |
| PP1 | Comment is substantively similar to KK1. | *See response to KK1.* |
| QQ1 | Comment is substantively similar to KK1. | *See response to KK1.* |
| RR1 | Comment is substantively similar to KK1. | *See response to KK1.* |
| SS1 | Comment is substantively similar to KK1. | *See response to KK1.* |
| TT1 | Please save Corticosteroid injections for the spine. Thank you for your time. | *Thank you for your comments.* |
| UU1 | I am writing to provide my clinical opinion.<br>Furthermore, I would like to express my opposition to the OHA draft coverage guideline "Corticosteroid injection - Low Back Pain."<br>I have provided epidural steroid injections to patients for at least ten years.<br>It has been my personal experience that many times the symptoms that patients experience with a radiculopathy, such as pain, numbness, and weakness, are related more to an inflammatory process than to a mechanical lesion.<br>Although there are situations in which a patient may benefit from surgery, for these inflammatory processes, they very well may not.<br>They may, however, benefit from the specific placement of anti-inflammatory medication (corticosteroids) to the site in question.<br>These injections provide relief, or treatment, when surgery cannot, or has not, been helpful.<br>These injections, frequently, forestall surgery all together.<br>These injections allow people to work, and live a more productive life. | *Thank you for your comments.* |
| VV1 | Today I had a client who has benefitted from being able to receive a variety of | *Thank you for your comments.* |

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| | different treatments that the Comprehensive Pain Center provides to deal with her long-term, chronic low back pain. I am a Licensed Massage Therapist at the Comprehensive Pain Center, in the community of other Pain Providers. I am a part of a group who provides an alternative to debilitating pain and/or opioids. With this particular client, I have been working to reduce her pain and tension at her source of pain in her low back, right hip, and right leg. Last week she received an injection that not only immediately reduced her pain, but also allowed me to significantly reduce the pain and tension by being able to work more effectively with tissues that were not in acute pain. Pain is complicated, with many aspects both emotional and physical. Every person reacts differently to pain. In the people I see for pain, I take the responsibility to do my best to break the cycle of pain, whether mentally or physically. The Comprehensive Pain Center is able to do this for so many people because of the many different treatments we provide: from Pain Psychology, to Massage, Acupuncture, Chiropractic, and Interventional Procedures. | |
| WW1 | I am writing regarding the proposed non-coverage of corticosteroid injections for spinal pain. Specifically, I am concerned that denying epidural steroid injections (ESIs) to patients with predominant radiculopathy and sacro-iliac joint injections (SIJIs) to those with clinical signs of sacro-iliac pain will limit treatment options and be a detriment for the population of Oregon.<br><br>I understand fully that at times these procedures are over-utilized and not placed in the context of comprehensive care for the entire patient. I think it is in the public interest to assure that these procedures remain available, but that they are performed only in selected patients after appropriate more conservative care.<br><br>For patients with ongoing radicular pain treatment choices are limited. There are no FDA approved medications. The evidence supporting physical therapy for radicular pain is scant. The most common class of medications prescribed for “low | *Thank you for your comments. The evidence for the effectiveness of other treatments for low back and SI joint pain are beyond the scope of this coverage guidance. Evidence for the effectiveness of alternative treatments is not substantially relevant to the estimates of the effectiveness of steroid injection therapies, except where direct comparisons between the treatments are made.*<br><br>*The evidence review did not show that steroid injection therapies improve long-term function or reduce the use of opioid or other analgesic medications or the long-term likelihood that a patient will undergo surgery to treat back pain.* |

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| | back pain" is opioids which clearly lack evidence for efficacy in this population and have overwhelming evidence for harm.[1] There are no studies supporting NSAIDs specifically for radicular pain. Surgery is only appropriate for a minority of these patients. In selected patients, ESIs are an appropriate alternative when the pain is mainly radicular, ongoing, limiting function, and has failed to respond to more conservative treatment. I am confident that the professional societies and other individuals have cited the literature in favor of these procedures, so I will not recount that data here. Please consider: if ESIs are denied in this setting, what is the alternative being offered? What is the true cost of non-treatment?<br><br>Those with ongoing sacro-iliac joint pain have even more limited treatment choices. There are no FDA approved medications (in fact no medications with any prospective data to support their use for sacro-iliac joint pain), no evidence based exercises, and no surgical options except for the very small minority with excess mobility. Again, without the option for injection in the subset who does not respond to more conservative care, what is the long term plan? I have no problem limiting the availability of SIJIs to those patients who have ongoing pain despite other treatment efforts and who have exam/clinical characteristics fitting sacro-iliac joint pain; but that is not the same as completely eliminating the option.<br><br>I am the Medical Director at the University of Washington's Center for Pain Relief (UW CPR) and was part of the statewide response to similar restriction proposals put forth by the Washington's Health Technology Clinical Committee. After considering the alternatives for patients with difficult situations and needs, they elected to continue coverage for ESIs in the setting of radicular pain, and similarly for SIJIs. Both of these were continued with appropriate, rational restrictions (requiring conservative care as a first step, limiting frequency, etc.).<br><br>While I currently reside in the state of Washington, I maintain an Oregon Medical License, own a home in Portland, and was a faculty member at Oregon Health & | |

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| | Science University (OHSU) for 18 years. My most recent position in Oregon was as Division Chief of the Division of Pain Medicine, Medical Director of the OHSU Comprehensive Pain Center (CPC), and Professor of Anesthesiology & Perioperative Medicine. At the CPC the clinicians employ a comprehensive team approach in which injections such as described above are but one component of the overall care that is focused on enhancing function and decreasing pain and suffering. All aspects of this advanced care deserve the full support of the residents of the state of Oregon. My friends and colleagues practice and live in the state; what happens in Oregon is important to me on a personal level and I remain involved and committed—thus this letter.<br><br>Please consider what the alternatives are for the patients who would be negatively impacted by a restriction that makes these procedures unavailable. As the alternatives are quite limited and even less supported by evidence it becomes clear that these treatments should remain as viable treatment options for selected patients. Please take appropriate action to make that the case for the citizens of Oregon. | |
| XX1 | I am an employee of the Oregon Health & Science University Comprehensive Pain Management Center. On behalf of patients we serve, I oppose the proposal to cut insurance coverage for low back pain interventional procedures.<br><br>I am a pain psychologist who is weighing in based upon 20 years of experience working with patients with chronic pain. I understand that these interventional procedures are not a cure for low back pain, however they can play an important role in improving function as part of multidisciplinary care. The patients who benefit from these procedures are often more active, have less opioid use, and have an improved quality of life. Increased activity levels leads to less depression, anxiety, and disability. | *Thank you for your comments.* |

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| | I strongly recommend further review before these decisions are finalized. | |
| YY1 | Pain is unpleasant and has sensory and emotional components. Pain is measured differently with each person. Pain is exacerbated with activity, inactivity, emotions, fear, depression, anxiety, and fatigue. Medication is an option of treatment for chronic pain, however, not always tolerated. Studies for opioid pain medication for managing pain have not shown good data for long term therapy. Opioids also have many side effects and can cause hyperalgesia, worsening their pain. Other medications may not be covered by insurance and are costly to the patient. There are other modalities that we try at home such as meditation, relaxation techniques, and heat/cold therapy. These modalities have minimal or short term relief. There are other tools available such as procedures that help alleviate the severe pain giving the body a chance to reset which allows the patient to participate in more physical activity and to continue their employment. These procedures also delay the need for surgery. Surgery is not always an option due to the severity being mild or the patient's age or health status is inoperable. The procedures include lumbar spine epidurals, facet injections, and ablations. These procedures are under review with insurance companies disputing continued covered benefit.<br><br>Here at OHSU Comprehensive Pain Clinic, we incorporate acupuncture, massage, chiropractic manipulation, physical therapy, and pain psychologist into our patient's pain management. We encourage improving our patient's activities of daily living with better lifestyle choices such as smoking cessation, joining a gym or starting an exercise regimen that is tolerated, and nutrition. We are never guaranteed a life without pain but when it becomes a problem, we have options. Pain is difficult to treat and with discontinued benefit coverage for these low back pain interventional procedures, our options are reduced and many of our patients suffering with pain will become stationary. | *Thank you for your comments.* |

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| | We, OHSU, are also a teaching facility. We have many residents and fellows who are educated by our physicians learning various treatment regimens. If low back pain interventional procedures are no longer a covered benefit then our teaching facility loses this teaching tool. These procedures are a standard of care nationally and have been for many years. Please do not deny Oregon the standard of care.<br><br>In conclusion, low back pain interventional procedures have been beneficial for many of our patient's. We see our patient's faces that express pain and suffering become comfortable and relieved. Their activities of daily living improves. Our fellows and residents are pleased with our teaching tools available and are confident in performing these procedures. They will carry these tools with them along their healthcare journey. Furthermore, the state of Oregon deserves the standard of care for its residents to continue to be healthy, happy, active, and adventurous. | |
| ZZ1 | I am writing to express my opinion and concern over your non coverage position of steroid injections for pain management. My medical career has spanned over a 40 year period and I have witnessed good and bad decisions in medicine during that time. We all watched as the pain scale became part of evaluation and pills appeared to be the answer through the 90s until a generation of addicts were created. Now as the public and CDC are in an uproar over the widespread addiction and how opioids are prescribed you are willing to take away the last option for people that need pain control to have a functional life. Are you going against CDC recommendations and pay for patients to get opioids not caring if they become addicted? How much sense does that make? Don't think with your pocket book use common sense. Injections do work and yes are not a cure, but neither are pills, operations, PT, etc. These all work in conjunction with one another to provide people with relief to be able to dance at their child's wedding, cut their grass and work contributing to society with taxes, etc. Don't debilitate | *Thank you for your comments.* |

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| | people to a point where you have taken their self-respect away and make them receiver of disability money when they don't want to be!! | |
| AAA1 | Comment is substantively similar to KK1. | *See response to KK1.* |
| BBB1 | Comment is substantively similar to KK1. | *See response to KK1.* |
| CCC1 | Comment is substantively similar to KK1. | *See response to KK1.* |
| DDD1 | Comment is substantively similar to KK1. | *See response to KK1.* |
| EEE1 | Comment is substantively similar to KK1. | *See response to KK1.* |
| FFF1 | Comment is substantively similar to KK1. | *See response to KK1.* |
| GGG1 | Comment is substantively similar to KK1. | *See response to KK1.* |
| HHH1 | Comment is substantively similar to KK1. | *See response to KK1.* |
| III1 | Comment is substantively similar to JJ1. | *Thank you for your comments.* |
| JJJ1 | Comment is substantively similar to JJ1. | *Thank you for your comments.* |
| KKK1 | Comment is substantively similar to JJ1. | *Thank you for your comments.* |
| LLL1 | Comment is substantively similar to JJ1. | *Thank you for your comments.* |
| MMM1 | Comment is substantively similar to JJ1. | *Thank you for your comments.* |
| NNN1 | Comment is substantively similar to JJ1. | *Thank you for your comments.* |
| OOO1 | Comment is substantively similar to JJ1. | *Thank you for your comments.* |
| PPP1 | Comment is substantively similar to JJ1. | *Thank you for your comments.* |
| QQQ1 | Representatives of the 11 undersigned medical specialty societies, comprising physicians who utilize and/or perform spinal injection procedures to accurately diagnose and treat patients suffering from spine pathologies, would like to take | *As noted above, we believe the AHRQ review offers the most comprehensive and methodologically rigorous analysis available of RCTs of steroid injection therapies.* |

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| | this opportunity to comment on Health Evidence Review Commission's (HERC) draft coverage guidance *Corticosteroid Injections – Low Back Pain.*<br><br>We are disappointed to see that the report is almost entirely based on a flawed systematic review.[1] As discussed in letters submitted to Oregon Health Authority/HERC in January and May of 2016, this review arrived at erroneous conclusions due to a significantly flawed methodology, which included studies with poor patient selection criteria (e.g., nonspecific diagnoses, varying symptom duration, psychosocial comorbidities); technical limitations (e.g., non-standardized procedures); and lack of categorical outcomes data. We extend an offer to HERC, as we have several times this year, to provide clinical expertise in reviewing the evidence. A 1,000-word restriction precludes a comprehensive assessment; however we encourage HERC to review a critique of the Agency for Healthcare Research and Quality's (AHRQ) review published in a peer-reviewed journal.[2] It is important that HERC carefully consider the AHRQ report's flaws. A coverage guidance based upon a biased assessment of the evidence does a disservice to all stakeholders. This will result in egregious denial of access to procedures that truly can help patients. In the absence of access to interventional pain procedures, patient outcomes will include: unnecessary suffering, additional drug dependency, unnecessary surgeries, increased utilization of more expensive therapies, and additional work disability. The aforementioned will result in the delivery of lower quality medical care and contribute to greater consumption of healthcare resources.<br><br>**Effectiveness of Corticosteroid Injections**<br><br>The AHRQ report, and by extension the HERC's coverage guidance, has arrived at erroneous conclusions. They relied on flawed randomized controlled trials (RCT), and failed to acknowledge the importance of high quality observational studies that include subgroup analyses assessing effectiveness of corticosteroid injections | *The limitations of the individual studies were assessed, noted, and reflected in the study quality and the overall assessment of the strength of evidence for various outcomes. As part of our evidence summary and the response to these public comments, we have reviewed in detail the public comments submitted for the AHRQ review, as well as the responses of the authors.*<br><br>*Many of the trials included in the AHRQ report relied on rigorous patient selection criteria. The authors of the AHRQ report also considered whether patient characteristics influence the likelihood of a successful injection; they concluded that there was "insufficient evidence to determine whether the cause of radicular symptoms, duration of symptoms, imaging findings, or other patient factors" influenced patient outcomes from injection therapies.*<br><br>*The evidence review that informs this coverage guidance was funded by AHRQ. The research was conducted by experienced systematic reviewers and was subject to peer review. The assertion of intellectual bias or conflict of interest rests on an assumption that AHRQ had a pre-supposed conclusion about the effectiveness of injection therapies for low back pain that resulted in pressure to reach certain conclusions. We find no basis to support such a claim.*<br><br>*HERC methodology relies on RCTs and systematic reviews of RCTs when considering evidence for the effectiveness* |

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| | by specific diagnosis, use of image guidance, and technical approach. An observational trial with appropriately selected patients and treatment indications, accurate contemporary treatment techniques, and appropriate categorical outcomes measured at rational time increments is far more relevant than an RCT with improper patient and treatment indications, antiquated or poor treatment technique, and weaker outcome measures. The effectiveness of transforaminal injections of steroid, in particular, has been confirmed in several RCTs and high quality observational studies.[3-9]<br><br>*Specific Diagnosis*<br><br>There is no physiologic process beyond systemic effect by which steroids delivered to the epidural space would be expected to relieve axial back pain arising from nociception in the intervertebral discs, facet joints, sacroiliac joints, or supporting musculature. There is, however, ample evidence that radicular pain has an inflammatory basis, potentially susceptible to targeted delivery of anti-inflammatory agents to the interface of neural tissue and the compressive lesion.[10] The identification of underlying pain etiologies is essential; different pathologies have varying responses to treatment and different natural histories which impact prognosis. The time frame of follow-up to determine clinical utility becomes imperative.<br><br>*Image Guidance*<br><br>Data show that "epidural" injections performed without image guidance may not universally reach the epidural space, even in expert hands.[11-13] Off-target medication delivery may not be efficacious and may be dangerous.<br><br>*Approach/Access/Accuracy*<br><br>Midline interlaminar ESIs and caudal injections may deliver medication distant from the site of pathology, without certainty that the steroid will reach, or in what | *of therapies. We agree with the authors of the AHRQ review that "well-conducted randomized trials remain the standard for evaluating the effectiveness of interventions. We do not agree that observational studies should take precedence over higher-quality randomized trials. In addition, over 50 trials of injections exist; therefore, we do not agree that trials are lacking in this area."*<br><br>*As part of the pre-specified scope and key questions of the AHRQ review, the authors considered whether specific diagnoses, imaging guidance, or the use of certain approaches or access methods influenced the effectiveness of these procedures. Those analyses are summarized in the coverage guidance.*<br><br>*The evidence review did not show that steroid injection therapies improve long-term function or reduce the use of opioid or other analgesic medications or the long-term likelihood that a patient will undergo surgery to treat back pain.*<br><br>*Indeed, the Bicket meta-analysis cited here found that epidural steroid injections provided no statistically significant difference in either the short-term (<1 year) or long-term (>1 year) risk of undergoing surgery.* |

