



# **Health Evidence Review Commission**

**June 14, 2012**

**Wilsonville Training Center  
Clackamas Community College Room 112  
29353 SW Town Center Loop E  
Wilsonville, Oregon 97070**

**AGENDA**  
**HEALTH EVIDENCE REVIEW COMMISSION**

Clackamas Community College  
Wilsonville Training Center Room 112

June 14, 2012

2:00-5:00 pm

*(All agenda items are subject to change and times listed are approximate)*

#	Time	Item	Presenter	Action Item
1	2:00 PM	Call to Order	Som Saha	
2	2:05 PM	Approval of Minutes (April 12, 2012)	Som Saha	X
3	2:10 PM	Director's Report	Darren Coffman	
4	2.15 PM	Value-based Benefits Subcommittee Report	Lisa Dodson Cat Livingston	X
5	2:40 PM	Health Technology Assessment Subcommittee Report <ul style="list-style-type: none"> <li>• MRI for Breast Cancer Screening</li> </ul>	Alissa Craft Wally Shaffer Dave Lenar Alison Little	
6	3:00 PM	Evidence-based Guidelines Subcommittee Report <ul style="list-style-type: none"> <li>• Knee Arthroscopy for Osteoarthritis</li> <li>• Routine Ultrasound in Pregnancy</li> <li>• Induction of Labor</li> <li>• Indications for Planned Cesarean Section</li> <li>• Non-Pharmacologic/Non-Invasive Interventions for Low Back Pain</li> <li>• Pharmacologic Interventions for Low Back Pain</li> <li>• Guideline - Percutaneous interventions for low back pain</li> </ul>	Wiley Chan Cat Livingston Alison Little	X
7	4:00 PM	Conflict of Interest	Cat Livingston	
8	4:15 PM	Public Input/Testimony <ul style="list-style-type: none"> <li>• Policy on Use of Experts for HERC and Subcommittees</li> <li>• Health Evidence Review Commission Policy on Acceptance of Testimony and Guidelines for Speakers &amp; Presenters</li> </ul>	Darren Coffman	X
9	4:30 PM	Additional Trusted Evidence Sources	Darren Coffman	X
10	4:35 PM	Potential Additional EbGS and HTAS Topics and Forecasted Schedule of Current Topics	Cat Livingston	X
11	4:45 PM	Next Steps <ul style="list-style-type: none"> <li>• Schedule next meeting – August 9, 2012 Meridian Park Room 117 B&amp;C</li> </ul>	Som Saha	
12	4:50 PM	Public Comment		
13	5:00 PM	Adjournment	Som Saha	

## Minutes

HEALTH EVIDENCE REVIEW COMMISSION  
Meridian Park Hospital,  
Health Education Center, Conference Room 117B&C  
Tualatin, Oregon  
April 12, 2012

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**Members Present:** Alissa Craft, DO, MBA, Vice-Chair; Wiley Chan, MD; Irene Crowell, RPh; Lisa Dodson, MD; Mark Gibson; Vern Saboe, DC; James Tyack, DMD; Kathryn Weit; Beth Westbrook, PsyD.

**Members Absent:** Som Saha, MD, MPH, Chair; Gerald Ahmann, MD; Leda Garside, RN.

**Staff Present:** Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Dave Lenar; Dorothy Allen.

**Also Attending:** Paul Nielsen, MedImmune; Denise Taray, DMAP; Joanie Cosgrave and Dena Scarce, Medtronic; Alison Little, MD MPH, Shannon Vandegriff, and Valerie King, MD MPH, OHSU CeBP; Dan Albrecht, Tuality; Ellen Lowe, OAHHS; Mike Willett, Pfizer.

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### Call to Order

Alissa Craft, Vice-Chair of the Health Evidence Review Commission (HERC), called the meeting to order, explaining Som Saha became unavailable today. Role was called.

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### Approval of Minutes

**MOTION: To approve the minutes of the February 9, 2012 meeting as presented.**  
**CARRIES 9-0.**

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### Director's Report

Darren Coffman reported the recent Health & Human Services (HHS) secretary decision to delay ICD-10-CM implementation until October 1, 2014. He explained how this decision affects the Prioritized List's implementation. Ordinarily, based on a biennial review, a new list is implemented on January 1 of even-numbered years. That new list is then amended with new/revised/deleted coding pairs as well as technical adjustments for a period of two years, until another list is implemented. The HSS ruling misses our mark by 9 months.

To conserve administrative resources Coffman suggested to DMAP to consider holding off implementation of a new list until October 1, 2014, which would encompass the ICD-10-CM conversion, rather than implementing a new ICD-9-CM code version for 9 months.

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## Subcommittee Structure

Coffman gave an update on subcommittee membership, naming two individuals who were recommended by the American College of Cardiology Association and who are willing to accept appointments as follows:

- Ed Toggart, MD – Health Technology Assessment Subcommittee (HTAS)
- Eric Stecker, MD – Evidence-based Guidelines Subcommittee (EbGS)

**MOTION: To approve the new members noted above. CARRIES 9-0.**

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## Conflict of Interest

Cat Livingston gave a brief outline of the conflict of interest issues. Option 1, based largely on the Washington Health Technology Assessment (HTA) process, was selected as the template (materials [pages 9-10](#)) with the following suggested amendments:

- Add language regarding individual healthcare company
- Remove minimum dollar amount criteria from Relationship statement #1: ~~in excess of \$10,000.~~
- Relationship clarification – specifically related to healthcare goods and services  
Amend #3 under *Relationship* to add: “Company” is a for-profit entity (other than the individual’s primary employer) that develops, produces, markets, or distributes drugs, devices, services or therapies used to diagnose, treat, monitor, manage and alleviate health conditions.

Based on the discussions above Livingston will the make discussed adjustments and send the document by email for members to comment on before the next meeting.

The Commission also considered implementing a document that would be presented to individuals giving public comment or public testimony. The document officially declares conflicts of interest, asks for a monetary gains statement and requires a signature. Currently, each person testifying is asked to verbally declare any conflicts for the record before speaking.

Beth Westbrook suggested adding a statement to HERC’s website indicating those wishing to give public comment or testimony should be prepared to indicate any conflicts of interest.

**MOTION: To continue the current public testimony practice and not adopt the suggested document. Carries 9-0.**

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## Subcommittee Reports

### Value-based Benefits Subcommittee (VbBS) Report

Ariel Smits reported the VbBS has met twice since the last HERC meeting, March 8<sup>th</sup> and earlier today, April 12<sup>th</sup>. She summarized a number of topics discussed at both subcommittee meetings including:

- ICD-10/Biennial Review specialty group recommendations including neurology, burns, dermatology and podiatry
- Gender identity disorder is recommended to be moved from the from Other Paraphilias line and creating a new Gender Dysphoria line with psychotherapy treatment on the new biennial list which would appear in the covered region
- Coverage is recommended to be added for HPV vaccination for males ages 9-26 as an interim modification effective October 1, 2012
- Inappropriate codes are recommended to be removed as treatment options of acute sinusitis as an interim change
- Some of the guideline revisions suggested during the ICD-10 conversion meetings seem to be appropriate to implement sooner, including neoplasm of urinary organs and management of acromioclavicular joint sprain, and are recommended to be made as interim change

Detailed information may be found in the [VbBS Minutes](#).