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| | concentration it will reach, the ventral epidural space. In contrast, transforaminal ESIs place the needle in direct proximity to the target nerve and verify delivery to that site by observing contrast media flow.[14] Recently described lateral parasagittal interlaminar ESIs have also been shown to preferentially deliver injectate to the target ventral epidural space.[15] It is not reasonable to combine these different injection techniques in an evaluation of "epidural steroid injections."<br><br>**General Public Health Concerns, Competing Therapies**<br><br>Some patients have no treatment options apart from spinal injections. Implicit in the discussion of spinal injections is that conservative care (e.g., lifestyle changes, physical therapy, medications) has failed. Surgery can be contraindicated due to comorbidities or age, and entails very real risks of immediate or delayed surgical failure, technical failure, serious infections, permanent paralysis, re-herniations, and subsequent segmental instability requiring fusion.<br><br>Opioid and non-opioid analgesics have limited utility with high numbers needed to treat (NNT) ranging from 4.5 to 16[16] and significant potential for harm including death, exceeding 16,500 for NSAIDS[17] and 18,663 from prescription opiates[18]. It has been estimated that at least 103,000 patients are hospitalized annually in the United States for serious gastrointestinal complications due to NSAID use. At an estimated cost of $15,000-$20,000 per hospitalization, annual direct costs of such complications exceed $2 billion.[17] By contrast, NNT for transforaminal epidural steroid injections to avoid surgery is 3, and to achieve 50% pain relief is 4.[3,4] In a meta-analysis of 26 trials, 33-50% of patients considering surgery who undergo ESI can avoid surgery.[19] Interventional procedures offer a safe alternative to opiates and an effective tool in tapering patients off of opiates. Evidence to support other "treatment options" available to patients (e.g., acupuncture, cognitive behavioral therapy, yoga) is inconsistent, weak, or non-existent.[20] | |

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| | **Summary**<br><br>Oregon Health Authority has effectively left Oregon Health Plan patients (low-income and disabled individuals), without hope for a future without debilitating pain. Elimination of coverage contradicts coverage policies implemented by all major health plans and Medicare.<br><br>Spinal injections are not the panacea for all spinal conditions. There are conditions best treated conservatively and others best treated surgically. Spinal injections provide a valuable alternative option for some people. Unlike some medical treatments that "cure" a problem, many spinal conditions cannot be cured. Repetitive, palliative treatments may be the only option. The risk-benefit ratio of intermittent spinal injections can be preferable to perpetual use of risk-laden medications, or simply living with pain and disability.<br><br>Thank you for considering our comments regarding the safety and effectiveness of corticosteroid injections -- effective tools in the treatment of appropriately selected patients. | |
| RRR1 | Comment similar to Y1 and Y2. | *See response to Y2.*<br><br>**NOTE: Submitted 113 references, including the 14 for footnotes in the comment itself. The additional 99 references are listed in the references for RRR.** |
| SSS1 | Comment is substantively similar to JJ1. | *Thank you for your comments.* |
| TTT1 | As one of only three pain management fellows currently training at the only academic pain medicine program in the state of Oregon, I would like to express my concern regarding the proposed dropping of coverage for low back procedures. Our fellowship is a comprehensive program – we get outstanding training not only in medication management but also for interventional procedures as well as | *Thank you for your comments.*<br><br>*This review was focused on the evidence for the effectiveness of steroid injection therapies; workforce training issues are thus beyond the scope of the evidence* |

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| | alternative medicine therapies. The majority of our patient population has low back pain and are provided a truly comprehensive approach to treating their pain.<br><br>Most of these patients take a leading role in their own care, but the relief provided by our interventional procedures is an integral part of them being able to do this. This is the right thing to do for these patients. I educate all of my patients on the importance of translating the pain relief we can offer them into long-term improvement in their function and thus their quality of life.<br><br>The rest of the country offers these procedures and recognize their importance in the comprehensive treatment of low back pain. To deny patients in Oregon these procedures would not only have a negative impact on their care, but as importantly on the training quality of future Oregon pain physicians. This would be a devastating blow to the only existing pain fellowship in Oregon- and one with a catchment reaching into Washington, California and Idaho. Future residents and fellows who will be trained in Oregon as a result of this change would certainly be less competent in comprehensive pain management and therefore ill-qualified to leave and practice pain management anywhere else in the country.<br><br>I am asking you to please reconsider this proposed coverage guidance for the sake of our patients, our future trainees and our entire pain management team. | *summary.* |
| UUU1 | I am a patient at Oregon Health & Science University (OHSU), and I was informed that the Health Evidence Review Commission (HERC) is proposing that insurance coverage be cut for corticosteroid injections for low back pain. I hope my story will influence the Commission not to proceed along this path of decision making.<br><br>In June of this year I was rear-ended while stopped at a stoplight. Since that day, I have been suffering an enormous amount of pain. At times the pain was so excruciating that it affected my ability to walk, stand, and sit – impacting other normal activities as well. This usually, but not always, followed some type of brief | *Thank you for your comments.* |

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| | activity that was previously non-problematic. My normal way of life was affected, causing me to be cautious about my normal activity, even limiting it. I was driving for a living at the time, but had to stop due to the amount of pain caused while driving. Home was the safest place, and laying down seemed to be the only remedy to help relieve the pain to some degree. Staying in bed majority of the day is a not normal activity for me.<br><br>I was eventually given a prescription anti-inflammatory that helped to ease my pain, but never completely took it away. I continued to have pain while walking, sitting, standing, and driving. It had continued to affect my normal daily routine, but allowed me to complete a full day's work in the office. Intermittent or constant pain throughout the day, would make for a painful evening.<br><br>Cooking a simple meal for my family had become a chore. I would sit on a stool to prepare meals, which elongated the process of cooking, leaving little time to do anything else. Standing to cook, resulted in days of unbelievable and unrelieved pain. It was hard for me to go to sleep, due to the throbbing and shooting pain going down my leg, back pain, and back numbness all from cooking while standing (a normal activity I love).<br><br>At work, my pain has caused me to decrease my activity. I work in an office manager capacity, making sure that the needs of the employees are met. This sometimes causes me to do a lot of walking. Painful days causes me to solicit the help of a coworker to do the strenuous and repetitive work and treat me with caution.<br><br>Physical therapy has helped some, but the pain is what guides what I do during my sessions. Painful days are stretching exercises only. Strengthening is only done on days that I have minimal pain.<br><br>It hasn't been long since my shot, but I am amazed to find that the pain I was | |

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| | having has decreased significantly so far. My body is still adjusting. Not feeling pain throughout majority of the day is a great relief.<br><br>Please reconsider your proposal. Without insurance coverage for this injection my life would not have returned to normal. | |
| VVV1 | I am writing to you as a concerned physician in Oregon regarding consideration of a blanket non authorization of epidural steroid injections for our OHP patients. As a physician who performs this procedure quite frequently to many patients of numerous insurance carriers in Douglas County, I find it unfortunate that this modality is unavailable to our OHP beneficiaries. Our CCO stopped authorizing this procedure earlier this year. I'm certain many of my concerned colleagues have provided evidence to support the usefulness of epidural steroid injections in reducing the need for surgical laminectomies, reducing opioid requirements, and improving overall function in appropriately selected patients.<br><br>I ask that you consider allowing this service for appropriately selected OHP patients. I provide this service to many carefully selected patients who have Medicare, Tricare, MODA, Blue Cross, Providence, PacificSource, and several Medicare Advantage plans. To not be able to offer this to selected OHP patients in our area seems to me unfortunate. | *Thank you for your comments.* |
| WWW1 | On behalf of the Oregon Ambulatory Surgery Association, which represents a majority of licensed Ambulatory Surgery Centers throughout Oregon, we would like to submit our strong opposition to coverage guidance for low back pain, and request that this guidance be withdrawn from consideration immediately to avoid drastic implications regarding access to effective interventional therapies.<br><br>Subject matter experts, including the American Society of Interventional Pain Physicians (ASIPP), Oregon Society of Interventional Pain Physicians, and the other 50 state interventional pain physician societies, including Puerto Rico, have | *Thank you for your comments.* |

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| | expressed concern over the assessment and review of data that supports this proposed guidance. We defer to their expertise and echo their concerns that the outcomes from this study present potential bias and inaccurate findings as to the efficacy of using pain management techniques to help with patient recovery and pain management.<br><br>It appears that the recommendations are based on a single study which has been widely criticized in medical circles, and which certainly runs counter to the decades of professional expertise and experience that our physicians have seen in real life situations. No decision of this significance for Oregon should be based on biased and inaccurate data.<br><br>Overall, we recommend that the agency withdraw the present recommendation and engage in a proper analysis of the literature, as well as an active engagement with subject matter experts in Oregon including stakeholders that practice in the Ambulatory Surgery Center environment.<br><br>Please feel free to contact me if you have any questions or would like our stakeholder input on this coverage guidance. | |
| XXX1 | Comment is substantively similar to KK1. | *See response to KK1.* |
| YYY1 | I am past member and Chair of the FDA Anesthetic and Analgesic Drug Products Advisory Committee. Several years ago I participated in an FDA review of epidural steroid administration. Although the focus was a discussion regarding the best (safest) approach for administration of epidural steroids in the cervical region, the FDA designated world experts who sat on that advisory panel clearly defined the positive therapeutic value of epidural steroids, particularly when administrated in the lumbar spinal region. It is simply unbelievable to me that you would discount strong support in the published literature and the absolutely most knowledgeable people in the U.S. on this topic. Thus, I currently write with disappointment and | *Thank you for your comments.* |

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| | strong opposition to the OHA draft coverage guideline "Corticosteroid injection - Low Back Pain." This proposal removes coverage for a well-established and evidence based treatment for low back pain. | |
| YYY2 | Comment is substantively similar to KK1. | *See response to KK1.* |
| ZZZ1 | As a senior academic anesthesiologist, I have witnessed the evolution of the use of non-surgical interventions for low back pain over the last 40 years, and during my generalist days, have performed a number of epidural steroid injections. I have also witnessed the abuse of this treatment in facilities that are not qualified to examine the etiology of such pain in sufficient detail to determine the specific causal factors and prescribe the appropriately directed interventions to achieve the most effective relief. I know that there are practitioners that incorporate minimal diagnostic investigations prior to performing large numbers of nonspecific epidural steroid procedures, and it is appropriate that you scrutinize these establishments carefully.<br><br>However, I am very cognizant of the degree to which low back pain is carefully investigated at the Comprehensive Pain Management Center at OHSU, and the judiciousness with which the various specific modalities of nonsurgical interventions are employed. To issue a blanket proscription against payment for all such procedures throughout the state will result in a drastic reduction in the care of many of our very deserving patients, and may have an unintended consequence of increasing the number of much more expensive invasive procedures which could be avoided.<br><br>I urge you to look further at this issue, and consider more specific limitations on practitioners who are not delivering the highest level of pain management services. | *Thank you for your comments.* |
| AAAA1 | Comment is substantively similar to KK1. | *See response to KK1.* |

# HERC Coverage Guidance: Low Back Pain - Corticosteroid Injections
## Disposition of Public Comments

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| AAAA2 | OHA should not underestimate the critical role epidural/peri-spinal percutaneous interventions have as a bridge to other longer term therapies such as cognitive behavior or surgery. ESI and associated procedures provide a varying interval of symptom improvement, so patients can rationally and without pain or the debilitating and consciousness clouding side effects of opioids, review their treatment options. Current practices such as the one I work in include this critical option as a part of an evidence based, well thought out and multidisciplinary practice deliberated protocol for these patients. I cannot believe that the organization I work as a part of would include this option if the pain management evidence does not support the value of epidural steroid injections. Do not remove ESI and associated procedures from OHA coverage options for our patients. | *Thank you for your comments.* |
| BBBB1 | As a retired anesthesiologist with experience in treating patients with back pain, I have seen patients who have benefitted from this treatment. Often a couple of injections over time has provided improvement to allow function & return to a normal pain free existence. Please do not eliminate this option of treatment. It is a more viable alternative to opioid prescriptions & potential addiction. | *Thank you for your comments.* |
| CCCC1 | Comment is substantively similar to JJ1. | *Thank you for your comments.* |
| DDDD1 | Comment is substantively similar to JJ1. | *Thank you for your comments.* |
| EEEE1 | Comment is substantively similar to JJ1. | *Thank you for your comments.* |
| EEEE2 | Presently, these interventions have been a longstanding part of low back pain treatment and are practiced by all academic pain institutions in the country. Eliminating them before high quality randomized controlled trials can be performed, I believe is a mistake. Instead we should refocus our energies to ensure that these high quality studies are performed in order to clarify appropriate patient criteria for each intervention. | *Thank you for your comments.*<br>*The limitations of the current evidence are reflected in the quality assessments made by the authors of the AHRQ review.*<br>*If new high-quality randomized trials are performed and demonstrate the effectiveness of steroid injection* |

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| | | *therapies for the critical and important outcomes considered by HERC, then it would be appropriate to reconsider the coverage guidance at that time.* |
| FFFF1 | Comment is substantively similar to KK1. | *See response to KK1.* |
| FFFF2 | Epidural steroid injections may not always cure low back pain, but in a select patient population, they can significantly reduce the pain that patients experience and the use, and subsequent potential abuse, of opiates. It is unconscionable to remove this non-opiate pain relieving alternative from our patients. | *Thank you for your comments.* |
| GGGG1 | Comment is substantively similar to JJ1. | *Thank you for your comments.* |
| HHHH1 | Comment is substantively similar to KK1. | *See response to KK1.* |
| HHHH2 | It is critical that evaluation of epidural steroid injections involve specialists trained in pain medicine. It is unclear that this has occurred with this HERC guideline. The HERC guideline has a heavy reliance on the AHRQ Technology Assessment Report. This paper was produced by the Pacific Northwest Evidence Based Practice Center with the first author, Roger Chou MD, is the director of this Center. Two members of the HERC are members of the Pacific Northwest Evidence Based Practice Center. It is not clear that there is a disclosure of this relationship in the HERC Guideline. | *Thank you for your comments.*<br><br>*As noted above, we believe the AHRQ review offers the most comprehensive and methodologically rigorous analysis available of RCTs of steroid injection therapies. The limitations of the individual studies were assessed, noted, and reflected in the study quality and the overall assessment of the strength of evidence for various outcomes.*<br><br>*No Commission staff or contractors or members of HERC are affiliated with the Pacific Northwest Evidence-based Practice Center or were authors of the Chou report. Dr. Janna Friedly served as an appointed expert on the coverage guidance but did not vote. The Commission recruits subcommittee members and experts with diverse expertise and perspectives including some with intellectual or* |

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| | | *financial conflicts of interest, which are fully disclosed.* |
| IIII1 | I am writing this letter in response to the recent recommendations by the Health Evidence Review Commission to cut coverage for a wide variety of interventional pain procedures. While it is our duty to seek ways to contain overall healthcare expenditure, it is also our duty to provide reasonable care for the patients we treat. In my opinion, a diffuse cut of this nature using selective literature void of expert deliberation is not reasonable patient care. Chronic pain patients represent a unique population with poorly understood disease processes who often have limited treatment options. An attempt to further limit their treatment options is not only unfair but lacks the basic compassion healthcare providers should have. Patients could well resort to harmful treatment options including self-medication which is not an end point anyone wants. These cuts will almost certainly damage our ability to train pain physicians at OHSU which is the only ACGME accredited chronic pain program in the state of Oregon. I hope you reconsider this decision and allow of a fair review of the literature while considering input from both patients and experts in chronic pain management. | *Thank you for your comments.* |
| JJJJ1 | Comment is substantively similar to JJ1. | *Thank you for your comments.* |
| KKKK1 | Comment is substantively similar to KK1. | *See response to KK1.* |
| LLLL1 | Comment is substantively similar to JJ1. | *Thank you for your comments.* |
| MMMM1 | We are writing in response to the coverage guidance on corticosteroid injections for low back pain. As a physiatrist with specialty training in the management of patients with disorders of the spine, we are deeply troubled by the conclusions of this coverage guidance. By eliminating coverage for essentially all corticosteroid injections in the spine for any reason, these recommendations will significantly | *Thank you for your comments.* |

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| | limit the tools available to treat the patients that we and other physicians like us see on a daily basis. It is particularly concerning that these recommendations come at a time when the medical community at large is becoming increasingly aware of the scope and implications of an opioid epidemic created in large part by treatment of back pain with narcotics.<br><br>The majority of the patients that we see on a daily basis have already tried and failed conservative management with treatments like physical therapy, acupuncture, massage and chiropractics. In all reality, if we are unable to help these patients with procedural spinal intervention (often with corticosteroid injections), many of them will go on to either surgical intervention or pain management with narcotics. We recognize that this coverage guidance contends that corticosteroid injections in the spine do not "change outcomes" or have any impact on surgical rates. However, we think that these conclusions are based on flawed data. It is our opinion that it is naïve to think that eliminating all corticosteroid injections in the spine will have no impact on rates of spine surgery and narcotic usage. In our experience, when pain-reducing injections are utilized in combination with a comprehensive rehabilitation program, patients not only reduce medication utilization, but also improve overall function. | |
| MMMM2 | The one thousand words allowed for response to this coverage guidance is not enough to comment in detail on all of the points included in this publication. For this reason we will focus this commentary on the most concerning aspect of the coverage guidance, which is the conclusion that epidural corticosteroid injections should not be covered as a treatment for lumbar radiculopathy. This seems to be based largely on the conclusions of the 2015 AHRQ technology assessment published by Chou et al. We feel that the conclusions of this publication are over simplified based on an inappropriate analysis of the available data. The quality of the conclusions from any large meta-analysis, such as this AHRQ report, are only | *As noted above, we believe the AHRQ review offers the most comprehensive and methodologically rigorous analysis available of RCTs of steroid injection therapies. The limitations of the individual studies were assessed, noted, and reflected in the study quality and the overall assessment of the strength of evidence for various outcomes.*<br><br>*As part of the pre-specified scope and key questions of the AHRQ review, the authors considered whether the use* |

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| | as good as the sum of the individual studies included in the analysis. When this report is looked at with this in mind it is hard for us to see how the authors can feel confident in the conclusions that they made. The results from this AHRQ report specific to epidural injections were separately published by Chou et al. in September of 2015 in the Annals of Internal Medicine.[1] This publication clearly states that of the 30 trials that they analyzed comparing epidural corticosteroid injections for the treatment of lumbar radiculopathy to a placebo control, only three were rated as being of "good quality."<br><br>Of these three "good quality" trials, one was a study published by Iverson et al. titled "Effect of Caudal Epidural Steroid or Saline Injection In Chronic Lumbar Radiculopathy".[2] As the title implies, this study investigated the efficacy of epidural injections via a caudal approach for the treatment of "chronic" radiculopathy. A study such as this should never have been lumped together with studies investigating epidural injections via a transforaminal or interlaminar approach for acute or subacute radiculopathy as these are fundamentally different treatments and fundamentally different patient populations. This study should have been excluded from the analysis on these grounds, and the fact that it was not should strongly call into question the overall results of the meta-analysis.<br><br>There are two remaining "good quality" trials. One, published by Ghahrerman et al., showed good efficacy of epidural corticosteroid injections.[3] In contrast, the other trial, published by Karppinen et al. did not. However, the Karppinen trial reported only mean values for their outcomes in contrast to the Ghahrerman trial, which reported categorical outcomes. Reporting mean values only is a widely criticized method of analyzing response to any pain intervention as a group of "non-responders" can easily hide a group of "responders" when pain scores or functional scores are averaged out. The Ghahrerman trial is an excellent example of why this is the case. In this trial a 50% reduction in pain was defined as a | *of certain approaches or access methods (along with many other characteristics) influenced the effectiveness of these procedures. Those analyses are summarized in the coverage guidance.*<br><br>*With respect to the use of categorical as opposed to continuous outcomes, the authors of the AHRQ review stated that, "[A]s presented in the results, analyses on both continuous and dichotomous outcomes were presented. If anything, results using dichotomous outcomes (likelihood of experiencing a clinically meaningful benefit) showed less evidence of effectiveness than analyses based on continuous outcomes (mean change in pain or function scores)." Furthermore, the use of composite categorical outcomes that include a mix of pain relief and functional outcomes would be beyond the scope of this coverage guidance.* |

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| | successful response. Using this categorical outcome, at one month after injection, a significantly greater proportion of patients treated with transforaminal injection of steroid (54%) achieved relief of pain than did patients treated with transforaminal injection of local anesthetic (7%) or transforaminal injection of saline (19%), intramuscular injection of steroids (21%), or intramuscular injection of saline (13%). However, the authors of this study point out that if their data were subjected to an analysis of group means, transforaminal injection of steroids would have failed to demonstrate superior efficacy to transforaminal normal saline. This would clearly be a misleading conclusion.<br><br>It is our opinion that the conclusions of the meta-analysis published by Chou et al. should have been that the highest quality evidence published to date clearly shows that epidural corticosteroid injections are effective for the treatment of lumbar radiculopathy. Unfortunately, this point was lost by inappropriately lumping this evidence together with inferior quality trials and fundamentally different trials.<br><br>We would like to request that the authors of this coverage guidance look closer at the individual studies available on the interventions before making their determinations rather than relying on the conclusions of a large, inappropriately conducted meta-analysis. We think that when this is done it will become clear that it would be inappropriate to eliminate coverage for these interventions. | |
| NNNN1 | Comment is substantively similar to JJ1. | *Thank you for your comments.* |
| NNNN2 | We at OHSU always try to practice evidence-based medicine; however the evidence for pain procedures, like that for many medical treatments, is not black and white, and can be cherry-picked to support multiple theses. I think the key to proper utilization is careful patient selection, and open mindedness to evolving practice when evidence does become clear. I simply do not believe the evidence is | *Thank you for your comments.* |

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| | there to make such a radical shift in approach in unilateral fashion.<br><br>I try to utilize the interventional procedures as judiciously and responsibly as possible. I certainly understand that there are some pain providers in Oregon who do not follow similar standards, but poor judgment and misutilization by some providers should not penalize all, patients in particular. | |

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# Section 4.0

# Coverage Guidances

# HEALTH EVIDENCE REVIEW COMMISSION (HERC)
# COVERAGE GUIDANCE:
# BREAST CANCER SCREENING IN WOMEN AT ABOVE-AVERAGE RISK

**For VbBS/HERC meeting materials 5/18/2017**

### HERC Coverage Guidance

Annual screening mammography and annual screening MRI are recommended for coverage for women at above-average risk of breast cancer *(weak recommendation)*. This coverage, beginning at 30 years of age, includes women who have one or more of the following:

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

For women with a history of high dose chest radiation (≥ 20 Grey) before the age of 30, annual screening MRI and annual screening mammography are recommended for coverage beginning 8 years after radiation exposure or at age 25, whichever is later *(weak recommendation).*

For women with both a personal history and a family history of breast cancer, annual mammography, annual breast MRI and annual breast ultrasound are recommended for coverage *(weak recommendation)*.

For women with increased breast density, supplemental screening with breast ultrasound, MRI, or digital breast tomosynthesis is not recommended for coverage *(weak recommendation)*.

Breast PET-CT scanning and breast-specific gamma imaging are not recommended for coverage for breast cancer screening in any risk group *(strong recommendation)*.

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

## RATIONALE FOR DEVELOPMENT OF COVERAGE GUIDANCES AND MULTISECTOR INTERVENTION REPORTS

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as they seek to improve patient experience of care, population health, and the cost-effectiveness of health care. In the era of the Affordable Care Act and health system transformation, reaching these goals may require a focus on population-based health interventions from a variety of sectors as well as individually-focused clinical care. Multisector intervention reports will be developed to

address these population-based health interventions or other types of interventions that happen outside of the typical clinical setting.

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

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

Our reports are based on a review of the relevant research applicable to the intervention(s) in question. For coverage guidances, which focus on clinical interventions and modes of care, evidence is evaluated using an adaptation of the GRADE methodology. For more information on coverage guidance methodology, see Appendix A.

Multisector interventions can be effective ways to prevent, treat, or manage disease at a population level. For some conditions, the HERC has reviewed evidence and identified effective interventions, but has not made coverage recommendations, as many of these policies are implemented in settings beyond traditional healthcare delivery systems.

## 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. Assessments of confidence are from the published systematic reviews and meta-analyses, where available. Otherwise, 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: What breast cancer screening tests should be covered for women with above-average risk of breast cancer due to known or suspected mutations based on family history?** | | | | |
|---|---|---|---|---|
| **Outcomes** | **Estimate of Effect for Outcome/ *Confidence in Estimate*** | **Resource Allocation** | **Values and Preferences** | **Other Considerations** |
| **All-cause mortality** *(Critical outcome)* | Women with BRCA mutations diagnosed with breast cancer through annual 2-view mammography beginning at age 30 have lower all-cause mortality compared to women diagnosed with breast cancer outside of a screening program<br>HR 0.44, 95% CI 0.25 to 0.77<br>●○○○ *(Very low confidence)* | Increasing the frequency and decreasing the age requirements for screening mammography adds costs, as does the addition of screening MRI coverage. However, the size of this high-risk group is limited, so the effect on overall expenditures is not as great as it | Women with known or suspected mutations would strongly value breast cancer screening strategies that accurately detect cancer that will impact future morbidity and mortality, but that also decrease their risk of unnecessary worry and | |
| **Breast cancer morbidity** *(Critical outcome)* | High-risk women diagnosed with breast cancer through screening have a lower risk of death from breast cancer compared to similar unscreened women who are diagnosed with breast cancer<br>Lead-time adjusted HR 0.54, 95% CI 0.09 to 0.66<br>●○○○ *(Very low confidence)* | | | |

| Coverage question: What breast cancer screening tests should be covered for women with above-average risk of breast cancer due to known or suspected mutations based on family history? | | | | |
|---|---|---|---|---|
| **Outcomes** | **Estimate of Effect for Outcome/ *Confidence in Estimate*** | **Resource Allocation** | **Values and Preferences** | **Other Considerations** |
| | Women under age 50 with a family history of breast cancer with screen-detected breast cancer have a lower 10 year risk of death from breast cancer compared to similar unscreened women diagnosed with breast cancer<br>RR 0.80, 95% CI 0.66 to 0.96<br>●○○○ *(Very low confidence)* | would be for the general population. Depending on the sensitivity and specificity of the enhanced screening strategy, further diagnostic costs might be lessened by avoiding some recalls and biopsies, or diagnostic costs might be increased in the work-up of false positive screening tests.<br>Detection of breast cancers at an earlier stage would lower treatment requirements, and this would offset some of the costs of enhanced screening. | procedures. There would be some variability in how women would value an increased risk of a false-positive test and the subsequent need for biopsy or recall compared to a possible missed cancer diagnosis, but we assume that most high-risk women would have a strong preference for a screening strategy that is most likely to avoid a missed cancer diagnosis.<br><br>Preferences of patients and providers would weigh highly in favor of modest | |
| **Test performance characteristics** *(Important outcome)* | MRI is more sensitive than mammography, ultrasound, or clinical breast examination; MRI with mammography is more sensitive than either modality alone<br>●●●○ *(Moderate confidence)*<br><br>MRI and mammography, alone or in combination and using a Breast Imaging Reporting and Data System (BI-RADS) threshold of ≥4, have specificity >95%<br>●●●○ *(Moderate confidence)* | | | |
| **Cancer stage at diagnosis** *(Important outcome)* | Proportion of breast cancers >2 cm at diagnosis is lower for screen-detected cancers than for those diagnosed in unscreened women of the same age<br>28%-30% vs. 45%-61%<br>●○○○ *(Very low confidence)* | | | |
| **Recall rate/false positive test results** | Mammography with a BI-RADS threshold of ≥4 has higher positive predictive value than either MRI or | | | |

| **Coverage question: What breast cancer screening tests should be covered for women with above-average risk of breast cancer due to known or suspected mutations based on family history?** | | | | |
|---|---|---|---|---|
| **Outcomes** | **Estimate of Effect for Outcome/ *Confidence in Estimate*** | **Resource Allocation** | **Values and Preferences** | **Other Considerations** |
| *(Important outcome)* | MRI + mammography with a BI-RADS threshold of ≥4<br>34% vs. 25%<br>●●●○ *(Moderate confidence)* | | expenditure to detect more breast cancers at an earlier stage in this high risk group. | |
| **Rationale:** Women at above-average risk for breast cancer, due to strong family history or known/suspected mutations, appear to benefit from annual 2-view mammography beginning at age 30. MRI plus mammography is more sensitive than either modality alone, which would mean fewer false negative screens when both are utilized. Moderate resource allocation would be required for enhanced screening with mammography plus MRI, but this cost could be offset to some extent by savings in treatment costs by detecting cancers at an earlier stage. | | | | |
| **Recommendation:** Annual screening mammography and annual screening MRI are recommended for coverage for women at above-average risk of breast cancer *(weak recommendation)*. This coverage, beginning at 30 years of age, should include women who have one or more of the following:<br>• Greater than 20% lifetime risk of breast cancer<br>• BRCA1 or BRCA2 gene mutation, or who have not been tested for BRCA but have a first degree relative who is a BRCA carrier<br>• Personal history or a first-degree relative diagnosed with Bannayan-Riley-Ruvalcaba syndrome, Cowden syndrome, or Li-Fraumeni syndrome<br>• Other germline gene mutations known to confer a greater than 20% lifetime risk of breast cancer | | | | |

| **Coverage question: What breast cancer surveillance tests should be covered for women with a personal history and a family history of breast cancer?** | | | | |
|---|---|---|---|---|
| **Outcomes** | **Estimate of Effect for Outcome/ *Confidence in Estimate*** | **Resource allocation** | **Values and Preferences** | **Other Considerations** |
| **All-cause mortality** *(Critical outcome)* | Insufficient evidence | Moderate resource allocation would be required to include MRI | Women and their health care providers would see | |

| Coverage question: What breast cancer surveillance tests should be covered for women with a personal history and a family history of breast cancer? | | | | |
|---|---|---|---|---|
| **Outcomes** | **Estimate of Effect for Outcome/ *Confidence in Estimate*** | **Resource allocation** | **Values and Preferences** | **Other Considerations** |
| **Breast cancer morbidity** *(Critical outcome)* | Insufficient evidence | and ultrasound imaging in a surveillance strategy for cancer recurrence in the sizable population of women with a history of breast cancer. | significant value in moderate expenditures for surveillance strategies that increase detection rates for recurrent cancer, even if improved clinical outcomes are not demonstrated by evidence at this time. | |
| **Test performance characteristics** *(Important outcome)* | MRI has the best combination of sensitivity and specificity to detect ipsilateral recurrence following breast conserving surgery<br><br>Clinical exam + mammography + ultrasound + MRI has the highest sensitivity for detection of metachronous contralateral breast cancer after breast conserving surgery<br><br>MRI is more sensitive than other modalities for detecting ipsilateral recurrence following mastectomy<br><br>Mammography + ultrasound had the best sensitivity and specificity for metachronous contralateral breast cancer following mastectomy<br>●●●○ *(Moderate confidence)* | | | |
| **Cancer stage at diagnosis** *(Important outcome)* | Insufficient evidence | | | |

| **Coverage question: What breast cancer surveillance tests should be covered for women with a personal history and a family history of breast cancer?** | | | | |
|---|---|---|---|---|
| **Outcomes** | **Estimate of Effect for Outcome/ *Confidence in Estimate*** | **Resource allocation** | **Values and Preferences** | **Other Considerations** |
| **Recall rate/false positive test results** *(Important outcome)* | Insufficient evidence | | | |
| **Rationale:** For women with a personal history and family history of breast cancer, supplemental imaging studies (MRI and ultrasound) provide additional sensitivity and specificity in surveillance and screening for breast cancer recurrence. However, there is insufficient evidence to assess the critical outcomes of all-cause mortality and breast cancer morbidity, or the important outcomes of cancer stage at diagnosis, recall rate, or false positive rate. Patient and provider preference would certainly favor testing strategies that have the highest detection rates for recurrent cancer. | | | | |
| **Recommendation:** For women with both a personal history and a family history of breast cancer, annual mammography, annual breast MRI and annual breast ultrasound are recommended for coverage *(weak recommendation)*. | | | | |

| **Coverage question: What breast cancer screening tests should be covered for women with a history of chest irradiation at a young age?** | | | | |
|---|---|---|---|---|
| **Outcomes** | **Estimate of Effect for Outcome/ *Confidence in Estimate*** | **Resource allocation** | **Values and Preferences** | **Other Considerations** |
| **All-cause mortality** *(Critical outcome)* | Insufficient evidence | The addition of MRI scanning to mammographic screening would add cost, but overall expenditures would be low, due to the small size of this risk group. | Because this subpopulation of women is at significant risk (a risk level similar to the BRCA1 mutation), patients and providers would | |
| **Breast cancer morbidity** *(Critical outcome)* | Insufficient evidence | | | |
| **Test performance characteristics** | <u>Sensitivity</u><br>Mammography: 68% | | | |