**MOTION: To approve the report of the VbBS with their recommendations. Carries 9-0.**

#### Health Technology Assessment Subcommittee (HTAS) Report

Dave Lenar reported the subcommittee met for the first time in March where they received a Center for Evidence-based Policy presentation on the use of evidence in making health policy decisions. This presentation was recorded and should be available for all to see in the next couple of weeks.

A draft coverage guidance on *MRI Screening for Breast Cancer* was approved and is being posted for public comment. The members are recommending this not be covered this due to a lack of proven benefit on morbidity or mortality, as well as concerns about over-diagnosis leading to potential harms.

The next meeting is scheduled for April 23, 2012. The members are slated to review:

- Discography
- Vertebroplasty, kyphoplasty and sacroplasty
- Artificial discs
- Hip resurfacing

**MOTION: To approve the HTAS report. Carries 9-0.**

#### Evidence-based Guidelines Subcommittee (EbGS) Report

Cat Livingston reported the subcommittee has met twice since the last HERC meeting. Work progresses to develop categories for each coverage guidance that address:

- individuals for which there is *benefit (green light)*
- individuals for which there is *harm (red light)*
- individuals for which there is *insufficient evidence (individual/clinician shared decision making) (yellow light)*

Five draft Coverage Guidances (four new, one revised) are in development. They will be available for public comment this month:

- Knee Arthroscopy for Osteoarthritis
- Femoracetabular Impingement (FAI) Syndrome Surgery
- Routine Ultrasound in Pregnancy
- Elective Induction of Labor
- Indications for Planned Cesarean Section (revised)

Review of Coverage Guidances that are in the post-public comment period continues on:

- Non-pharmacologic management of low back pain
- Pharmacologic treatment of low back pain (forwarded to P&T Committee for additional public input)

Livingston stated each Coverage Guidance topic would be presented to the Commission after it is reviewed, analyzed and vetted publically. This process will take approximately two to three months.

Dr. Chan, chair of the subcommittee, noted a potential dilemma might exist because this work relies on currently published guidelines; how do we compensate for studies which were completed after the last systematic review? How do we evaluate new available studies and if that evaluation changes efficacy, what is the process? Coffman stated if it appears the new studies would change recommendations, the guideline could be reassigned to the HTAS for further study.

Mark Gibson opened a discussion about the yellow-light category, "*Insufficient evidence.*" He asked if there are areas of future study where we might lessen our reliance on provider judgment. Chan stated there are many treatments and diagnostic procedures which are considered "standard of care" yet have no actual proven efficacy. Dodson added we might be wise to limit this type of investigation to procedures which have a potential for abuse, are costly and have a wide discrepancy of clinic use. A brief discussion focused on medical, legal, population perspectives and monetary control issues. Members expressed interest in continuing this line of discussion at a future meeting.

**MOTION: To approve the EbGS report. Carries 9-0.**

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### **Guideline on Advanced Imaging for Low Back Pain**

Alison Little, Center for Evidence-based Policy, summarized a presentation (available in the meeting materials [pages 89-91](#)), touching on the history of the project, research criteria and base guideline selection.

The draft guideline on advanced imaging for low back pain was posted for public comment February 17 through March 18, 2012. There were no comments received. The Evidence-based Guideline Subcommittee reviewed and revised and now submits the amended draft version for approval of the Commission today.

The guideline includes three main recommendations:

1. Clinicians **should not** routinely obtain imaging in patients with nonspecific low back pain.
2. Clinicians should perform diagnostic imaging and testing for patients with low back pain when severe or progressive neurologic deficits are present or when serious underlying conditions are suspected on the basis of history and physical examination.
3. Clinicians should evaluate patients with persistent low back pain and signs or symptoms of radiculopathy or spinal stenosis with magnetic resonance imaging (preferred) or computed tomography only if they are potential candidates for surgery or epidural steroid injection (for suspected radiculopathy).

Livingston reviewed last-minute changes to Table B: Potentially Serious Conditions (“Red Flags”) and Recommendations for Initial Diagnostic Work-up:

- Add to “Cancer” section: **Symptoms such as painless neurologic deficit, night pain or pain increased in supine position**
- Amend statements under “Nerve compression /disorders” to read:
  - Back pain with leg pain in an L4, L5, or S1 nerve root distribution **present < 1 month**
  - Severe/progressive neurologic deficits, progressive motor weakness (**such as foot drop**)

If approved today, EbGS will develop a coverage guidance that will be reviewed by VbBS before it is presented to HERC. If the process is completed and approved by the August meeting it could become effective 10/1/12.

**MOTION: To approve the Advanced Imaging for Low Back Pain guideline. Carries 9-0.**

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## Public Input Process

### Proposal for Public Input into Health Technology Assessment Process

Coffman framed this discussion by stating there is statutory language which requires staff to develop administrative rules around the health technology assessment process (materials pages [113-114](#)). Details include a 30-day public notice of selected topics and a minimum of 14 days for subcommittee members to review materials prior to a meeting. With the Commission’s approval, Coffman will create temporary rules to guide this work. Shortly there will be a filing for permanent rules, which includes a 45-60 day process, with a public comment period.

Coffman then directed the Commission to the proposed [Coverage Guidance Process](#) document, which spells out the proposed process for developing coverage guidance using existing evidence reports from named [trusted sources](#). These guidances should succinctly give direction that supports if certain health services should be:

- covered as part of a standard benefit package
- covered only under specific circumstances or with other limitations
- not be covered

Further, Coffman stated, topics with reports over three years old will not be considered; studies from trusted sources must be more current. Gibson felt the language should be written more loosely to account for topics where it is unlikely any future studies will be available.

Accepted language:

*“In general, only topics with an existing report from a trusted source within the past three years will be considered for addition to the list for potential coverage guidance development, but topics with older reports may be added if it is felt that any future studies in the topic area are unlikely.”*

Further, selected potential topics will be prioritized by the Commission or delegated as they see fit. Once a guideline has been vetted through a public process and ultimately approved, staff will notify the several other public and private organizations such as Coordinated and Managed Care Organizations which provide services to Oregon Health Plan clients, Public Employees Benefit Board (PEBB) and Oregon Employers Benefit Board (OEBB) administrators, Office of Private Health Partnerships director and other public purchasers of health care.

**MOTION: To approve the coverage guidance process. Carries 9-0.**

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## Future EbGS and HTAS Topics

### Trusted Evidence Sources for Future Coverage Guidances

Little asked the Commission to review a list of submitted potential [trusted evidence sources](#) which will be used to developing the guidances. The sources listed are reliable, high quality and employ strong research methods. Coffman noted there are sources where a subscription is required to view the study's full text. In those cases, the Center will provide a more detailed summary to share with the public.