| Coverage question: What breast cancer screening tests should be covered for women with a history of chest irradiation at a young age? | | | | |
|---|---|---|---|---|
| **Outcomes** | **Estimate of Effect for Outcome/ *Confidence in Estimate*** | **Resource allocation** | **Values and Preferences** | **Other Considerations** |
| *(Important outcome)* | MRI: 67%<br>Mammography + MRI: 94%<br><br><u>Specificity</u><br>Mammography: 93%<br>MRI: 94%<br>Mammography + MRI: 90%<br>●○○○ *(Very low confidence)* | | clearly value increased screening test sensitivity, even in the absence of proven benefit in any clinical outcome. Because of the small population size, long term clinical benefit would be challenging to establish. | |
| **Cancer stage at diagnosis** *(Important outcome)* | Insufficient evidence | | | |
| **Recall rate/false positive test results** *(Important outcome)* | Insufficient evidence | | | |
| **Rationale:** The combination of mammography and MRI appears to increase sensitivity of testing, and each modality detects malignancies that are missed by the other. Women who have had ≥20 Grey chest irradiation in childhood, adolescence, or early adulthood have a breast cancer risk similar to BRCA1 carriers. There is insufficient evidence to assess any outcome other than test performance characteristics. Expenditures would be relatively low, given the small numbers in this subpopulation. | | | | |
| **Recommendation:** For women with a history of high dose chest radiation (≥20 Grey) before the age of 30, annual screening MRI and annual screening mammography are recommended for coverage beginning 8 years after radiation exposure or at age 25, whichever is later *(weak recommendation).* | | | | |

| Coverage question: What breast cancer screening tests should be covered for women with heterogeneously or extremely dense breasts? | | | | |
|---|---|---|---|---|
| **Outcomes** | **Estimate of Effect for Outcome/ *Confidence in Estimate*** | **Resource allocation** | **Values and Preferences** | **Other Considerations** |
| **All-cause mortality** *(Critical outcome)* | Insufficient evidence | Supplemental screening with ultrasound, MRI, or DBT would add costs for those imaging studies, and total expenditures would be high, given the high percentage of women with increased breast density in the general screening population. Related to low positive predictive values, it is likely that costs for additional biopsies and other diagnostic testing would be significant, in the evaluation of false positive imaging. In the absence of clinical outcomes data, it is unknown whether any supplemental imaging | In the absence of clinical outcomes evidence, values and preferences for these supplemental screening tests would be highly variable. The challenges to accurate mammographic detection in women with dense breasts would suggest to many patients and providers that any additional advantage seen with these imaging studies has significant value.<br><br>There would be significant variability | There are no standardized criteria that define this risk group. The reproducibility of breast density determinations is quite limited, and breast density changes over time. Administratively it is difficult to separate out screenings for women with increased breast density, as there is no specific diagnosis code. |
| **Breast cancer morbidity** *(Critical outcome)* | Insufficient evidence | | | |
| **Test performance characteristics** *(Important outcome)* | HHUS<br>Sensitivity 83% to 88%<br>Specificity<br>CDR: 4.4/1000<br>●●○○ *(Low confidence)*<br><br>ABUS<br>Sensitivity 68%<br>Specificity 92%<br>CDR: 1.9 to 15.2/1000<br>●○○○ *(Very low confidence)*<br><br>MRI<br>Sensitivity 75% to 100%<br>Specificity 87% to 93%<br>CDR: 3.5 to 28.6/1000<br>●●○○ *(Low confidence)* | | | |

| Coverage question: What breast cancer screening tests should be covered for women with heterogeneously or extremely dense breasts? | | | | |
|---|---|---|---|---|
| **Outcomes** | **Estimate of Effect for Outcome/ *Confidence in Estimate*** | **Resource allocation** | **Values and Preferences** | **Other Considerations** |
| | DBT<br>CDR 1.4 to 3.9/1000<br>●●○○ *(Low confidence)* | costs would be offset by earlier detection and lower treatment expenses. | in how women would value an increased risk of a false-positive test and the subsequent need for biopsy or recall compared to a possible missed cancer diagnosis, but we assume that many women would have a strong preference to err on the side of avoiding a missed cancer diagnosis. | |
| **Cancer stage at diagnosis** *(Important outcome)* | Insufficient evidence | | | |
| **Recall rate/false positive test results** *(Important outcome)* | HHUS<br>Recall rate 14%<br>Positive predictive value 3% to 7%<br>●●○○ *(Low confidence)*<br><br>ABUS<br>Recall rate 2% to 14%<br>Positive predictive value 4%<br>●○○○ *(Very low confidence)*<br><br>MRI<br>Recall rate 9% to 23%<br>Positive predictive value 3% to 33%<br>●●○○ *(Low confidence)*<br><br>DBT<br>Recall reduction of 23.3/1000<br>●●○○ *(Low confidence)* | | | |

| Coverage question: What breast cancer screening tests should be covered for women with heterogeneously or extremely dense breasts? | | | | |
|---|---|---|---|---|
| **Outcomes** | **Estimate of Effect for Outcome/ *Confidence in Estimate*** | **Resource allocation** | **Values and Preferences** | **Other Considerations** |
| **Rationale:** Screening mammography is less accurate in women found to have increased breast density. Supplemental screening with breast ultrasound, breast MRI, or digital breast tomosynthesis may detect additional cancers, but we have low confidence in this effect. Positive predictive values for these supplemental screening tests are low. Additional expenditures would be significant for these imaging studies, and potentially significant for evaluation of false positive results. We are not confident that any improvement in cancer detection rates with these supplemental studies, even if clearly demonstrated, would result in cancers being detected at earlier stages, leading to earlier interventions that improve clinical outcomes. | | | | |
| **Recommendation:** For women with increased breast density, supplemental screening with breast ultrasound, MRI, or digital breast tomosynthesis is not recommended for coverage *(weak recommendation)*. | | | | |

| Coverage question: Is PET CT or breast specific gamma imaging recommended for coverage as a part of a screening strategy for any population at high risk for breast cancer? | | | | |
|---|---|---|---|---|
| **Outcomes** | **Estimate of Effect for Outcome/ *Confidence in Estimate*** | **Resource allocation** | **Values and Preferences** | **Other Considerations** |
| Insufficient evidence for any of the outcomes: all-cause mortality, breast cancer morbidity, test performance characteristics, cancer stage at diagnosis, recall rate/false positive test results | | Additional imaging modalities would increase the costs associated with breast cancer screening for any high risk group. It is unknown whether any portion of those costs would be offset by savings in diagnostic or treatment services. | It is unlikely that there would be strong preferences in favor of PET-CT scanning or breast-specific gamma imaging, in the absence of evidence of positive contributions to health outcomes. | |

| **Coverage question: Is PET CT or breast specific gamma imaging recommended for coverage as a part of a screening strategy for any population at high risk for breast cancer?** |
|---|
| **Rationale:** Considering that no outcomes evidence met the search criteria, that additional imaging studies add to the cost of screening, and that there are not strong values or preferences, we recommend against coverage of PET-CT or breast-specific gamma imaging for breast cancer screening in above average risk women. |
| **Recommendation:** Breast PET-CT scanning and breast-specific gamma imaging are not recommended for coverage for breast cancer screening in any risk group *(strong recommendation)*. |

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

# EVIDENCE OVERVIEW

## Clinical Background

Approximately 1 in 8 (12%) women in the United States develop invasive breast cancer during their lifetime, making breast cancer the second most common cancer (following skin cancer) in American women (American Cancer Society [ACS], 2016c). In 2013, there were 230,815 breast cancer diagnoses and 40,860 breast cancer deaths in women in the United States (Centers for Disease Control and Prevention [CDC], 2016a). In men, breast cancer is relatively rare, accounting for an additional 2,109 breast cancer diagnoses and 464 breast cancer deaths in 2013. The breast cancer mortality rate overall has steadily declined since 1989, but this trend disproportionately represents a larger decrease in breast cancer deaths among white women compared to other races and ethnicities (CDC, 2012).

An individual is considered at higher risk for breast cancer based on either a single factor that significantly increases risk or a combination of several factors that together greatly increase risk. Factors that significantly increase an individual's breast cancer risk include the following (Susan G. Komen, 2016a):

- BRCA1 or BRCA2 gene mutation
- Strong family history of breast cancer
- Personal history of invasive breast cancer or ductal carcinoma in situ (DCIS)
- Personal history of lobular carcinoma in situ (LCIS) or atypical lobular hyperplasia (ALH)
- Radiation treatment to the chest area between ages 10 and 30
- Li-Fraumeni syndrome, Cowden syndrome or Bannayan-Riley-Ruvalcaba syndrome, and ATM, CHEK2, or PALB2 gene mutations

The Breast Cancer Risk Assessment Tool, which is based on the Gail statistical model, is commonly used by health care providers to estimate both an individual's five-year and lifetime risk of breast cancer. The tool determines risk level based on seven risk factors: age, age at first menstrual period, age at birth of first child (or has not given birth), family history of breast cancer, number of past breast biopsies showing atypical hyperplasia, and race/ethnicity. Women evaluated as having a five-year risk of 1.67% or greater are often considered high-risk (Susan G. Komen, 2016c), as well as women who have a lifetime risk of 20% or greater (ACS, 2015). Women with a 15% to 20% lifetime risk of breast cancer are often considered to be at moderately increased risk of breast cancer (ACS, 2015). Additional risk factors associated with breast cancer include starting menopause after age 55, physical inactivity, dense breasts, use of combination hormone therapy, taking oral contraceptives, and alcohol consumption (CDC, 2016b).

There are a variety of tools that have been developed and validated to assess the lifetime or annual risk of breast cancer. These predictive tools usually incorporate information about family and personal history. Reviewing the operating characteristics of these models is beyond the scope of this review, though evidence reviews on this topic exist.

## Indications

The declining breast cancer mortality rate in the United States is partially attributed to greater screening efforts and thus earlier detection, in addition to fewer women using hormone therapy after menopause and improved quality of treatment (ACS, 2016c). Screening technology, such as mammography, can identify cancer at an earlier stage, before an individual experiences symptoms (ACS, 2016b). When detected early, abnormal tissue or cancer is easier to treat and patients have better outcomes. Women diagnosed with breast cancer in earlier stages have higher relative five-year survival rates from breast cancer (ACS, 2016a). The five-year survival rate for women with Stage 0 or Stage I breast cancer in the United States is almost 100%, compared to 22% for women with Stage IV breast cancer. Mammograms are the most widely used tool for breast cancer screening for asymptomatic women (ACS, 2017); however, other options include breast ultrasound, breast magnetic resonance imaging (MRI), positron emission tomography-computed tomography (PET-CT), breast self-exam, breast clinical exam, and breast-specific gamma imaging.

The Breast Imaging Reporting and Data System (BI-RADS) is a standard system used by physicians to describe the findings of a mammogram. BI-RADS defines mammogram results using seven categories, numbered zero through six (ACS, 2017).

- **Category 0**: Incomplete—Need additional imaging evaluation and/or comparison to previous mammograms
- **Category 1**: Negative—no significant abnormality to report
- **Category 2**: Benign (non-cancerous) finding
- **Category 3**: Probably benign finding
- **Category 4**: Suspicious abnormality
    - **Category 4a**: Low suspicion of cancer
    - **Category 4b**: Intermediate suspicion of cancer
    - **Category 4c**: Moderate suspicion of cancer
- **Category 5**: Highly suggestive of malignancy
- **Category 6**: Known biopsy-proven malignancy

The following terms are commonly used to describe the accuracy of screening tests:

- **Sensitivity** refers to the proportion of patients who have the condition in question who have a positive test result.
- **Specificity** refers to the proportion of patients who do not have the condition in question who have a negative test result.
- **Positive predictive value (PPV)** is the ratio of the number of true positives (patients who have a positive test result and have the condition) to the total number of patients with a positive test result.

- **Negative predictive value (NPV)** is the ratio of the number of true negatives (patients who have a negative test result and do not have the condition) to the total number of patients with a negative test result.
- The **receiver operating curve (ROC)** is a graphical illustration of the trade-off between sensitivity and specificity for an index diagnostic test (specifically for a test that has continuous rather than binary, or yes/no results) compared to a reference standard. The "index" test refers to the test being assessed for how accurate it is. The reference standard has sometimes been referred to as the "gold standard," but given that some reference standards are not themselves perfectly accurate, the terminology has shifted to "reference standard."
- The **area under the receiver operating curve (AUROC)** is an overall measure of how well the index test compares to the reference standard across a range of possible cutoffs. An index test that has a cutoff value that allows perfect sensitivity and specificity (i.e., perfect classification of patients with and without the condition) would have an AUROC of 1.0; an AUROC of 0.5 represents a useless test (no better than a coin flip, on average). A test with an AUROC of 0.80–0.89 is generally regarded as a good test, and tests with an AUROC >0.90 are regarded as excellent tests. These distinctions are conventional, but arbitrary.

# Technology Description

## Mammography (Standard and DBT)

A mammogram involves the patient standing in front of an X-ray machine with the breast placed on a clear plastic plate. A second plate is used to flatten the breast by pressing on the breast from above. In this position, a technologist takes an X-ray image of the breast. The process is repeated to capture multiple views of each breast. A radiologist reviews the images and provides a report to the patient or patient's doctor, typically within a few weeks (CDC, 2016c). Standard mammograms were printed on large sheets of film. Digital mammograms, now the most common type of mammograms, are recorded and saved on a computer. Digital breast tomosynthesis (DBT), a newer mammography technology, involves compressing the breast once as a machine moves over the breast to capture many X-rays at once, rather than a single image (ACS, 2016f).

## Breast MRI

A breast MRI uses strong magnets to take detailed, cross-sectional pictures of the breast from many angles. MRI technology is sometimes able to capture images of body tissue that are not easily detected by other imaging tests. The procedure involves the patient lying face down on a flat table with the breasts hanging down into an opening to be scanned. The table slides into a long, narrow cylinder. Typically, a contrast material called gadolinium is injected into an arm vein to help reveal more clearly the details of the breast tissue. A technologist checks to ensure that no further images are required, and a radiologist reviews the images (ACS, 2016d).

### Breast Ultrasound

A breast ultrasound is typically used to further examine a breast change identified on a mammogram. It can be used to distinguish between a solid mass and a lump that is really a cyst. During a breast ultrasound, a gel is applied to the breast and a transducer is moved across the breast to reveal the underlying tissue structure. The transducer uses sound waves to pick up echoes as they bounce off breast tissue, which are then represented as a computer image. The test does not involve radiation and is typically painless (ACS, 2016e).

### Clinical Breast Exam

A clinical breast exam, often completed during a patient's regular medical check-up, involves a trained provider carefully feeling the patient's breast, underarm, and breast bone for any changes or abnormalities such as a lump. The patient sits up while the provider visually checks the breasts, and lies down while the provider physically examines the breasts (Susan G. Komen, 2016b).

### Breast Self-Exam

A breast self-exam is a technique that involves patients examining their own breasts for any changes. Typically, the patient should perform a physical examination lying down and a visual examination standing up in front of a mirror. Instruction regarding the procedure and signs of change a patient should check for are often provided in patient education (Maurer Foundation, 2016).

### PET-CT Scan

A PET-CT scan is an imaging technique that combines PET and CT into one machine. The patient is injected with a glucose solution containing a small amount of radioactive material, which is absorbed more by cancer cells because these cells tend to be more active than non-cancerous cells. The patient lies on a table, which slides into a large tunnel-shaped scanner. The scanner detects abnormal or cancerous cells based on the distribution of the glucose solution. The combination of PET with CT provides more detailed images of the breast than either test alone (Cancer Treatment Centers of America, 2015)

### Breast-Specific Gamma Imaging

Breast-specific gamma imaging can be used to detect additional lesions missed by mammography and a physical exam. A radiotracer, Technetium-Tc99m-Sestamibi, is injected into the patient's bloodstream. The radiotracer tends to accumulate in areas with cancerous cells, which are more active than non-cancerous cells. A gamma camera modified for breast imaging is used to produce images, which reveal sites of abnormal cells based on the distribution of the radiotracer (Society of Nuclear Medicine and Molecular Imaging, n.d.).

## Key Questions and Outcomes

The following key questions (KQ) guided the evidence search and review described below. For additional details about the review scope and methods, please see Appendix C.

1. What is the comparative effectiveness of enhanced strategies for breast cancer screening in women with above-average risk?
2. Does the comparative effectiveness of enhanced strategies for breast cancer screening in women with above-average risk vary by:
    a. Reason for above-average risk
    b. Age
    c. Race or ethnicity
    d. Breast density
3. What are the harms of enhanced screening strategies for breast cancer in women with above-average risk?
4. What is the optimal screening interval in above-average risk women? Does the optimal screening interval vary by the:
    a. Characteristics listed in Key Question 2?
    b. Screening modality?

Critical outcomes selected for inclusion in the GRADE table were all-cause mortality and breast cancer morbidity. Important outcomes selected for inclusion in the GRADE table were test performance characteristics, cancer stage at diagnosis, and recall rate/false-positive test results.

# Evidence Review

## Women at Above-Average Risk of Breast Cancer Due to Family History or Known or Suspected Mutations

### *NICE, 2013*

This is a high-quality systematic review (including GRADE ratings) that was conducted to inform the creation of NICE clinical guidance. For the diagnostic operating characteristics, the authors identified one systematic review (Warner et al., 2008) of 11 observational studies, as well as three additional studies. To date, there are no randomized controlled trials that compare various screening strategies in women with above-average risk of breast cancer. Most of the studies included in the review enrolled women over the age of 25; the rate of known mutation carriers (when this was reported) varied by study from 8% to 100%. For women without a known mutation, high-risk criteria were variably defined as ≥15% lifetime risk, ≥20-25% lifetime risk, an annual risk of ≥0.9%, or a ≥30% mutation carrier probability as determined by various calculators and scoring systems. All but three of the studies included women with a personal history of breast cancer. The NICE estimates for the operating characteristics of the various tests (alone or in combination and at different BI-RADS thresholds for a positive screen) are reproduced in Table 1 below. The predictive values assume a 2% prevalence of breast cancer based on the findings from Warner and colleagues (2008).

**Table 1. Operating Characteristics of Breast Cancer Screening Tests for Women at Above-Average Risk Due to Family History or Known/Suspected Mutations (NICE, 2013)**

| Test | BI-RADS Threshold | # of studies (# of screens) | Sensitivity (95% CI) | Specificity (95% CI) | PPV (95% CI) | NPV (95% CI) |
|---|---|---|---|---|---|---|
| Mammography | ≥3 | 5 (6,678) | 0.39 (0.37 to 0.41) | 0.95 (0.93 to 0.97) | 15% (8% to 26%) | 1.3% (1.1% to 1.5%) |
| Mammography | ≥4 | 7 (8,818) | 0.32 (0.23 to 0.41) | 0.99 (0.98 to 0.99) | 34% (19% to 52%) | 1.4% (1.2% to 1.6%) |
| MRI | ≥3 | 5 (6,719) | 0.77 (0.7 to 0.84) | 0.86 (0.81 to 0.92) | 8% (6% to 11%) | 0.6% (0.4% to 0.8%) |
| MRI | ≥4 | 8 (8,857) | 0.75 (0.62 to 0.88) | 0.96 (0.95 to 0.97) | 25% (18% to 34%) | 0.4% (0.2% to 0.9%) |
| Mammography + MRI | ≥3 | 3 (2,509) | 0.94 (0.90 to 0.97) | 0.77 (0.75 to 0.80) | 8% | 0.2% (0.08% to 0.4%) |
| Mammography + MRI | ≥4 | 5 (4,272) | 0.84 (0.70 to 0.97) | 0.95 (0.94 to 0.97) | 25% (18% to 33%) | 0.3% (0.1% to 0.8%) |
| Ultrasound | ≥4 | 4 (2,971) | 0.32 to 0.60 | 0.91 to 1.0 | 10% to 100% | 1.8% to 4.2% |
| Mammography + Ultrasound | ≥4 | 1 (529) | 0.52 | 0.89 | 12% | 1.4% |
| Clinical breast examination | NA | 5 (12,325) | 0.09 to 0.50 | 0.94 to 0.99 | 4% to 81% | 0.4% to 8.7% |

Based on this, the authors concluded that there is moderate-quality evidence that MRI screening is more sensitive than other screening tests, and that the combination of MRI and mammography is more

sensitive than either test alone. In the single trial that stratified the operating characteristics by age groups (<40, 40 to 49, and >50), MRI was more sensitive than mammography in each group.

The authors of the NICE review identified only sparse evidence regarding clinical outcomes. Two studies provided very low-quality evidence that mammographically screen-detected invasive breast cancers in women under age 50 tend to be smaller than those diagnosed in unscreened women of the same age (proportion of screen-detected cancers >2 cm 28% to 30% vs. 45% to 61% >2 cm in the unscreened group). The same studies also provide very low-quality evidence that screen-detected invasive breast cancers in women under age 50 are less likely to have nodal involvement compared to cancers diagnosed in unscreened women of the same age. There is very low-quality evidence from one of these studies that death from breast cancer was less likely for women under age 50 with mammographically screen-detected cancers compared to those diagnosed in unscreened women of the same age (lead time adjusted HR 0.54, 95% CI 0.09 to 0.66). There is very low-quality evidence from a modeling study that mammography screening in women under age 50 with a family history of breast cancer results in lower 10-year risk of death from breast cancer when compared to similar women who were not screened (RR 0.80, 95% CI 0.66 to 0.96). Finally, there is very low-quality evidence from one study that among women with BRCA1 or BRCA2 mutations, all-cause mortality was lower for women diagnosed with breast cancer as part of an intensive mammography screening program when compared to similar women who were diagnosed with breast cancer outside the screening program (HR 0.44, 95% CI 0.25 to 0.77).

The authors also reviewed evidence about the risks of low-dose diagnostic radiation exposure in women with a genetic predisposition to breast cancer. Based on the results of case-control studies, there is low-quality evidence of an increased risk of breast cancer after exposure to mammography or chest X-ray (OR 1.3, 95% CI 0.9 to 1.8). This is further supported by the observed dose-response gradient in which the odds of developing breast cancer are greater in women with low-dose radiation exposure before age 20 (OR 2.0, 95% CI 1.3 to 3.1), and women who have had five or more low-dose exposures (OR 1.8, 95% CI 1.1 to 3.0).

### *Phi et al., 2016*

This is a good-quality systematic review and individual patient data meta-analysis of six high-risk screening studies to determine the added contribution of mammography beyond MRI screening in women with known BRCA mutations. The study included 1,219 women with BRCA1 mutations and 732 women with BRCA2 mutations. Among women with BRCA1 mutations, the combination of MRI and mammography improved sensitivity and reduced specificity compared to MRI alone in each age group, but the differences were not statistically significant. Among women with BRCA2 mutations, the combination of MRI and mammography improved sensitivity and reduced specificity compared to MRI alone, but the differences were not statistically significant. The authors noted that among women under age 40 with a BRCA2 mutation, combined mammography and MRI increased sensitivity to 0.87 over MRI alone (0.53), but this finding still did not achieve statistical significance (p=0.075). The authors calculated that the number of mammographic screens needed to detect one breast cancer missed by MRI in the initial screening round is 527 in women with BRCA1 mutations and 94 in women with BRCA2 mutations. In subsequent screening rounds, the number of mammographic screens needed to detect on breast

cancer missed by MRI increases to 717 for women with BRCA1 mutations and 231 for women with BRCA2 mutations.

## Women with a Personal History and Family History of Breast Cancer

### *NICE, 2013*

This is a high-quality systematic review (including GRADE ratings) that was conducted to inform the creation of NICE clinical guidance. For the diagnostic operating characteristics, the authors identified one systematic review of eight observational studies (Robertson et al., 2011) and one additional study. The additional study (Sardanelli et al., 2011), which contributes the estimates for most of the combined modalities, included high-risk women with and without a personal history of breast cancer. The studies included in the systematic review and the additional study were judged to be of moderate quality; meta-analysis was not attempted because of heterogeneity across the studies. The NICE estimates for the sensitivity and specificity of the various tests (alone or in combination) are in Table 2.

**Table 2. Sensitivity and Specificity of Breast Cancer Screening Tests for Women with a Personal History of Breast Cancer (NICE, 2013)**

| Test | # of studies | Sensitivity | Specificity |
|---|---|---|---|
| Clinical breast exam | 5 | 0.0 to 0.89 | 0.49 to 0.99 |
| Mammography | 6 | 0.50 to 0.83 | 0.50 to 0.99 |
| Ultrasound | 3 | 0.43 to 0.87 | 0.31 to 0.98 |
| MRI | 7 | 0.86 to 1.0 | 0.50 to 0.97 |
| Mammography + Ultrasound | 2 | 0.62 to 0.95 | 0.98 to 0.99 |
| MRI + Mammography | 1 | 0.93 | 0.96 |
| MRI + Ultrasound | 1 | 0.93 | 0.96 |
| Clinical exam + Mammography | 1 | 1.0 | 0.67 |
| Clinical exam + Mammography + Ultrasound | 1 | 0.64 | 0.84 |
| Clinical exam + Mammography + Ultrasound + MRI | 1 | 1.0 | 0.89 |

Based on the diagnostic operating characteristics, the authors concluded that there is moderate-quality evidence that MRI has the best combination of sensitivity and specificity to detect ipsilateral recurrence after breast-conserving surgery. There is moderate-quality evidence that the combination of clinical exam, mammography, ultrasound, and MRI had the highest sensitivity for detection of metachronous contralateral breast cancer after breast-conserving surgery. There was moderate-quality evidence that MRI is more sensitive than other modalities for detecting ipsilateral recurrence after mastectomy, and

that combined mammography and ultrasound had the best sensitivity and specificity for metachronous contralateral breast cancer after mastectomy. The authors found no evidence comparing different screening modalities on clinical outcomes including stage at detection and survival.

## Women Who Have Undergone Breast-Conserving Therapy for Breast Cancer

### *Shah et al., 2016*

This is a poor-quality narrative systematic review that addresses the role of MRI in women who have undergone breast-conserving therapy (BCT) for breast cancer. There were no randomized controlled trials that addressed the use of MRI after BCT. The review identified three prospective observational studies, 12 retrospective observational studies, two systematic reviews, and one clinical guideline that addressed the sensitivity of MRI in this population. Inclusion and exclusion criteria were not clearly specified and the review did not describe all of the studies identified for inclusion; the studies that are described were not critically appraised. One of the included systematic reviews (Robertson et al, 2011) also included women with an above-average risk of breast cancer due to family history and routine and non-routine surveillance populations. Overall, the authors of the review concluded that "MRI has been found to have increased sensitivity in detecting recurrences as compared with mammography" (p. 317). The authors recommended breast MRI in three scenarios: 1) when mammographic abnormalities are identified in women who have undergone BCT, 2) before surgical intervention or biopsy for suspected recurrence, and 3) routinely for patients at high risk of local recurrence. They acknowledged that no threshold for high risk of local recurrence has been established. Because of the serious limitations of this review, the conclusions should be interpreted with caution.

## Screening in Women with a History of Chest Irradiation at a Young Age

### *Koo et al., 2015*

This is a fair-quality narrative review of the management and prevention of breast cancer in women who received chest radiation in childhood, adolescence, or young adulthood. Data from cohorts and systematic reviews of patients who received mantle irradiation for Hodgkin's lymphoma have found overall relative risk of breast cancer of 8.2 compared to the general population and the risk of breast cancer by age 50 after chest radiation is similar to that of women with BRCA1 mutations. The authors of the review identified four studies evaluating MRI and mammography in women with a history of chest irradiation. Three of the studies were retrospective. The authors reported that the sensitivity of mammography, MRI, and mammography + MRI ranged from 67% to 70%, 67% to 92%, and 94% to 100% respectively.

In the single prospective study that was included (Ng et al., 2013), 148 Hodgkin's lymphoma survivors underwent annual breast MRI and mammography for three years, during which time 18 women had screen-detected malignancies (eight with invasive ductal carcinoma, nine with DCIS, and one with a Phyllodes tumor). Seven of the tumors were detected by both modalities (six invasive), five by MRI only (one invasive), and six by mammogram only (one invasive, one Phyllodes). Only one of the screen-detected cancers was associated with positive lymph nodes; all women underwent surgery with or

without adjuvant chemotherapy and all were free of disease at 9 to 67 months of follow-up. There was only one tumor (a small focus of DCIS discovered in a contralateral prophylactic mastectomy specimen) that was not detected by either screening modality. After excluding women undergoing first-ever screening with one or both of the modalities and women with fewer than 12 months of follow-up after the third year of screening, the sensitivity of mammography, MRI, and mammography + MRI was 68%, 67%, and 94% respectively. The specificity of mammography, MRI, and mammography + MRI was 93%, 94%, and 90% respectively. Notably, two of the women in the cohort died from potential late complications of radiation therapy (cardiac disease and non-small cell lung cancer), an observation that the authors stated could attenuate the survival benefits of breast cancer screening in this population. Additionally, the women included in this cohort were mainly treated during a time when larger fields and higher doses of radiation were used to treat Hodgkin's lymphoma.

The authors of the review highlighted the recommendations of the International Late Effects of Childhood Cancer Guideline Harmonization Group that women with a history of ≥20 Gray of chest radiation before age 30 should undergo annual screening with mammography and MRI beginning eight years after radiation or age 25 (whichever is later).

## Supplemental Screening in Women with Dense Breasts

### *Melnikow et al., 2016*

This is a good-quality systematic review of supplemental or adjunctive screening after negative mammography in women with heterogeneously or extremely dense breasts. The authors summarized data about the reproducibility of breast density determinations. They noted that on ensuing screening exams for women identified as having dense breasts, there is an approximately 1 in 5 chance that breast density will be reclassified when read by the same radiologist; when a different radiologist interprets the subsequent images, the likelihood of reclassification rises to about 1 in 3.

The authors identified two good-quality and three fair-quality studies of operating characteristics of handheld ultrasound (HHUS) after a negative mammogram. The estimates of sensitivity of HHUS were 0.8 to 0.83 and the cancer detection rate was 4.4 per 1,000 in the two good-quality studies. The estimates of specificity of HHUS after a negative mammogram was 0.86 to 0.95 in the two good-quality studies; the PPV1 was 3% in one study and 7% in the other study. One of the high-quality studies reported a recall rate of 14% (U.S.-based study), and the other study did not report recall rate. The authors noted that the sensitivity and specificity of HHUS were similar for invasive and noninvasive cancers. There was no data on the effect of supplemental screening with HHUS on clinical outcomes.

The authors identified one fair-quality study of operating characteristics of automated whole-breast breast ultrasound (ABUS) after negative mammography. In that study, the sensitivity and specificity of ABUS were 0.68 and 0.92 respectively; the PPV1 was 4%. The cancer detection rate for ABUS was 3.6 per 1,000 and the recall rate was 9%. Two other fair-quality studies that only reported on cancer detection outcomes for ABUS found cancer detection rates ranging from 1.9 to 15.2 per 1,000 and recall rates of 2% to 14%. There was no data on the effect of supplemental screening with ABUS on clinical outcomes.

The authors identified three good-quality studies of operating characteristics of MRI after a negative mammogram. Because these studies also included women with heightened risk of breast cancer (including those with BRCA mutations), the authors only considered the subgroups of lower risk women with dense breasts. The sensitivity and specificity of MRI ranged from 0.75 to 1.0 and 0.87 to 0.93 respectively; the PPV1 ranged from 3% to 33%. The cancer detection rate in these studies ranged from 3.5 to 28.6 per 1,000; two studies reported that 67% and 86% of the cancers detected by MRI were invasive. The recall rate after MRI ranged from 9% to 23%, and was highest in the study with multiple rounds of supplemental MRI screening. There were no data on the effect of supplemental screening with MRI on clinical outcomes.

The authors identified four fair-quality studies of DBT in women with dense breasts that reported on cancer detection outcomes. In the three studies that reported the cancer detection rate, DBT + DM (5.4–6.9 per 1,000) was superior to DM (4.0–5.2 per 1,000), with one study also demonstrating equivalent proportions of invasive cancers in both groups. All four studies reported that recall rates were also lower with DBT + DM (range 7% to 11%) compared to DM (9% to 17%). There were no data on the effect of combined DBT + DM on clinical outcomes.

### *Houssami & Turner, 2016*

This is a rapid review and meta-analysis of cancer detection and recall rates for DBT in women with dense breasts. The authors divided the trials into prospective studies that compared screening detection in the same subjects between DM and DBT, and retrospective studies that compared screening detection in different groups of subjects. It should be noted that in one of the included trials, the patients had been referred for adjunctive screening after a negative digital mammogram. In the meta-analysis of prospective studies, the incremental cancer detection rate was 3.9 additional cancers identified per 1,000 screens with DBT (95% CI 2.7 to 5.1 per 1,000). In the meta-analysis of the retrospective studies, the incremental cancer detection rate was 1.4 additional cancers identified per 1,000 screens with DBT (95% CI 0.9 to 2.0 per 1,000). Pooled estimates for the difference in recall rates could only be estimated from the retrospective trials; in that analysis, DBT resulted in 23.3 fewer recalls per 1,000 screens compared to DM (95% CI -29.9 to -16.8 per 1,000).

## EVIDENCE SUMMARY

There is no direct evidence that compares different screening regimens for women at above-average risk of breast cancer with respect to clinical outcomes.

There is very low-quality evidence that women with mammographically screen-detected cancers have better clinical outcomes compared to unscreened women who are diagnosed with breast cancer. There is moderate-quality evidence that MRI is more sensitive than other screening tests in women with known or suspected mutations that increase the risk of breast cancer.