**MOTION: To approve the trusted sources as written. Carries 9-0.**

### Potential Additional EbGS and HTAS Topics and Forecasted Schedule of Current Topics

Livingston stated staff would soon have access to the [All Payer All Claims](#) (APAC) database. It is hoped that data will help identify treatment or diagnostic areas that may benefit from coverage guidance. In the mean time, she asked the members to weigh in on the proposed topics presented in the meeting materials (pages [118-121](#)). Commissioners asked staff to complete an evidence search first before a decision is made.

Staff will also complete an evidence search on the following five topics to help determine if they should be added to the list of potential future topics:

- Opiates for chronic pain
- Medical management of migraine headaches
- Diagnostic MRI for breast cancer
- Carotid endarterectomy versus medical management
- Treatment of sleep apnea in children

PEBB and OEBB asked their carriers to share information on their current coverage status of services currently under consideration for guidance development. That information is included in the meeting materials (pages [122-149](#)). The coverage data is very similar, each employing

similar prior authorization and step-therapies. It was concluded that the Commission's work has a great potential to impact the use of public dollars.

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### **Next Steps**

Due to the volume of work the VbBS is undertaking in June, the HERC meeting scheduled June 14, 2012 will meet from 2:00 to 5:00 pm.

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### **Public Comment**

Dan Albright, a Hillsboro physical medicine and rehab physician, asked questions about the treatment of low back pain and imaging for patients on the Oregon Health Plan. The questions were implementation-related in nature. HERC and DMAP staff will work with him to have his specific practice questions and concerns addressed.

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### **Adjournment**

Meeting was adjourned at 4:00pm. Next meeting will be from 2:00 to 5:00 pm on Thursday, June 14, 2012 at the Wilsonville Training Center in Conference Room 112.

## **Value-based Benefits Subcommittee Recommendations Summary**

*For Presentation to:*

Health Evidence Review Commission on April 12, 2012

*For specific coding recommendations and guideline wording, please see the text of the 4/12/12 VbBS minutes.*

### **CODE MOVEMENT**

- Added a diagnosis code for acquired pulmonary valve disorders to a covered heart surgery line; this code will also remain on another covered line for medical treatments. Added a series of pulmonary valve repair procedures to the surgical line and remove two surgical codes from the medical line
- Rename line 274 DISEASES OF MITRAL, ~~AND~~ TRICUSPID, AND PULMONARY VALVES
- Multiple nasal endoscopy codes were removed from various lines where they were not appropriately placed. These codes were specifically removed from the acute sinusitis line
- Add cardiac MRI (CPT 75561-5) to line 349 NON-DISSECTING ANEURYSM WITHOUT RUPTURE
- A series of straightforward code corrections was made

### **ITEMS CONSIDERED BUT NO CHANGES MADE**

- Vascularized bone grafting as treatment for acute vascular necrosis (AVN) of the hip was not added to the line with mild AVN disease

### **GUIDELINE CHANGES**

- Changes to the Heart-Kidney Transplant guideline, Frenulectomy/Frenulotomy guideline, and Bariatric Surgery guideline were accepted for implementation October 1, 2012 as shown in Appendix B
- A new guideline restricting immune modifying agents in Multiple Sclerosis was added as shown in Appendix B
- A new guideline for the treatment of benign neoplasms of the urinary tract was accepted as shown in Appendix B for implementation October 1, 2012 in ICD-9 notation
- A modified guideline for ventricular assist devices was accepted for implementation October 1, 2012 as shown in Appendix B.
- A modified guideline for use of erythropoiesis-stimulating agents was accepted for implementation October 1, 2012 as shown in Appendix B

### **CHANGES FOR THE OCTOBER 1, 2014 (TENTATIVE) PRIORITIZED LIST AS PART OF THE ICD-10 CONVERSION PROCESS**

- Specialty group recommendations reviewed: Podiatry, Dermatology, Sports Medicine, Oral Maxillofacial Surgery, Burns, Plastic Surgery, and Neurology
- Multiple lines were renamed
- Multiple lines were deleted or merged
- Move Q66.1 (Congenital talipes calcaneovarus) to line 297 DEFORMITY/CLOSED DISLOCATION OF JOINT
- A new guideline for the management of acromioclavicular joint sprain was accepted as noted in Appendix A, with earlier implementation in ICD-9 for October 1, 2012 accepted as shown in Appendix B

- Move K00.0/520.0 (Anodontia) moves from line 675 DENTAL CONDITIONS WHERE TREATMENT IS CHOSEN PRIMARILY FOR AESTHETIC CONSIDERATIONS to line 477 DENTAL CONDITIONS (EG. MISSING TEETH, PROSTHESIS FAILURE) Treatment: REMOVABLE PROSTHODONTICS (E.G. FULL AND PARTIAL DENTURES, RELINES). The ICD-9 move will be effective October 1, 2012
- A new guideline for the treatment of benign neoplasms of the urinary tract was accepted as shown in Appendix B for implementation October 1, 2014 in ICD-10 notation
- A new guideline for complicated hemangiomas was accepted as shown in Appendix A
- A new guideline for the management of acromioclavicular joint sprain was accepted as noted in Appendix A

**CHANGES FOR THE OCTOBER 1, 2014 (TENTATIVE) PRIORITIZED LIST AS PART OF THE BIENNIAL REVIEW**

- The Paraphilias line was split into two lines, Gender Dysphoria and Paraphilias. The Gender Dysphoria line will be in the covered area of the List and initially include only psychotherapy as a treatment. HERC staff will work with experts and advocates to determine additional treatments needed. The Paraphilias line will be in a non-covered portion of the List

## MEETING MINUTES

### VALUE-BASED BENEFITS SUBCOMMITTEE

Meridian Park Health Education Center

April 12, 2012

8:30 AM – 1:30 PM

**Members Present:** Lisa Dodson, MD, chair; Kevin Olson, MD, vice-chair; James Tyack, DMD; Laura Ocker LAc; David Pollack MD; Mark Gibson; Irene Crowell RPh.

**Members Absent:** Chris Kirk, MD

**Staff Present:** Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Dave Lenar; Dorothy Allen.

**Also Attending:** Isabel Bickle; and Denise Taray, DMAP; Chris Scheuferling, DPM; Clifford Mah, DPM; Claire Merinar and Ann Neilson, Amgen; Paul Nielsen, MedImmune; Mike Willett, Pfizer; Jessie Little, ASU; Michael Adkins; Ellen Lowe, OAHHS; Brian Neiburt, OHA; Paul Flint, MD; Adam Mirarchi, MD (by phone).

The meeting was called to order at 8:35 AM and roll call was done. Minutes from the March, 2012 VbBS meeting were reviewed and approved with the correction of adding Dr. Pollack's name to the members present list. ACTION: HERC staff will post the approved minutes on the website as soon as possible.

Smits gave the staff report. ICD-10 implementation has been delayed by the Centers for Medicare/Medicaid Services (CMS) with new date of implementation given as October 1, 2014. Coffman reviewed the process for adopting a new Prioritized List. The usual biennial review List would be implemented January 1, 2014. However, there are ongoing discussions with DMAP about whether there should be a new List implemented January 1, 2014 and another major List revision with ICD-10 moved forward for October 1, 2014. It appears that the most practical, and lowest cost option would be to implement a new biennial review/ICD-10 List on October 1, 2014 with no new List implanted for the January date. HERC staff will keep the VBBS/HERC updated on this process and any decisions made at the state level.

Smits informed the VBBS that changes adopted at the March, 2012 meeting regarding continuous blood glucose monitoring have been put on hold pending the guidance creation process. These changes will not be moved to approval by the full HERC until the guidance process has been completed.

*Note: All ICD-10 review changes take effect with the next Biennial Review Prioritized List (tentatively October 2014).*

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#### **Topic: ICD-10 Podiatry**

**Discussion:** Smits introduced a summary document with suggested changes to the List from the Podiatry review group. Dr. Chris Scheuferling and Dr. Clifford

Mah were present from the Podiatry review group to answer questions and discuss these changes with the VBBS.

Initial discussion centered around moving treatment of certain foot deformities from one of two uncovered lines to a covered line (172, Preventive Foot Care) with a guideline restricting this treatment to certain high risk groups. Olson asked for evidence that treatment of this foot conditions for high risk groups is effective at reducing complications or costs. Scheuferling responding that such evidence exists, and provided some summary information to staff and stated that the podiatry group would be happy to work with staff to identify additional evidence of effectiveness. Olson asked about the history of lack of coverage for these conditions; Coffman noted that the podiatry lines wre created in the early 1990's and have not been reviewed since. The group feeling was that more information on the effectiveness of these types of treatments for this population was needed. The experts agreed to help staff identify this type of information.

The second discussion item revolved around adding bone surgical treatment CPT codes to the tendon/ligament injury line as many tendon ruptures require bone resection for full treatment. Olson again asked for more background on the effectiveness and utility of these types of treatment; Dodson and Gibson concurred. Dodson asked the experts what non-surgical types of treatment exist for these conditions. Mah responded that bracing and casting would be the typical non-surgical treatments. The group asked for more information on the effectiveness of this type of procedure.

Next, prioritization of hallux rigidus and ankle ankylosis was discussed. The experts pointed out that their major concern with this area was that ankle/large toe arthritis was prioritized lower than arthritis of other major joints such as the knee. The question was raised about why ankle and large toe arthritis has historically been given lower priority than arthritis of other joints. Coffman pointed out that ankylosis of shoulder and lower leg were covered, but not ankylosis of the upper or lower arm, hand, ankle, large toe, etc were not covered. Gibson expressed concern that there was not logical consistency on how various joints with similar conditions (i.e. arthritis of the shoulder vs the hip vs the ankle) were prioritized on the List. Dodson agreed that there should be a more comprehensive/bigger picture presentation to the VBBS on where various joint arthritis conditions were prioritized and why. Olson requested information on weither distal joint arthritis was more or less debilitating than proximal joint arthritis. The decision was to have HERC staff work with the podiatry and orthopedic experts to review how similar conditions of various joints are prioritized.

The group discussed moving certain diagnoses to the line with club feet. The experts pointed out that Q66.1 (Congenital talipes calcaneouvarus) is another term for club foot and should be moved to the same line (line 297). This was agreed on by the group. The other two codes proposed for movement were not approved as they were felt to represent flat feet. The podiatry experts pointed out that the higher degree of foot tilt sometimes seen in these codes are important to fix. The decision was made to obtain more information on the need to treat Q66.3 and Q66.6, and perhaps draft a guideline to determine at what degree of deformity do these conditions require treatment.

**Action:**

- 1) HERC staff will work with the podiatry experts to create an evidence review regarding the effectiveness of preventive foot care for high risk patients which would include repair of deforming foot lesions such as bunions
- 2) HERC staff will work with podiatry experts to determine the effectiveness and utility of bone procedures for the treatment of certain tendon and ligament injuries
- 3) HERC staff will work with podiatry experts and orthopedist experts to create a review of 1) where arthritis of various joints are currently located on the Prioritized List, and 2) how should treatment of arthritis of various joints be prioritized
- 4) Move Q66.1 (Congenital talipes calcaneovarus) to line 297  
DEFORMITY/CLOSED DISLOCATION OF JOINT
- 5) HERC staff will work with podiatry experts to determine when treatment of Q66.3 (Other congenital varus deformities of feet) and Q66.6 (Other congenital valgus deformities of feet) should be covered and consider a guideline to clarify coverage

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**Topic: ICD-10 Review Dermatology**

**Discussion:** Livingston introduced a summary document with suggested changes to the Dermatology lines base on the ICD-10 review. There was an extensive discussion about the new proposed funded moderate/severe skin disease line. The main concern was about expensive biologics for the non-psoriasis skin disorders, and not having clear evidence of benefit. Additionally, there was concern about the term “moderate” and how at the moderate level, would this truly affect an individual’s functioning. While this is clear for severe, moderate may not have similar effects, especially in a subjective data point.

There was a motion to table this new Moderate/Severe Inflammatory Skin Disease Line proposal with the need to clarify the following: determine if plans are able to implement the current severe psoriasis guideline, determine evidence on biologics, clarify definition of moderate/severe, consider face as one category (as facial skin disorders can be highly debilitating in terms of occupational and social functioning). There were also question sof the progressive potential of some of these diseases and if prevention is effective, and how to measure functional impairments. Additionally, there was a concern of having biologics listed without a clear evidence review and at potential considerable expense.

**Action**

- 1) Staff to follow up on issues relating to new proposed moderate/severe inflammatory skin disease line, with plans, dermatologists and P&T committee
- 2) Staff to ask consultant dermatologists about proposed guideline for new line Acne Conglobata
- 3) Make no change to coverage of Actinic Keratoses which are currently on line 655

- 4) Pend decisions on the following recommendations until further discussion occurs:
- a. New Line: Acne conglobata
  - b. Delete Line 134 PYODERMA; MODERATE/SEVERE PSORIASIS MEDICAL THERAPY. Pyoderma codes move to cellulitis line 214. Psoriasis divided into mild and moderate/severe disease
  - c. Guideline modification: Delete current moderate/severe psoriasis guideline to New moderate/severe inflammatory skin disease guideline as above.
  - d. Rename line 545 ~~CYSTIC ACNE~~ ACNE; ROSACEA
  - e. Code movement and coding specification : Move Q82.8 Other specified congenital malformations of skin to both higher severe line and 688.  
New coding specification  
Q82.8 is only included [on the higher line] for the diagnosis of Keratosis follicularis that meets the severity guideline criteria. Other diseases included within Q82.8 are not covered on this line.
- 5) Create the following lines:
- a. **HYDRADENITIS SUPPURATIVA; DISSECTING CELLULITIS OF THE SCALP**  
*Category 7.*  
*Impact on Healthy Life Years 2*  
*Impact on Pain and Suffering 3*  
*Population effects 0*  
*Vulnerable populations 0*  
*Tertiary prevention 1 (decreases risk of scarring down axilla; abscesses; but surgery end stage decision, cure, but 50% graft entire axilla and get disease around graft)*  
*Effectiveness 1*  
*Need for treatment 1*  
*Net cost 4*  
**SCORE 120 . PUTS ON LINE 550**
  - b. **HEMANGIOMAS, COMPLICATED**  
TREATMENT: MEDICAL THERAPY  
*Category 7*  
*Impact on Healthy Life Years 5*  
*Impact on Pain and Suffering 2*  
*Population effects 0*  
*Vulnerable populations 0*  
*Tertiary prevention 5*  
*Effectiveness 4*  
*Need for treatment 1*  
*Net cost 3*  
**SCORE 960 . PUTS ON LINE 350**
- 6) Add a new guideline regarding coverage of complicated hemangiomas as shown in Appendix A
- 7) **Delete the following lines:**
- a. 573 Xerosis, moving single code to 688