For women with a personal history and family history of breast cancer, there is moderate-quality evidence that MRI has the best combination of sensitivity and specificity to detect ipsilateral recurrence after breast-conserving surgery. There is moderate-quality evidence that the combination of clinical exam, mammography, ultrasound, and MRI had the highest sensitivity for detection of metachronous

contralateral breast cancer after breast-conserving surgery. There was moderate-quality evidence that MRI is more sensitive than other modalities for detecting ipsilateral recurrence after mastectomy, and that combined mammography and ultrasound had the best sensitivity and specificity for metachronous contralateral breast cancer after mastectomy.

For women with a history of chest irradiation at a young age, there is low-quality evidence that the combination of mammography and MRI offers the highest sensitivity for screen detection of breast cancer.

For women with heterogeneously or extremely dense breasts, there is low- to moderate-quality evidence that supplemental screening with HHUS, ABUS, or MRI after a negative mammogram can detect additional cancers, with recall rates and positive predictive value of supplemental screening varying by modality. There is low-quality evidence that supplemental screening with DBT increases the cancer detection rate while decreasing the recall rate.

# Other Decision Factors

## Resource Allocation

Based on the fee schedule for fee-for-service Medicare, the costs of relevant imaging studies are as follows (2017, Portland, OR service area):

- Digital mammography (screening) $143.61:
- Breast MRI (bilateral): $569.61
- Breast ultrasound (complete): $113.45
- Digital breast tomosynthesis: $58 (in addition to digital mammography fee)

Total costs to implement additional screening strategies will vary, depending on the prevalence of risk factors in the population to be screened.

The lifetime risk of breast cancer in U.S. women is 12%, so the proportion of mammographic screenings for women with a personal history of breast cancer is not insignificant.

BRCA1 and BRCA2 gene mutations are relatively rare in the general population. In the U.S., between 1 in 400 and 1 in 800 people have a BRCA1/2 mutation, with prevalence varying by ethnic group. However, women who have the BRCA1 or BRCA2 mutation (BRCA1/2 carriers) have a significantly increased risk of breast cancer. BRCA1 carriers have a 55-65% chance of developing breast cancer by age 70, and BRCA2 carriers have about a 45% chance of developing breast cancer by age 70 (Komen, 2016a).

To the extent that enhanced screening strategies lower rates of recall and/or detect cancer at an earlier stage, leading to improved outcomes, the additional costs of the imaging studies would be offset by savings in diagnostic and treatment costs.

## Values and Preferences

Women would strongly value breast cancer screening strategies that accurately detect cancer that will affect future morbidity and mortality, but that also decrease their risk of unnecessary worry and

procedures. If a test is much more likely to pick up a cancer, women would strongly favor it if they knew it would affect their long-term outcomes. There would be significant variability in how women would value an increased risk of a false-positive test and the subsequent need for biopsy or recall compared to a possible missed cancer diagnosis, but we assume that many women would have a strong preference to err on the side of avoiding a missed cancer diagnosis.

Because the prevalence of breast cancer is higher in certain risk groups, the value of expenditures for enhanced screening becomes more apparent, as cancers will be detected in a higher proportion of the performed tests. Preferences of patients and providers would weigh highly in favor of modest expenditure to detect more breast cancers at an earlier stage in groups at high risk for breast cancer.

Breast cancer screening carries a risk of harm, with potential morbidity from overdiagnosis and overtreatment of detected abnormalities. However, detection of carcinoma-in-situ and other suspicious lesions in high-risk populations is more likely to be seen as beneficial in groups that have a high likelihood of developing invasive breast cancer. As an example of such preferences, BRCA-positive women have prophylactic bilateral mastectomy as an accepted treatment option, even in the absence of known or suspected lesions.

# POLICY LANDSCAPE

## Quality measures

A search of the National Quality Measures Clearinghouse did not identify any measures directly related to breast cancer screening for women at above-average risk for breast cancer.

## Payer Coverage Policies

Coverage policies were assessed for Aetna, Cigna, Moda, and Regence for breast screening for women at above-average risk for breast cancer and are outlined below.

### *Coverage Policies for Standard Mammography*

In addition to providing coverage for annual mammography screening for women aged 40 and older, both Aetna and Cigna consider annual mammography medically necessary for certain women younger than 40 who are at increased risk of breast cancer. This includes patients with a history of breast cancer, a BRCA mutation, a history of high-dose thoracic irradiation, as well as patients with a personal history or a first-degree relative diagnosed with Bannayan-Riley-Ruvalcaba syndrome, Cowden syndrome, or Li-Fraumeni syndrome. Aetna additionally covers women who meet criteria for BRCA mutation testing, prophylactic mastectomy, or prophylactic oophorectomy. Cigna additionally provides coverage for women who have not been tested for a BRCA mutation with a first-degree relative who is a carrier, as well as women with at least a 1.7% five-year risk or 20% lifetime risk of invasive breast cancer. Regence covers annual mammography screening for women aged 40 and older and provides additional coverage for women at high risk, without specifying criteria for defining high risk. Moda covers breast cancer screening for women ages 40 and older, but no policy further detailing coverage by level of risk was identified.

### *Coverage Policies for DBT*

Aetna, Moda, and Regence all consider DBT experimental and investigational and do not provide coverage for DBT for patients at any risk level. Cigna considers DBT medically appropriate for the screening of breast cancer.

### *Coverage Policies for MRI*

Aetna provides coverage for breast MRI as an adjunct to mammography for screening women who are considered to be at high genetic risk of breast cancer, including women with certain genetic mutations (e.g., BRCA mutation, Li-Fraumeni syndrome, Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome), a first degree relative with a BRCA mutation (if patient is untested), or a 20% to 25% lifetime risk of breast cancer as determined by a standard risk assessment tool. Aetna also considers breast MRI medically necessary for patients with a history of radiation treatment to the chest between ages 10 and 30 who have had a mammogram or breast sonogram within the past year when the MRI may affect clinical management of the patient.

## Medicaid

Washington Medicaid provides coverage for an annual screening mammography for patients ages 40 and over, as well as for DBT when performed with a screening mammography for clients ages 40 through 74. Prior authorization is required for screening mammograms, with or without DBT, for clients younger than 40. A medical necessity review by Qualis Health is required prior to coverage for a breast MRI when billed as an outpatient hospital claim.

## Medicare

No National Coverage Determinations or Local Coverage Determinations specifically related to breast cancer screening for women at above-average risk were identified.

# Professional Society Guidelines

Recommendations related to any of the breast cancer screening modalities discussed in this Coverage Guidance are outlined below from five guidelines that address breast cancer screening for women at above-average risk for breast cancer. The guidelines consistently recommend considering earlier or enhanced breast cancer screening for women at increased risk of breast cancer. Annual breast MRI, in addition to annual mammography screening, is recommended by most guidelines for women who have a lifetime risk of breast cancer that is 20% or greater, a BRCA mutation (or a first-degree relative carrier if untested), or a history of radiation therapy to the chest between ages 10 and 30. Some of the guidelines specify an age restriction, stating that an MRI should not be performed before the age of 25 and a mammography screening should not be performed before the age of 30. Two of the guidelines recommend the use of ultrasound when MRI is contraindicated for patients who would otherwise be candidates for MRI.

The USPSTF 2016 Final Recommendation Statement, *Breast Cancer: Screening,* which is endorsed in the American Academy of Family Physicians 2016 *Summary of Recommendations for Clinical Preventive*

*Services*, makes the following recommendations regarding breast cancer screening for women at above-average risk for breast cancer (USPST, 2016):

- The decision to use screening mammography in women younger than 50 is an individual one. Women who have a first-degree relative with breast cancer may benefit more than average-risk women from beginning screening in their 40s because of their increased risk.
- The current evidence is insufficient to recommend for or against adjunctive screening (i.e., breast ultrasound, MRI, DBT, or other methods) for breast cancer in women with dense breasts on an otherwise negative screening mammogram.

The 2015 *American Cancer Society Recommendations for Early Breast Cancer Detection in Women Without Breast Symptoms* makes the following recommendations regarding breast cancer screening for women at above-average risk for breast cancer (ACS, 2015):

- Women at high risk of breast cancer based on certain risk factors should receive annual screening using both mammography and MRI; this includes women with a 20% or greater lifetime risk of breast cancer, a known BRCA gene mutation or first-degree relative with a BRCA gene mutation (if untested), a history of radiation therapy to the chest between ages 10 and 30, Li-Fraumeni syndrome, Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome, or a first-degree relative with one of these syndromes.
- There is not sufficient evidence to recommend for or against annual MRI screening as an adjunct to mammography for women who are at a moderately increased risk of breast cancer, which is defined as a lifetime risk of 15% to 20%. This also includes women who are at increased risk of cancer because of a personal history of breast cancer, DCIS, LCIS, atypical ductal hyperplasia (ADH), or ALH, as well as women with dense breasts.
- For women at high risk of breast cancer, screening with both MRI and mammography should begin at age 30. However, evidence regarding the best age to begin screening is limited and thus it is important this decision is made based on shared decision-making between patients and their health care providers.

The American College of Obstetricians and Gynecologists (ACOG) 2011 Practice Bulletin, *Breast Cancer Screening* (reaffirmed 2014), makes the following recommendations regarding breast cancer screening for women at above-average risk for breast cancer (ACOG, 2014):

- Enhanced screening is recommended for women who test positive for BRCA mutations or for untested women with first-degree relatives with these mutations, as well as for women who have an estimated lifetime risk of breast cancer that is 20% or greater as determined by risk assessment tools. Enhanced screening for this population should include biannual clinical breast examination, annual mammography, annual breast MRI, and instruction in breast self-examination.
- Enhanced screening is recommended for women with personal history of invasive breast cancer or high-risk breast biopsy results (e.g., atypical hyperplasia, LCIS, and DCIS). Enhanced screening for this population should include a clinical breast examination every 6 to 12 months, annual mammography, and instruction in breast self-examination. Additionally, annual breast MRI is

recommended for women with a history of LCIS by some organizations, but is not consistently recommended for women with a personal history of invasive breast cancer or DCIS.

- Enhanced screening, involving an annual mammogram, annual MRI, and a clinical breast exam every 6 to 12 months, is recommended for women who received thoracic irradiation between ages 10 and 30 to begin 8–10 years after they received treatment, but not before the age of 25.
- Ultrasound may be considered for additional screening in women at high risk who are candidates for MRI but cannot receive MRI because of a contraindication.

The 2012 *American College of Radiology* (*ACR) Appropriateness Criteria for Breast Cancer Screening* (last reviewed 2016) makes the following recommendations regarding breast cancer screening for women at above-average risk for breast cancer (ACR, 2016):

- Women at high risk of breast cancer (i.e., women with a BRCA mutation and their untested first-degree relatives, women with a history of chest irradiation between the ages 10 and 30, and women with a 20% or higher lifetime risk of breast cancer) should receive a mammography screening, DBT screening, and breast MRI beginning at age 25 to 30 or 10 years before the youngest age at diagnosis of a first-degree relative with breast cancer or eight years after radiation therapy (but not before the age of 25). Breast ultrasound should be considered if a patient is contraindicated for a breast MRI.
- It is appropriate for women at intermediate risk of breast cancer (i.e., women with personal history of breast cancer, lobular neoplasia, or atypical ductal hyperplasia, or with a 15% to 20% lifetime risk of breast cancer) to receive mammography, DBT, and breast MRI screenings.

The National Comprehensive Cancer Network (NCCN) 2016 guidelines, *Breast Cancer Screening and Diagnosis*, makes the following recommendations regarding breast cancer screening for women at above-average risk for breast cancer (NCCN, 2016):

- Women ages 35 and older with a 1.7% five-year risk of invasive breast cancer (based on the Gail statistical model) should receive an annual screening mammogram and a clinical breast exam every 6 to 12 months to begin at an age identified as being at increased risk.
- Women who have a 20% or greater lifetime risk of breast cancer based on high-risk biopsy results (i.e., LCIS or atypical hyperplasia) should receive an annual mammogram and clinical breast exam every 6 to 12 months to begin at age of diagnosis, but a mammogram should not be offered before the age of 30. MRI should also be considered for annual breast screening, but breast MRI should not be offered before the age of 25.
- Women who have a 20% or greater lifetime risk of breast cancer based on models relying largely on family history should receive both an annual mammogram and annual breast MRI to begin 10 years before the youngest family member's age at diagnosis. However, an MRI should not be offered before the age of 25 and a mammogram should not be offered before the age of 30. A clinical breast exam is recommended every 6 to 12 months to begin at the age identified as being at increased risk.
- Women with a history of thoracic radiation therapy between the ages of 10 and 30 should receive an annual clinical breast exam to begin 8 to 10 years after treatment when younger than 25. At the age of 25 and older, these women should receive an annual screening mammogram

and breast MRI, as well as a clinical breast exam every 6 to 12 months, to begin 8–10 years after treatment.

- DBT technology should be considered when mammography is advised.

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

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

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# APPENDIX A. GRADE INFORMED FRAMEWORK – ELEMENT DESCRIPTIONS

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

## Strong recommendation

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

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

## Weak recommendation

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

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

## Confidence in estimate rating across studies for the intervention/outcome[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.

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

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

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

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

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

# APPENDIX B. GRADE EVIDENCE PROFILE

| Quality Assessment (Confidence in Estimate of Effect)<br>Screening in Women with a Known or Suspected Mutation | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No. of Studies** | **Study Design(s)** | **Risk of Bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Factors** | **Quality** |
| **All-cause mortality** | | | | | | | |
| 1 | Observational | High | None | None | None | None | Very low confidence in estimate of the effect ●○○○ |
| **Breast cancer morbidity** | | | | | | | |
| Death from breast cancer 2 | Observational | High | None | Not serious in one study, serious in the other | None | None | Very low confidence in estimate of the effect ●○○○ |
| **Test performance characteristics** | | | | | | | |
| See note | | | | | | | See note |
| **Cancer stage at diagnosis** | | | | | | | |
| Tumor size at diagnosis 1 | Observational | High | None | None | None | | Very low confidence in estimate of the effect ●○○○ |
| **Recall rate/False positive rate** | | | | | | | |
| See note | | | | | | | See note |

Note: At the time the NICE evidence review was prepared, it was not common practice to assign GRADE ratings to diagnostic performance characteristics of tests. Thus, the authors merely present the findings as moderate-quality evidence based on the risk of bias assessment for the included studies; other GRADE domains were not assessed.

| Quality Assessment (Confidence in Estimate of Effect)<br>Screening in Women with a Personal History of Breast Cancer | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No. of Studies** | **Study Design(s)** | **Risk of Bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Factors** | **Quality** |
| **All-cause mortality** | | | | | | | |
| | | | | | | | Insufficient evidence |
| **Breast cancer morbidity** | | | | | | | |
| | | | | | | | Insufficient evidence |
| **Test performance characteristics** | | | | | | | |
| See note | | | | | | | See note |
| **Cancer stage at diagnosis** | | | | | | | |
| | | | | | | | Insufficient evidence |
| **Recall rate/False positive rate** | | | | | | | |
| | | | | | | | Insufficient evidence |

Note: At the time the NICE evidence review was prepared, it was not common practice to assign GRADE ratings to diagnostic performance characteristics of tests. Thus, the authors merely present the findings as moderate-quality evidence based on the risk of bias assessment for the included studies; other GRADE domains were not assessed.

| Quality Assessment (Confidence in Estimate of Effect)<br>Screening in Women with a History of Chest Irradiation at a Young Age | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No. of Studies** | **Study Design(s)** | **Risk of Bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Factors** | **Quality** |
| **All-cause mortality** | | | | | | | |
| | | | | | | | Insufficient evidence |
| **Breast cancer morbidity** | | | | | | | |
| | | | | | | | Insufficient evidence |
| **Test performance characteristics** | | | | | | | |
| 1 | Observational | Moderate | None | Serious (only included patients with a history of | None | Sparse data | Very low confidence in the estimate of the effect ●○○○ |

| Quality Assessment (Confidence in Estimate of Effect)<br>Screening in Women with a History of Chest Irradiation at a Young Age | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No. of Studies** | **Study Design(s)** | **Risk of Bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Factors** | **Quality** |
| | | | | Hodgkin's lymphoma) | | | |
| **Cancer stage at diagnosis** | | | | | | | |
| | | | | | | | Insufficient evidence |
| **Recall rate/False positive rate** | | | | | | | |
| | | | | | | | Insufficient evidence |

| Quality Assessment (Confidence in Estimate of Effect)<br>Screening in Women with Heterogeneously or Extremely Dense Breasts | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No. of Studies** | **Study Design(s)** | **Risk of Bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Factors** | **Quality** |
| **All-cause mortality** | | | | | | | |
| | | | | | | | Insufficient evidence |
| **Breast cancer morbidity** | | | | | | | |
| | | | | | | | Insufficient evidence |
| **Test performance characteristics** | | | | | | | |
| HHUS 5 | Observational | Low to moderate | None | None | None | | Low confidence in the estimate of the effect ●●○○ |
| ABUS 1 | Observational | Moderate | None | None | None | Sparse data | Very low confidence in the estimate of the effect ●○○○ |
| MRI 3 | Observational | Low | None | None | None | | Low confidence in the estimate of the effect ●●○○ |

| Quality Assessment (Confidence in Estimate of Effect)<br>Screening in Women with Heterogeneously or Extremely Dense Breasts | | | | | | | |
|---|---|---|---|---|---|---|---|
| **No. of Studies** | **Study Design(s)** | **Risk of Bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other Factors** | **Quality** |
| DBT<br>8 | Observational | Low to moderate | None | None | None | | Low confidence in the estimate of the effect<br>●●○○ |
| **Cancer stage at diagnosis** | | | | | | | |
| | | | | | | | Insufficient evidence |
| **Recall rate/False positive rate** | | | | | | | |
| HHUS<br>2 | Observational | Low to moderate | None | None | None | | Low confidence in the estimate of the effect<br>●●○○ |
| ABUS<br>3 | Observational | Moderate | None | None | None | | Very low confidence in the estimate of the effect<br>●○○○ |
| MRI<br>3 | Observational | Low | None | None | None | | Low confidence in the estimate of the effect<br>●●○○ |
| DBT<br>4 | Observational | Low to moderate | None | None | None | | Low confidence in the estimate of the effect<br>●●○○ |