- b. 603 Erythema Multiforme Minor, codes moving 530 Erythematous Conditions line

**8) Rescore the following lines:**

- a. 225 TOXIC EPIDERMAL NECROLYSIS AND STAPHYLOCOCCAL SCALDED SKIN SYNDROME; STEVENS-JOHNSON SYNDROME; ERYTHEMA MULTIFORME MAJOR; ECZEMA HERPETICUM

Category 6

Impact on Healthy Life Years 9

Impact on Pain and Suffering 5

Population effects 0

Vulnerable populations 0

Tertiary prevention 2

Effectiveness 3

Need for treatment 1

Net cost 1

SCORE 1920, PUTS around LINE 160

**8) Rename the following lines:**

- a. 530 TOXIC ERYTHEMA, ACNE ROSACEA, DISCOID LUPUS rename TO ERYTHEMATOUS CONDITIONS
- b. 566 FOREIGN BODY GRANULOMA OF MUSCLE, GRANULOMA OF SKIN, AND SUBCUTANEOUS TISSUE
- c. 578 KERATODERMA, ACANTHOSIS NIGRICANS, STRIAE ATROPHICAE, MILD ECZEMATOUS AND OTHER HYPERTROPHIC OR ATROPHIC CONDITIONS OF SKIN

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**Topic: ICD-10 review—Sports Medicine**

**Discussion:** Smits introduced a summary document with suggested changes to the Sports Medicine lines base on the ICD-10 review. Discussion concerned creation of a new line for coverage of Achilles tendonitis, and lateral and medial epicondylitis. Smits pointed out that the experts had given staff articles about the effectiveness of treatment for these conditions on intermediate outcomes such as ability to participate in physical therapy. Dodson was concerned about the considerable cost of covering these conditions, given the treatments which would be available including injections and physical therapy. Gibson pointed out that the evidence concerned only intermediate outcomes, not final outcomes. Pollack pointed out that a large population would be affected. The group felt that the proposed line scoring which included a need for treatment of 0.9 was much too high. It was felt that most patients would only need office advice or over the counter braces. The proposed need for treatment was reduced to 50%, which resulted in a line placement roughly equivalent to the current placement of these conditions. The decision was made to not accept the suggested new line.

The proposed new guideline regarding AC joint sprain treatment was accepted with minimal discussion.

The proposal to change the names of lines 455 and 406 was discussed. The group felt that the proposed wording of “significant injury/impairment” needed to be clarified. The group wanted either more specific wording in the line title or a guideline outlining what was considered significant in terms of injury and impairment.

**Actions:**

- 1) The proposal to create a new line for Achilles tendonitis and lateral and medial epicondylitis was not accepted
- 2) A new guideline for the management of acromioclavicular joint sprain was accepted as noted in Appendix A, with earlier implementation in ICD-9 for October 1, 2012 accepted as shown in Appendix B
- 3) HERC staff will work with sports medicine and orthopedic experts to further define what would be significant injury/impairment for the title of lines 455 and 406

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**Topic: ICD-10 review—Oral maxillofacial surgery**

**Discussion:** Smits introduced a summary document with suggested changes to the oral maxillofacial surgery lines base on the ICD-10 review. The group discussed coverage for odontogenic cysts (K09.0 and K09.1). Olson wondered who often these types of cysts need to be treated. The group determined that these codes could be moved to a covered line if they are uncommon and usually treated; however if they are common and/or only infrequently need treatment, then HERC staff should work with experts to create a guideline for coverage to accompany the movement of these codes to the upper line.

Discussion then moved to moving anodontia to a covered line. Coffman indicated that this diagnosis is on the upper line in CDT coding, and this move is mainly a correction. The decision was made to move this code, effective October 1, 2012 in ICD-9 as well as in the ICD-10 List when released.

**Actions:**

- 1) Change the title of line 627 ~~CYSTS OF ORAL SOFT TISSUES~~  
INCONSEQUENTIAL CYSTS OF ORAL SOFT TISSUES
- 2) HERC staff will work with experts to determine if moving K09.0 (Developmental odontogenic cysts) and K09.1 (Developmental (nonodontogenic) cysts of oral region) requires a guideline
- 3) Move K00.0/520.0 (Anodontia) moves from line 675 DENTAL CONDITIONS WHERE TREATMENT IS CHOSEN PRIMARILY FOR AESTHETIC CONSIDERATIONS to line 477 DENTAL CONDITIONS (EG. MISSING TEETH, PROSTHESIS FAILURE) Treatment: REMOVABLE PROSTHODONTICS (E.G. FULL AND PARTIAL DENTURES, RELINES). The ICD-9 move will be effective October 1, 2012

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**Topic: ICD-10 review--Burns**

**Discussion:** Smits introduced a summary document with suggested changes to the burn lines on the Prioritized List based on ICD-10 review. There was no discussion.

**Actions:**

- 1) Rename line 80 BURN, PARTIAL THICKNESS GREATER THAN 30% OF BODY SURFACE OR WITH VITAL SITE; ~~FULL THICKNESS WITH VITAL SITE, LESS THAN 10% OF BODY SURFACE~~

- 1) Rename line 202 BURN, PARTIAL THICKNESS WITHOUT VITAL SITE REQUIRING GRAFTING, UP TO 40-30% OF BODY SURFACE

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**Topic: ICD-10 Review—Plastic surgery**

**Discussion:** Livingston introduced a summary document outlining the changes suggested during the expert review of the plastic surgery lines as part of the ICD-10 conversion process. The members clarified that the new peripheral nerve injury line only relates to motor nerves. They desired clarification as to what defines “acute” versus chronic. There was some concern raised that this may differ depending on the specialty.

The suggested rescoring for more and less severe skin ulcers was reviewed, given that the new scores would have been so close, and the lines only 2 apart, the decision was made not to split these two lines.

**Actions:**

- 1) Staff to contact consulting plastic surgeon to confirm definition of “acute nerve injury” and present this at the following meeting
- 2) Make no change to the 410 Chronic Ulcer of Skin line
- 3) Remove the following codes from Line 358 Hyperbaric oxygen
  - a. L92.1 Necrobiosis lipoidica, not elsewhere classified 358,652
  - b. L94.2 Calcinosis cutis 358,652
- 4) Rename Line 315 ~~CRUSH~~ CLOSED INJURY OF DIGITS

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**Topic: ICD-10 Review—Neurology**

**Discussion:** Livingston introduced a summary document outlining the changes suggested during the expert review of the neurology lines as part of the ICD-10 conversion process. The proposed guideline note about immune modifying therapies for multiple sclerosis was discussed. The wording was clarified to ensure that treatment of those with an unknown diagnosis is appropriate, unless the diagnosis changes to primary progressive or secondary progressive, in which case there is no further benefit from the therapies.

**Actions:**

- 1) Adopt the following new Guideline Note was created restricting immune modifying therapies in multiple sclerosis for implementation October 1, 2012 as shown in Appendix B
- 2) Consider the following topics for future coverage guidance:
  - a. Management of migraine headaches
  - b. Carotid endarterectomies, indications, and in comparison with medical management
- 3) Rename Line 441 PERIPHERAL NERVE ENTRAPMENT; PALMAR FASCIAL FIBROMATOSIS

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**Topic: Pulmonary valve repair**

**Discussion:** Smits introduced a summary document regarding coverage of acquired pulmonary valve disease repair. There was minimal discussion.

**Actions:**

- 1) Add 424.3 (pulmonary valve disorders) to line 274 and keep on line 363 for medical treatments
- 2) Rename line 274 DISEASES OF MITRAL, ~~AND~~ TRICUSPID, AND PULMONARY VALVES
- 3) Add pulmonary valve repair CPT codes to line 274
  - a. 33470 Valvotomy, pulmonary valve, closed heart; transventricular
  - b. 33471 Valvotomy, pulmonary valve, closed heart; via pulmonary artery
  - c. 33472 Valvotomy, pulmonary valve, open heart; with inflow occlusion
  - d. 33474 Valvotomy, pulmonary valve, open heart; with cardiopulmonary bypass
  - e. 33475 Replacement, pulmonary valve
  - f. 33476 Right ventricular resection for infundibular stenosis, with or without commissurotomy
  - g. 33478 Outflow tract augmentation (gusset), with or without commissurotomy or infundibular resection
- 4) Remove 32660 and 33496 from line 363 DISEASES OF ENDOCARDIUM

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**Topic: Nasal endoscopy for acute sinusitis**

**Discussion:** Smits introduced a summary document outlining proposed changes to the coverage for nasal endoscopy for acute sinusitis. 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.

**Actions:**

- 1) Advise DMAP to remove 31237 from the Diagnostic File
- 2) Remove 31238 from line 654
- 3) Remove 31256 from line 262
- 4) Remove 31276 from lines 391 and 548 and advise DMAP to remove from the Diagnostic File
- 5) Remove 31295 from line 391
- 6) Remove 31296 from line 391
- 7) Remove 31297 from line 391

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**Topic: Vascular bone grafting for avascular necrosis of the hip**

**Discussion:** Smits introduced a summary document outlining a new evidence review on the effectiveness of vascular bone grafting (VBG) for avascular necrosis of the hip (AVN). An expert, Dr. Mirarchi from OHSU Orthopedics, was available to answer subcommittee questions via phone.

The first question raised was whether vascular bone grafting should continue to be on lines with advanced forms of AVN. The evidence review found that more advanced forms has worse outcomes than less advanced forms. Dr. Mirarchi felt that this procedure was needed in some advanced cases of AVN. Specifically, he felt that VBG was a reasonable surgical options for patients with femoral neck fracture when there are no other surgical repair options (i.e. the patient was too young to be a good total hip replacement candidate). By young, he agreed with the age restriction of less than 50 years, as well as the other restrictions outlined in the proposed guideline in the packet (AVN not related to steroid or alcohol use as these increase the probability of thrombosis, life expectance of 20-25 years). He specified that VBG is useful when there is a requirement to have some type of structural support for the hip as well as improved blood flow. He noted that he personally stopped doing VBG due to concerns about lack of benefit to patients with this procedure. He pointed out that this surgery is very highly technically demanding surgery, takes about 8 hours, and that better outcomes are strongly correlated with high volume. He also has concerns about the high complication rate with this surgery, particularly at the harvest site. These complications include nerve injuries of foot, leg and ankle weakness, hematomas. He noted that the surgery takes muscle and bone from harvest site. He reported a 25% complication rate (major and minor) per literature.

The proposal was made to include the procedure on the more serious AVN condition lines (hip fracture, etc.) with a guideline specifying that the surgery was only indicated for young patients with need for structural support of the femoral neck, and that two physicians need to provide recommendation for the surgery.

Mr. Michael Adkins then asked Dr. Mirarchi what he would recommend for a patient with his particular situation. The subcommittee stopped this line of questioning as being inappropriate—experts cannot given medical advice to patients as part of their VBBS testimony. Mr. Adkins also gave public testimony regarding his research that found that most major medical plans (BCBS, Aetna, Cigna, etc.) cover VBG as medically necessary, and most state Medicaid plans cover without a guideline. He reported that he spoke with a surgeon at USC who had agreed to see him if this procedure is added for treatment for AVN (currently no surgeons in Oregon or Washington were found who provide this surgery). Mr. Adkins also reported that he spoe with Dr. Urbaniak at Duke, who felt that the proposed guideline for VBG restricted surgical judgment unnecessarilly. He argued that VBG is standard of care for stage 2/3 AVN in most parts of the country and argued that guidelines are not good medicine.

Gibson made a final comment that the HERC's job was to create coverage policies within the context of limited finanacial resources.

The final decision was to leave VBG on the current lines with a guideline restricting use to young patients with femoral neck fractures needing structural support. VBG will not be added to line 384.

**Actions:**

- 1) Do not add vascular bone grafting (CPT 27170) to line 384

- 2) Keep 27170 on lines 297, 467, and 531 with a guideline. HERC staff will work with Dr. Mirarchi and other orthopedic experts to craft this guideline and will bring back to a future VBBS meeting.

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**Topic: Paraphilia line placement**

**Discussion:** Smits introduced a summary document discussing follow up issues for the creation of two lines, Paraphilias and Gender Dysphoria, from the current Paraphilias line.

Tyack raised concerns about the possible harms associated with hormone treatment of adolescents. The previous discussion in March had approved adding puberty suppressing hormone medications to the Gender Dysphoria Line. Since that discussion, Tyack has spoken with a pediatric endocrinologist, who raised concerns about this type of treatment on the developing brain. Tyack requested testimony from a developmental neuropsychologist prior to finalizing the decision to add such puberty suppressing medications to this line. Gibson agreed that if significant adverse events could result from treatment, then this issue needs to be fully addressed before a final decision is made. Pollack felt that there was only a small group of providers who worked with these puberty suppressing medications and that these providers were fully aware of the risks and that these medications were used judiciously. Livingston noted that the MED project has treatment of gender identity disorder on its list of possible upcoming reviews, so more information may be forthcoming soon. The group felt that being conservative and only including the current treatments on the line (mainly psychotherapy) for the initial line split was the right thing to do. Further research could be done in to puberty suppressing medications. HERC staff will communicate this decision to the advocacy groups and keep them in the loop.