# APPENDIX C. METHODS

## Scope Statement

### *Populations*

Women at above-average age-adjusted risk of breast cancer or who have dense breasts

Population scoping notes: Includes women with preexisting breast cancer, a personal history of breast cancer, clinically significant BRCA gene mutations (Li-Fraumeni syndrome, Cowden syndrome, hereditary diffuse gastric cancer, or other familial breast cancer syndromes), high-risk lesions (ductal or lobular carcinoma in situ, atypical ductal or lobular hyperplasia), or previous large doses of chest radiation therapy (≥20 Gy) before age 30 years

### *Interventions*

Standard digital (2-D) mammography, digital breast tomosynthesis (3-D/2-D), breast ultrasound, breast MRI, PET CT, self-exam, clinical exam, breast-specific gamma imaging, screening regimens involving combinations or alternating use of the above tests at various intervals

Intervention exclusions: *None*

### *Comparators*

No screening, average risk screening regimens, comparisons of above tests to each other

### *Outcomes*

Critical: All-cause mortality, breast cancer morbidity

Important**:** Test performance characteristics, cancer stage at diagnosis, recall rate/false-positive test results

*Considered but not selected for the GRADE table: cancer-specific mortality, radiation exposure PPV for recalls, PPV for biopsies, cancer detection rate, and invasive cancer detection rate*

### *Key Questions*

KQ1: What is the comparative effectiveness of enhanced strategies for breast cancer screening in women with above-average risk?

KQ2: Does the comparative effectiveness of enhanced strategies for breast cancer screening in women with above-average risk vary by:

a. Reason for above-average risk
b. Age
c. Race or ethnicity
d. Breast density

KQ3: What are the harms of enhanced screening strategies for breast cancer in women with above-average risk?

KQ4: What is the optimal screening interval in above-average risk women? Does the optimal screening interval vary by the:

a. Characteristics listed in Key Question 2?
b. Screening modality?

## Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, technology assessments, and clinical practice guidelines meeting the criteria for the PICO above. Searches of core sources were limited to citations published after 2012.

The core sources searched included:

Agency for Healthcare Research and Quality (AHRQ)
Blue Cross/Blue Shield Health Technology Assessment (HTA) program
BMJ Clinical Evidence
Canadian Agency for Drugs and Technologies in Health (CADTH)
Cochrane Library (Wiley Interscience)
Hayes, Inc.
Institute for Clinical and Economic Review (ICER)
Medicaid Evidence-based Decisions Project (MED)
National Institute for Health and Care Excellence (NICE)
Tufts Cost-effectiveness Analysis Registry
Veterans Administration Evidence-based Synthesis Program (ESP)
Washington State Health Technology Assessment Program

A MEDLINE® search was conducted to identify systematic reviews, meta-analyses, and technology assessments, using the search terms for each intervention and breast cancer screening. The search was limited to publications in English published since 2012. In addition, a MEDLINE® search was conducted for randomized controlled trials published after the search dates of the most recent systematic review selected for each indication.

Searches for clinical practice guidelines were limited to those published since 2012. A search for relevant clinical practice guidelines was also conducted, using the following sources:

Australian Government National Health and Medical Research Council (NHMRC)
Centers for Disease Control and Prevention (CDC) – Community Preventive Services
Choosing Wisely
Institute for Clinical Systems Improvement (ICSI)
National Guidelines Clearinghouse
New Zealand Guidelines Group
NICE
Scottish Intercollegiate Guidelines Network (SIGN)
United States Preventive Services Task Force (USPSTF)
Veterans Administration/Department of Defense (VA/DOD)

*Inclusion/Exclusion Criteria*

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

# APPENDIX D. APPLICABLE CODES

| CODES | DESCRIPTION |
|---|---|
| **CPT Codes** | |
| 76641 | Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete |
| 76642 | Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; limited |
| 77059 | Magnetic resonance imaging, both breasts, without and/or with contrast material(s); bilateral |
| 77063 | Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure) |
| 77067 | Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed |
| **HCPCS Level II Codes** | |
| G0202 | Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (cad) when performed |

Note: Inclusion on this list does not guarantee coverage

Coverage Guidance: Breast Cancer Screening in Women at Above-Average Risk

Question: How should the draft Coverage Guidance **Breast Cancer Screening in Women at Above-Average Risk** be applied to the Prioritized List?

Question source: HERC Staff, HTAS

Issue:
The HTAS approved the following draft "box language":

Annual screening mammography and annual screening MRI are recommended for coverage for women at above-average risk of breast cancer *(weak recommendation)*. This coverage, beginning at 30 years of age, includes women who have one or more of the following:

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

For women with a history of high dose chest radiation (≥ 20 Gray) before the age of 30, annual screening MRI and annual screening mammography are recommended for coverage beginning 8 years after radiation exposure or at age 25, whichever is later *(weak recommendation).*

For women with both a personal history and a family history of breast cancer, annual mammography, annual breast MRI and annual breast ultrasound are recommended for coverage *(weak recommendation)*.

For women with increased breast density, supplemental screening with breast ultrasound, MRI, or digital breast tomosynthesis is not recommended for coverage *(weak recommendation)*.

Breast PET-CT scanning and breast-specific gamma imaging are not recommended for coverage for breast cancer screening in any risk group *(strong recommendation)*.

Rationale for Recommendations

Risk factors have been identified that place certain groups of women at above-average risk for development of breast cancer. At present, evidence is limited for

improved outcomes attributable to additional screening strategies, but most clinicians and patients would favor testing that decreases the likelihood of missed cancers in these high-risk subpopulations of women.

For women at above-average risk for breast cancer due to strong family history or known/suspected mutations (for example, BRCA), MRI plus mammography is more sensitive than either modality alone, which would mean fewer false negative screens when both are utilized. Moderate resource allocation would be required for enhanced screening with mammography plus MRI, but this cost could be offset to some extent by savings in treatment costs by detecting cancers at an earlier stage.

For women with both a personal history and a family history of breast cancer, supplemental imaging studies (MRI and ultrasound) provide additional sensitivity and specificity in surveillance and screening for breast cancer recurrence. Although there is insufficient evidence to assess outcomes such as breast cancer morbidity or cancer stage at diagnosis, patient and provider preference would clearly favor testing strategies that have the highest detection rates for recurrent cancer in these individuals.

Women who have had ≥20 Gray chest irradiation in childhood, adolescence, or early adulthood have a breast cancer risk similar to BRCA1 carriers. The combination of mammography and MRI appears to increase sensitivity of testing, and each modality detects malignancies that are missed by the other. There is insufficient evidence to assess any outcome other than test performance characteristics. Expenditures would be relatively low, given the small numbers in this subpopulation.

Screening mammography is less accurate in women found to have increased breast density. Supplemental screening with breast ultrasound, breast MRI, or digital breast tomosynthesis may detect additional cancers, but we have low confidence in this effect. Positive predictive values for these supplemental screening tests are low. Additional expenditures would be significant for these imaging studies, and potentially significant for evaluation of false positive results. We are not confident that any improvement in cancer detection rates with these supplemental studies, even if clearly demonstrated, would result in cancers being detected at earlier stages, leading to earlier interventions that improve clinical outcomes. Therefore, additional screening modalities are not recommended for coverage in women with dense breasts.

No outcomes evidence met the search criteria for PET-CT or breast-specific gamma imaging for breast cancer screening in above average risk women.

Current Prioritized List Status: Codes

| CODES | DESCRIPTION | |
|---|---|---|
| **CPT Codes** | | |
| 76641 | Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete | Diagnostic |
| 76642 | Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; limited | Diagnostic |
| 77059 | Magnetic resonance imaging, both breasts, without and/or with contrast material(s); bilateral | Diagnostic |
| 77063 | Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure) | SRNC |
| 77067 | Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed | Line 3 |
| **HCPCS Level II Codes** | | |
| G0202 | Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (cad) when performed | Diagnostic |

Current Prioritized List Guideline:

## DIAGNOSTIC GUIDELINE D6, MRI FOR BREAST CANCER SCREENING

Breast MRI is not covered for screening for breast cancer.

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/herc/Pages/blog-mri-breast-cancer-screening.aspx

HERC Staff Recommendation:

1) Revise Diagnostic Guideline D6, as follows:

**DIAGNOSTIC GUIDELINE D6, ~~MRI FOR~~ BREAST CANCER SCREENING IN ABOVE AVERAGE RISK WOMEN**

~~Breast MRI is not covered for screening for breast cancer~~

Annual screening mammography and annual screening MRI are covered for women at above-average risk of breast cancer. This coverage, beginning at 30 years of age, includes women who have one or more of the following:

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

For women with a history of high dose chest radiation (≥ 20 Gray) before the age of 30, annual screening MRI and annual screening mammography are covered beginning 8 years after radiation exposure or at age 25, whichever is later.

For women with both a personal history and a family history of breast cancer, annual mammography, annual breast MRI and annual breast ultrasound are covered.

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

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

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/herc/Pages/Breast Cancer Screening in Women at Above-Average Risk. ~~See http://www.oregon.gov/oha/herc/Pages/blog-mri-breast-cancer-screening.aspx~~

# Breast Cancer Screening in Women at Above-Average Risk

Draft Coverage Guidance for VbBS/HERC Consideration

May 18, 2017

Oregon Health Authority

Oregon Health & Science University

Center For Evidence-based Policy

# Background: Breast Cancer

- 1 in 8 (12%) women develop invasive breast cancer during their lifetime
- The breast cancer death rate has steadily declined in the last 15 years, but there are still significant disparities in terms of race/ethnicity
- Decline in breast cancer mortality is attributed to
  - Screening efforts leading to earlier cancer detection
  - Fewer women using hormone therapy after menopause
  - Improved quality of treatment

# Background: Risk Factors

- Factors that significantly increase an individual's breast cancer risk include the following:
  - BRCA1 or BRCA2 gene mutation
  - Strong family history of breast cancer
  - Personal history of invasive breast cancer or ductal carcinoma in situ
  - Personal history of lobular carcinoma in situ or atypical lobular hyperplasia
  - Radiation treatment to the chest area between ages 10 and 30
  - Li-Fraumeni syndrome, Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome, and ATM, CHEK2, or PALB2 gene mutations
- Additional risk factors include starting menopause after age 55, physical inactivity, dense breasts, and alcohol consumption

# Background: Risk Assessment

- The Breast Cancer Risk Assessment Tool is used to estimate 5-year and lifetime risk based on these factors:
  - Age
  - Age at first menstrual period
  - Age at birth of first child (or has not given birth)
  - Family history of breast cancer
  - Number of past breast biopsies showing atypical hyperplasia
  - Race/ethnicity
- A 5-year risk of ≥1.67% or a lifetime risk of ≥20% is often considered “high risk”
- A 15% to 20% lifetime risk is often considered “moderately increased risk”

# Scope Statement

- **Population:** Women with above-average age-adjusted risk of breast cancer or dense breasts; includes women with:
  - Preexisting breast cancer
  - Personal history of breast cancer
  - Clinically significant BRCA gene mutations (Li-Fraumeni syndrome, Cowden syndrome, hereditary diffuse gastric cancer, or other familial breast cancer syndromes)
  - High-risk lesions (ductal or lobular carcinoma in situ, atypical ductal or lobular hyperplasia)
  - Previous large doses of chest radiation therapy (≥20 Gy) before age 30

# Scope Statement

- **Interventions:**
  - Standard digital (2-D) mammography
  - Digital breast tomosynthesis (3-D)
  - Breast ultrasound
  - Breast MRI
  - PET CT
  - Self-exam
  - Clinical exam
  - Breast-specific gamma imaging
  - Screening regimens involving combinations or alternating use of the above tests at various intervals
- **Comparators:** No screening, average-risk screening regimens, comparisons of above tests to each other

# Scope Statement

- **Critical outcomes:**
  - All-cause mortality (critical outcome)
  - Breast cancer morbidity (critical outcome)
- **Important outcomes:**
  - Test performance characteristics (important outcome)
  - Cancer stage at diagnosis (important outcome)
  - Recall rate/false-positive test results (important outcome)

# Scope Statement

**Key Questions**

1. What is the comparative effectiveness of enhanced strategies for breast cancer screening in women with above-average risk?
2. Does the comparative effectiveness of enhanced strategies for breast cancer screening in women with above-average risk vary by:
    a. Reason for above-average risk
    b. Age
    c. Race or ethnicity
    d. Breast density

# Scope Statement

**Key Questions**

3. What are the harms of enhanced screening strategies for breast cancer in women with above-average risk?
4. What is the optimal screening interval in above-average risk women? Does the optimal screening interval vary by the following:
    a. Characteristics listed in Key Question 2?
    b. Screening modality?

# Evidence Sources

- **Reviews**
  - Phi et al., 2016 (risk: BRCA mutation)
  - Shah, 2016 (risk: history of breast cancer)
  - Robertson et al., 2011 (risk: family history)
  - Melnikow et al., 2016 (risk: dense breasts)
  - Houssami & Turner, 2016 (risk: dense breasts)
  - Koo et al., 2015 (risk: history of chest radiation)
  - NICE, 2013 (multiple risk factors)
  - Warner et al., 2008 (multiple risk factors)
- **Additional Studies**
  - Sardanelli et al., 2011 (risk: genetic)
  - Ng et al., 2013 (risk: history of chest radiation)

# Evidence Summary

- No direct evidence comparing screening regimens for women at above-average risk of breast cancer with respect to clinical outcomes
- Low-quality evidence that women with mammographically screen-detected cancers have better clinical outcomes compared to unscreened women who are diagnosed with breast cancer
- Moderate-quality evidence that MRI is more sensitive than other screening tests in women with known or suspected mutations that increase the risk of breast cancer

# Evidence Summary

Women with a personal history and family history of breast cancer:

- Moderate-quality evidence that MRI has the best combination of sensitivity and specificity to detect ipsilateral recurrence after breast-conserving surgery
- Moderate-quality evidence that the combination of clinical exam, mammography, ultrasound, and MRI had the highest sensitivity for detection of metachronous contralateral breast cancer after breast-conserving surgery
- Moderate-quality evidence that MRI is more sensitive than other modalities for detecting ipsilateral recurrence after mastectomy
- Moderate-quality evidence that combined mammography and ultrasound had the best sensitivity and specificity for metachronous contralateral breast cancer after mastectomy

# Evidence Summary

For women with a history of chest irradiation at a young age:

- Low-quality evidence that the combination of mammography and MRI offers the highest sensitivity for screen detection of breast cancer

For women with heterogeneously or extremely dense breasts:

- Low- to moderate-quality evidence that supplemental screening with handheld ultrasound (HHUS), automated whole-breast breast ultrasound (ABUS), or MRI after a negative mammogram can detect additional cancers; recall rates and positive predictive value of supplemental screening vary by modality
- Low-quality evidence that supplemental screening with DBT increases the cancer detection rate while decreasing the recall rate

# Guidelines

- The following guidelines were reviewed:
  - U.S. Preventive Services Task Force Final Recommendation Statement, *Breast Cancer: Screening*, 2016
  - Academy of Family Physicians, *Summary of Recommendations for Clinical Preventive Services,* 2016
  - *American Cancer Society Recommendations for Early Breast Cancer Without Breast Symptoms,* 2015
  - American College of Obstetricians and Gynecologists 2011 Practice Bulletin, *Breast Cancer Screening,* Reaffirmed 2014
  - *American College of Radiology (ACR) Appropriateness Criteria for Breast Cancer Screening,* 2016
  - The National Comprehensive Cancer Network, *Breast Cancer Screening and Diagnosis,* 2016