The group then discussed the new paraphilias line. The major diagnosis on this line which drives need for treatment is pedophilia. Dodson felt that perhaps this diagnosis should be removed from the line and made its own line. Pollack replied that he had considered this when advising HERC staff about the new line, and felt that it was appropriate to keep on the paraphilias line. Gibson was concerned that pedophilia would not be treated under OHP as the new paraphilias line scores below the current funding line. Smits noted that the current paraphilias line is unfunded, so this would not represent a change. Pollack noted that pedophilia was a reportable offense, and most treatment was court mandated, usually through the justice system.

The final decision was to move forward with splitting the current paraphilia line into gender dysphoria and paraphilia, with only the current treatments (psychotherapy) included on the two new lines. The two additional diagnoses proposed for the upper line were approved. The line scoring of the paraphilias line was approved.

**Actions:**

- 1) Split the current Paraphilias line into two new lines, Gender Dysphoria and Paraphilias, as noted in the March 2012 VBBS minutes
- 2) Move 302.0 (Ego-dystonic sexual orientation) and 302.50 (Trans-sexualism with unspecified sexual history) to the new Gender Dysphoria line

- 3) Rank the new Paraphilias line to approximately line 530
- 4) Add only psychotherapy to both new lines. HERC staff will work with experts and advocates to determine whether puberty suppression or other hormone therapy should be added to the Gender Dysphoria line.

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**Topic: Neoplasm of uncertain behavior**

**Discussion:** Livingston introduced a summary document outlining suggested changes to the placement of the diagnosis “neoplasm of uncertain nature.” Smits pointed out that this is now, per CMS rules, a pathologic diagnosis. The diagnostic work up of lesions would be covered under the diagnosis of “neoplasm of unspecified nature.” These were felt to be transitory diagnoses, and so are appropriate to be placed in the Diagnostic File.

**Actions:**

- 1) 272 family of codes will be placed on relevant lines as shown in the packet document

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**Topic: Cardiac MRI for thoracic aneurysm**

**Discussion:** Smits introduced a summary document with recommendations to add cardiac MRI for evaluation of thoracic aneurysms. There was minimal discussion.

**Actions:**

- 1) Add cardiac MRI (CPT 75561-5) to line 349 NON-DISSECTING ANEURYSM WITHOUT RUPTURE

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**Topic: Earlier implementation of guideline changes from the ICD-10 review**

**Discussion:** Smits introduced a summary document outlining guidelines which were modified as part of the ICD-10 review process which are appropriate for earlier implementation. The three guidelines in the initial document were accepted for earlier implementation with minimal discussion.

A new guideline for treatment of benign neoplasm of urinary organs was reviewed for earlier placement. The proposed guideline was modified to more clearly specify then diagnoses are covered on line 228 and when on line 538.

The proposed wording for the VAD guideline was accepted with no discussion.

**Actions:**

- 1) Changes to the Heart-Kidney Transplant guideline, Frenulectomy/Frenulotomy guideline, and Bariatric Surgery guideline were accepted for implementation October 1, 2012 as shown in Appendix B
- 2) A new guideline regarding treatment of benign neoplasms of the urinary tract was accepted with wording for both ICD-9 (to be implemented October 1, 2012) and ICD-10 (to be implemented October 1, 2014 tentatively)
- 3) A modified guideline for ventricular assist devices was accepted for implementation October 1, 2012 as shown in Appendix B

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**Topic: ESA guideline modifications**

**Discussion:** Livingston introduced a summary document outlining suggested changes to the ESA guideline based on new safety concerns. Amgen submitted a request to have the language on the upper limit for hemoglobin for dosing in chronic renal patients changed. The group felt that clear language would be important for implementation. Olson pointed out that the label information was not necessarily meant for clinical practice. The guideline was approved with specific direction not to exceed hemoglobin limits.

**Motion to approve – unanimous.**

**Actions:**

- 1) Modify guideline for ESAs approved as shown in Appendix B

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**Topic: ICD-10 Otolaryngology**

**Discussion:** Livingston introduced a summary document outlining suggested changes to the otolaryngology lines as part of the ICD-10 review process. Dr. Paul Flint was present to answer questions about the otolaryngology recommendations. Modifications were made to the guideline note for clarity. Regarding Line 498 Chronic Sinusitis, it was discussed that complications occur in about 3% with frontal and sphenoid sinusitis carrying the highest risk, but that the mortality rate is well below 1%. Effectiveness is about 50%. The decision was made to change healthy life years score to 4.

**Actions:**

- 1) **CREATE NEW LINES**

**LARYNGEAL STENOSIS OR PARALYSIS WITH AIRWAY COMPLICATIONS**

**Scoring**

Category 6  
Impact on healthy life years 7  
Impact on pain and suffering 4  
Population 0  
Impact on vulnerable populations 2  
Tertiary Prevention – 3  
Need for service – 2  
Effectiveness – 4  
Score 2560

**New Line 80**

- 2) A new guideline was created for the new laryngeal stenosis line as shown in Appendix A
- 3) Modify scoring of Chronic Sinusitis Line 498
  - a. Change Health Life Years to 4, which changes the score to 240, placing it around Line 495

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**Topic: Straightforward items**

**Discussion:** Smits introduced a summary document outlining suggested straightforward changes to the List, as well as changes to the placement of partial and total colectomy codes. There was no discussion.

**Actions:**

- 1) Add 92081-3 to line 435
- 2) Add 21076 to line 325
- 3) Add 67121 to line 448
- 4) Add 27030 to line 308
- 5) Add 69711 to line 308
- 6) Add 36147, 37207, and 75791 to line 308
- 7) Add 43269 to lines 308 and 448
- 8) Add 57295 to line 448
- 9) Add 26432 to line 550
- 10) Add 20661 to line 448
- 11) Add 37224, 37228, and 49429 to line 448
- 12) Add 69424 to line 308
- 13) Add 65920 to line 448
- 14) Add 63707 and 63709 to line 308 and 448
- 15) Remove 36822 from lines 14, 98, 111, 154, 248, and 310. Advise DMAP to place 36822 on the Ancillary File.
- 16) Add 27886 to lines 308 and 448
- 17) Add 25909 to line 308 and 448
- 18) Add 21501 to line 308
- 19) Add 32120 to line 308
- 20) Add 15200-1 to line 197
- 21) Affirm the placement of 38542 on line 221
- 22) Add 51525 to line 351
- 23) Add 29425 to lines 467, 536 and 565
- 24) Add 28300 to line 550
- 25) Add 11982 to line 308
- 26) Add 77418 and 77421 to line 218
- 27) Add 97530 to line 441
- 28) Add 34451 to line 303
- 29) Add 45905 and 45910 to line 111
- 30) Add 48545 to line 88
- 31) Add 47350 and 47360 to line 88
- 32) Add 40830 and 40831 to line 216
- 33) Add 35476 to line 303
- 34) Add 27430 to line 318
- 35) Add 25645 to line 143
- 36) Add 62010 to line 101. Remove 62010 from line 273
- 37) Add 44204 to lines 78, 111, 163, 339, 503
- 38) Add 44205 to lines 78, 111, 163, 339, 503 and 667. Remove 44205 from line 666
- 39) Remove 44213 from line 593. Add 44213 to line 667

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**Public Comment**

No public testimony was received except as noted in topic sections above.