# Guidelines

- Guidelines consistently recommend considering earlier or enhanced breast cancer screening for women at increased risk of breast cancer
  - For example, the American Cancer Society recommends annual screening with both MRI and mammography beginning at age 30
- Most guidelines recommend annual breast MRI, in addition to mammography screening, for women at high risk of breast cancer with:
  - Lifetime risk of breast cancer that is ≥20%
  - A BRCA mutation (or a first-degree relative carrier if untested)
  - History of radiation therapy to the chest between ages 10 and 30
- Some guidelines specify age restrictions
  - MRI should not be performed before the age of 25
  - Mammography screening should not be performed before the age of 30
- Two of the guidelines recommend the use of ultrasound when MRI is contraindicated for patients who would otherwise be candidates for MRI

# Policy Landscape: Medicaid

Washington Medicaid:

- Covers annual screening mammography for patients ages 40 and over, as well as DBT when performed with a screening mammography for clients ages 40 through 74
- Requires prior authorization for screening mammograms, with or without DBT, for patients younger than 40
- Requires a medical quality necessity review by Qualis Health for a breast MRI billed as an outpatient claim

# Policy Landscape: Private Payers

- Aetna and Cigna cover breast cancer screening for women younger than 40 at increased risk, including patients with:
  - History of breast cancer
  - BRCA mutation
  - History of high-dose thoracic irradiation
  - Personal history or a first-degree relative diagnosed with Bannayan-Riley-Ruvalcaba syndrome, Cowden syndrome, or Li-Fraumeni syndrome
  - Aetna also covers patients who meet criteria for BRCA mutation testing, prophylactic mastectomy, or prophylactic oophorectomy
  - Cigna also covers patients not tested for a BRCA mutation with a first-degree relative carrier, as well as patients with a ≥1.7% five-year risk or ≥20% lifetime risk

# Policy Landscape: Private Payers

- Regence provides additional breast cancer screening coverage for women at high risk, but does not specify criteria for defining high risk
- No policy on women at high risk was found for Moda

# Policy Landscape: Private Payers

- Aetna, Moda, and Regence all consider DBT experimental and investigational and do not provide coverage for DBT for patients at any risk level
- Cigna considers DBT medically appropriate for the screening of breast cancer (at any risk level)
- Aetna covers breast MRI as an adjunct to mammography for screening patients at increased risk including patients with:
  - Certain genetic mutations (e.g., BRCA mutation, Li-Fraumeni syndrome, Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome)
  - A first-degree relative with a BRCA mutation (if patient is untested)
  - A 20% to 25% lifetime risk

# Public Comment

Two public comments submitted, from Hologic and Myriad Genetics

- Comment: Women with dense breasts are at high risk
  - *Lifetime risk for women with dense breasts is less than 20%, so not in scope for this Coverage Guidance*
- Comment: Oregon state law mandates that women are notified if determined that they have dense breasts
  - *State law does not specifically endorse the use of supplemental screening techniques for women with dense breasts*

# Public Comment

- Comment: There are other genes, not listed in the Coverage Guidance, that confer a greater than 20% lifetime risk of breast cancer
  - *Providing a complete list of genes associated with an increased risk of breast cancer is beyond the scope of this Coverage Guidance. The Coverage Guidance recommends coverage for supplemental screening if a woman has any known mutation that demonstrably confers a greater than 20% lifetime risk of breast cancer.*

# HERC Coverage Guidance

Annual screening mammography and annual screening MRI are recommended for coverage for women at above-average risk of breast cancer *(weak recommendation)*. This coverage, beginning at 30 years of age, includes women who have one or more of the following:

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

# HERC Coverage Guidance

For women with a history of high dose chest radiation before the age of 30, annual screening MRI and annual screening mammography are recommended for coverage beginning 8 years after radiation exposure or at age 25, whichever is later *(weak recommendation)*.

For women with both a personal history and a family history of breast cancer, annual mammography, annual breast MRI and annual breast ultrasound are recommended for coverage *(weak recommendation)*.

# HERC Coverage Guidance

For women with increased breast density, supplemental screening with breast ultrasound, MRI, or digital breast tomosynthesis is not recommended for coverage *(weak recommendation)*.

Breast PET-CT scanning and breast-specific gamma imaging are not recommended for coverage for breast cancer screening in any risk group *(strong recommendation)*.

# HERC Coverage Guidance: Breast Cancer Screening in Women at Above-Average Risk
# Disposition of Public Comments

## Table of Contents



## Discussion Table

| IDs/#s | Summary of Issue | Subcommittee response |
|---|---|---|
| A1 | Oregon law requires that women found to have dense breast tissue on mammography be advised by letter to consider whether further screening might be of benefit. Our coverage recommendations do not include coverage of any additional screening modalities for these women. | Oregon law requires that women found to have dense breast tissue on mammography be advised by letter to consider whether further screening might be of benefit. Our coverage recommendations do not include coverage of any additional screening modalities for these women.<br>• The state mandated notification letter does not recommend or require the use of any specific additional screening technique.<br>• The letter is primarily intended to promote discussion with her health care provider.<br>• We have not found sufficient evidence at this time to support the use of DBT, MRI, or ultrasound as additional screening modalities for women with dense breasts.<br>Many professional societies, including the American Cancer Society and the American College of Obstetrics and Gynecology, state that there is insufficient evidence to recommend supplemental screening for this population. |
| B1 | In addition to BRCA and the syndromes specified in the coverage recommendations, other gene mutations have been identified that are associated with a greater than 20% lifetime breast cancer risk, even when there is no known personal or family history. | In addition to BRCA and the syndromes specified in the coverage recommendations, other germline gene mutations have been identified that are associated with a greater than 20% lifetime breast cancer risk, even when there is no known personal or family history.<br>• We have added a recommendation providing coverage for those women with other germline gene mutations known to confer a greater than 20% lifetime risk of breast cancer.<br>• The listing of additional specific germline gene mutations is beyond the scope of this coverage guidance, as such listing would require review of evidence concerning breast cancer risk levels and penetrance for each of the mutations. |

| IDs/#s | Summary of Issue | Subcommittee response |
|---|---|---|
| | | • Identification of additional germline gene mutations conferring elevated cancer risk is a rapidly evolving field, and the listing of other specific mutations would limit the applicable time span of our recommendations. |

## Commenters

| Identification | Stakeholder |
|---|---|
| A | Veronica Miller, MHA, Hologic *[Submitted March 14, 2017]* |
| B | Karen Heller, MS, CGC, Myriad Genetics *[Submitted March 15, 2017]* |

## Public Comments

| ID/# | Comment | Disposition |
|---|---|---|
| A1 | This public comment is in response to the HTAS meeting on February 16, 2017, Breast Cancer Screening in Women at Above Average Risk. The discussion on dense breasts was robust, however there are a few points that should be examined.<br><br>The HTAS Committee recommendations for high-risk women (BRCA carriers, history of chest irradiation) to receive mammography and MRI is consistent with professional society's guidelines. However, there may be question as to women with dense breast tissue.<br><br>Effective January 1, 2014, the state of Oregon passed legislation requiring some level of breast density notification after a mammogram. The required notification reads:<br><br>"Your mammogram shows that your breast tissue is dense. Dense breast tissue is common and is not abnormal. However, dense breast tissue can make it harder to evaluate the results of your mammogram and may also be associated with an increased risk of breast cancer. This information about the results of your mammogram is given to you to raise your awareness and to promote discussion with your health care provider. Together, you | *Thank you for your comments.*<br><br>*Based on the information provided in the evidence review prepared for the United States Preventive Services Taskforce (USPSTF), the relative hazard of breast cancer in women with dense breasts ranges from 1.5 to 1.83 depending on the age group. This roughly translates to a lifetime risk of 12% to 18%. However, the authors also cited a study demonstrating that "[i]ncreased breast density is not associated with higher breast cancer mortality among women with dense breasts diagnosed with breast cancer,* |

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| | can decide if you may benefit from further screening. A report of your results was sent to your health care provider."<br><br>While the participants at the HTAS meeting briefly discussed that women with dense breasts have a moderately increased risk for breast cancer, additional imaging for these women appears to have been dismissed because "the risk was not increased enough" to warrant consideration of improved testing. Missing from the discussion was any consideration of the critical fact that not only are women with dense breasts at increased risk for developing breast cancer, traditional mammography does not perform as well in these patients. A recent publication from the Netherlands demonstrated that the sensitivity of mammography decreases from 85.7% in women with almost entirely fatty breasts to 69.5% in women with heterogeneously dense breasts and 61.0% in women with extremely dense breasts.[1] This reduction in sensitivity occurs because cancers may be hidden by "shadowing" which occurs from overlapping breast tissue. This patient population should have access to additional screening services which are capable of detecting lesions better than traditional mammography. The data on digital breast tomosynthesis (DBT) is compelling for women with dense breasts and the cost of DBT is minimal when compared to other alternatives for improving mammography.<br><br>**Evidence for the use of Digital Breast Tomosynthesis in Women with Dense Breasts**<br><br>• The panel should carefully consider the Houssami review of tomosynthesis breast cancer screening in women with dense breasts.[2] The pooled analysis in the Houssami review concludes that the use of DBT significantly lowers recall rate (pooled difference of -23.3/1000 screens) and significantly increases cancer detection (pooled difference of 1.4/1000 screens). As such, DBT directly addresses the limitations of mammography in women with dense breasts. | *after adjustment for stage and mode of detection."*<br><br>*Many professional societies, including the American Cancer Society and the American College of Obstetrics and Gynecology, state that dense breasts confer a moderately increased risk of breast cancer, but that there is insufficient evidence to recommend supplemental screening for this population.*<br><br>*Additionally, the authors of the USPSTF evidence review also raise questions about the reliability of breast density determinations: "BI-RADS density assessments at a population level were generally consistent across sequential examinations by the same or different readers, but there was important variability among readings for individual women. Approximately 80% of examinations received a b or c BI-RADS density assessment; these categories were also most likely to be reassessed differently, whether on a separate reading of the same examination or on a subsequent examination, and whether* |

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| | **Budget Impact of DBT**<br><br>• A reimbursement rate of $35-40 is appropriate for digital breast tomosynthesis in the Medicaid population. This rate is considerably lower than the cost of other alternatives for improving mammography such as MRI, Ultrasound, and Breast-specific imaging. The cost differences are magnified when you consider that DBT reduces recalls in women with dense breast, while MRI and Ultrasound are associated with increasing the rate of costly follow-up testing.<br>• Studies have demonstrated that the recall rate is ~40% higher in women with dense breasts when compared to women with non-dense breasts.[3] As such, the ability of DBT to significant reduce recall rates is even especially impactful for women with dense breasts. A recent multi-state Medicaid claims analysis reported that the approximate cost of a recall for a Medicaid patient is $694.95.[4] Therefore, the cost reductions of eliminating some portion of these recall costs should be factored when considering the budget impact of DBT.<br>• The Medicaid claims analysis also reported that less than 2% of a typical Medicaid population receives a screening mammogram in a given year.[4] Considering that approximately 50% of women have dense breasts, the number of DBT exams per year in women with dense breasts is likely to be relatively small. Therefore, the budget impact of DBT is also likely to be small, even if there is uncertainty about the exact cost savings due to reduced recall and early detection.<br><br>In summary, due to state law, approximately half of Medicaid-insured women in Oregon will receive a letter informing them that "your breast tissue is dense" and "you can decide if you may benefit from further screening." It is inconsistent to inform women that they may benefit from further screening, but not cover the cost of such screening. As the least costly alternative for improving mammography in women with dense breasts, Digital Breast Tomosynthesis testing should be the standard of care for women with dense breasts. | *read by the same or a different reader. As a result, across studies a sizeable 13% to 19% of women were reclassified from 'nondense' to 'dense' or vice versa. In these instances, mandated communications about elevated breast cancer risk or the need for additional clinical screenings could provide inconsistent information for the same woman in the span of 2 to 3 years."*<br><br>*The rapid review by Houssami was already included in the evidence review in the coverage guidance.*<br><br>*DBT is undoubtedly less expensive than other forms of supplemental screening.*<br><br>*The cost-effectiveness study cited here was intended to compare combined DBT+DM to DM alone in a standard screening context; it does not specifically address the cost-effectiveness of DBT as a supplemental screening modality after a normal mammogram for women with dense breasts. Additionally, several of the model inputs are from unpublished data from Truven Health Analytics.*<br><br>*The state-mandated breast density notification letter simply states that* |

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| | | *women with dense breasts should discuss further screening with their provider; it does not specifically endorse the use of supplemental screening techniques.* |
| B1 | We respectfully submit the following suggested addition (in red) to incorporate into the coverage guidance on Breast Cancer Screening in Women at Above-Average Risk.<br><br>Annual screening mammography and annual screening MRI are recommended for coverage for women at above-average risk of breast cancer (weak recommendation). This coverage, beginning at 30 years of age, includes women who have one or more of the following:<br><br>• Greater than 20% lifetime risk of breast cancer<br>• BRCA1 or BRCA2 gene mutation, or who have not been tested for BRCA but have a first-degree relative who is a BRCA carrier<br>• A personal history or a first-degree relative diagnosed with Bannayan-Riley-Ruvalcaba syndrome, Cowden syndrome, or Li-Fraumeni syndrome<br>• Mutation in PALB2, ATM, CHEK2, STK11, CDH1, NBN, NF1, or other gene known to confer greater than 20% lifetime risk for breast cancer<br><br>The draft appropriately suggests that women with a lifetime breast cancer risk of at least 20% be considered for breast MRI screening. The draft goes on to call out specific genes that confer a level of breast cancer risk that is greater than 20%, namely, BRCA1, BRCA2, PTEN (Bannayan-Riley-Ruvalcaba/Cowden syndrome) and TP53 (Li-Fraumeni syndrome). However, other genes have also been shown to confer a breast cancer risk of at least 20% on female mutation carriers. In fact, knowledge of the presence of pathogenic mutations in these genes can provide a more accurate estimate of breast cancer risk than personal and family history factors alone. Leaving other genes off of the list could be interpreted to | *Thank you for your comments.*<br><br>*Providing a complete listing of genes associated with an increased risk of breast cancer is beyond the scope of this coverage guidance. However, based on the current coverage recommendation, women would qualify for supplemental screening if they had a known mutation that demonstrably confers a greater than 20% lifetime risk of breast cancer.*<br><br>*The question of when genetic testing is indicated and which genes to test for is beyond the scope of this coverage guidance and an area of ongoing debate.* |

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mean that carriers of mutations in those genes are not included. We encourage the guidance to also list carriers of pathogenic mutations in PALB2, ATM, CHEK2, STK11, CDH1, NBN and NF1 as candidates for enhanced breast cancer screening, per the current guidelines of the National Comprehensive Cancer Network (NCCN).[1,2]

The table below summarizes the reported breast cancer risks associated with each of these genes, together with supporting references.

| GENE | BREAST CANCER RISK | REFERENCES |
|---|---|---|
| PALB2 | 17-58% (to age 70) | 3,4,5,6 |
| ATM | 17-52% (to age 80) | 7,8,9 |
| CHEK2 | 23-48% (to age 80) | 10,11,12,13 |
| CDH1 | 39-52% (to age 80) | 14,15,16 |
| NBN | Up to 30% (to age 80) | 17,18 |
| NF1 | 36-60% (to age 80) | 19,20 |
| STK11 | 45-50% (to age 70) | 2 |

The National Comprehensive Cancer Network (NCCN) guidelines include a recommendation for breast MRI screening in addition to mammography for carriers of mutations in the following genes: BRCA1, BRCA2, PTEN, TP53, PALB2, ATM, CHEK2, CDH1, NBN, NF1[1] and STK11.[2]

The Blue Cross Blue Shield Association recently published an evidence review of genes that are considered to be of "moderate penetrance" for breast cancer, i.e. having a 2-4 fold increased risk of developing breast cancer compared with the general population.[21] The report concludes that there is sufficient evidence that PALB2 testing for individuals at risk for hereditary breast/ovarian cancer results in a meaningful improvement in the net health outcome. The report also states that "…identifying a PALB2 variant provides a more precise estimated risk of developing breast cancer compared with family history alone…"

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| | Rosenthal et al. published a recent study[22] demonstrating that 75% of 9,175 carriers of mutations in BRCA1, BRCA2, PTEN, TP53, PALB2, ATM, CHEK2, CDH1 or STK11 would not have been identified as having a breast cancer risk >20% based on family history alone. This confirms that knowledge of a mutation in one of these genes provides a more accurate estimate of breast cancer risk than family history alone. | |

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| ID/# | References |
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