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**Issues for next meeting:**

- 1) ICD-10 review for Infectious Disease, Ophthalmology, Obstetrics and Gynecology

- 2) Follow up issues for ICD-10 topics
  - 3) Unspecified disorders of the nervous system
  - 4) Amputation for burns resulting in deep tissue necrosis
  - 5) Percutaneous testing for drug allergies
- 

**Next meeting:** May 10, 2012 at Wilsonville Training Center in Wilsonville, OR.

## Appendix A

### Guideline Changes as Part of the ICD-10 and/or Biennial Review

Note: these take effect with the next Biennial Review List (tentatively October 1, 2014)

## New Guidelines

### **GUIDELINE NOTE XXX MANAGEMENT OF ACROMIOCLAVICULAR JOINT SPRAIN**

*Line 443, 638*

Sprain of acromioclavicular joint (ICD-10 S43.50-S43.52, and S43.60-S43.62) are only included on line 443 for Grade 4-6 sprains. Surgical management of these injuries is covered only after a trial of conservative therapy. Grade 1-3 acromioclavicular joint sprains are included only on line 638.

### **GUIDELINE NOTE XXX HEMANGIOMAS, COMPLICATED**

**New Line**

Hemangiomas are covered on this line when they are ulcerated, infected, recurrently hemorrhaging, or function-threatening (e.g. eyelid hemangioma).

### **GUIDELINE NOTE XXX TREATMENT OF BENIGN NEOPLASM OF URINARY ORGANS**

*Line 228, 538*

Treatment of benign urinary system tumors (ICD-9 223.0, ICD-10 D30.00-D30.02) are included on line 228 with evidence of bleeding or urinary obstruction. Treatment of 1) oncocytoma which is >5 cm in size or symptomatic and 2) angiomyolipoma (AML) which is >5cm in women of child bearing age or in symptomatic men or women is covered. Otherwise, these diagnoses are included on line 538.

### **GUIDELINE NOTE XXX LARYNGEAL STENOSIS OR PARALYSIS WITH AIRWAY COMPLICATIONS**

**New Line**

Laryngeal paralysis is covered on this line if associated with recurrent aspiration pneumonia (unilateral or bilateral) or airway obstruction (bilateral). Hoarseness is on line 543. Laryngeal stenosis is included on this line only if it causes airway obstruction.

## Appendix B

### Guideline Changes to be Implemented October 1, 2012

#### New Guidelines

##### **GUIDELINE NOTE XXX MANAGEMENT OF ACROMIOCLAVICULAR JOINT SPRAIN**

*Line 443, 638*

Sprain of acromioclavicular joint (ICD-10 840.0) is only included on line 443 for Grade 4-6 sprains. Surgical management of these injuries is covered only after a trial of conservative therapy. Grade 1-3 acromioclavicular joint sprains are included only on line 638.

##### **GUIDELINE NOTE XXX IMMUNE MODIFYING THERAPIES FOR MULTIPLE SCLEROSIS**

*Line 268*

Once a diagnosis of primary progressive or secondary progressive multiple sclerosis is reached, immune modifying therapies are no longer covered.

##### **GUIDELINE NOTE XXX TREATMENT OF BENIGN NEOPLASM OF URINARY ORGANS**

*Line 228, 538*

Treatment of benign urinary system tumors (ICD-9 223.0, ICD-10 D30.00-D30.02) are included on line 228 with evidence of bleeding or urinary obstruction. Treatment of 1) oncocytoma which is >5 cm in size or symptomatic and 2) angiomyolipoma (AML) which is >5cm in women of child bearing age or in symptomatic men or women is covered. Otherwise, these diagnoses are included on line 538.

#### Modified Guidelines

##### **GUIDELINE NOTE 70, HEART-KIDNEY TRANSPLANTS**

*Line 279*

Patients under consideration for heart/kidney transplant must qualify for each individual type of transplant under current DMAP administrative rules and transplant center criteria with the exception of any exclusions due to heart and/or kidney disease. Qualifying renal disease is limited to Stage V or VI.

##### **GUIDELINE NOTE 48, FRENUECTOMY/FRENULOTOMY**

*Line 373*

Frenulectomy/frenulotomy (D7960) is included on this line for the following situations:

- ~~1. In the presence of ankyloglossia~~
- ~~2.~~1. When deemed to cause gingival recession
- ~~3.~~2. When deemed to cause movement of the gingival margin when frenum is placed under tension.
- ~~4.~~3. Maxillary labial frenulectomy not covered until age 12 and above

## **GUIDELINE NOTE 8, BARIATRIC SURGERY**

*Lines 33,607*

Bariatric surgery for obesity is included on Line 33 TYPE II DIABETES MELLITUS, and Line 607 OBESITY under the following criteria:

- A) Age  $\geq$  18
- A) For inclusion on Line 33: BMI  $\geq$  35 with co-morbid type II diabetes. For inclusion on Line 607: BMI  $\geq$  35 with at least one significant co-morbidity other than type II diabetes (e.g., obstructive sleep apnea, hyperlipidemia, hypertension) or BMI  $\geq$  40 without a significant co-morbidity.
- B) 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.
- C) 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 nicotine or illicit drugs and must remain abstinent from their use during the six-month observation period. Testing will, at a minimum, be conducted within one month of the surgery to confirm abstinence from nicotine and illicit drugs.
    - c) No mental or behavioral disorder that may interfere with postoperative outcomes<sup>1</sup>.
    - 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<sup>2</sup>)
    - 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<sup>3</sup> 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
- D) 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).

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

<sup>2</sup> All surgical services must be provided by a program with current certification by the American College of Surgeons (ACS) or the ~~Surgical Review Corporation (SRC)~~, American Society for Metabolic and Bariatric Surgery (ASMBS) 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 ACS or ~~SR~~ ASMBS-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).

<sup>3</sup> Only Roux-en-Y gastric bypass, laparoscopic adjustable gastric banding and sleeve gastrectomy are approved for inclusion.

<sup>4</sup> The patient must meet criteria #1, #2, and #3, and be referred by the OHP primary care provider as a medically appropriate candidate, to be approved for evaluation at a qualified bariatric surgery program.

## **GUIDELINE NOTE 18, VENTRICULAR ASSIST DEVICES**

*Lines 108,279*

Ventricular assist devices are covered only in the following circumstances:

1. as a bridge to cardiac transplant;
  2. as treatment for pulmonary hypertension when pulmonary hypertension is the only contraindication to cardiac transplant and the anticipated outcome is cardiac transplant;
- or,
3. as a bridge to recovery.

Ventricular assist devices are not covered for destination therapy.

Ventricular assist devices are covered for cardiomyopathy only when the intention is bridge to cardiac transplant.

Long-term VADs are covered for indications 1 and 2. Long-term VADs are defined as a VAD that is implanted in a patient with the intent for the patient to be supported for greater than a month with the potential for discharge from the hospital with the device. Temporary or short term VADs are covered for indications 1 and 3. Short-term VADs are defined as a VAD that is implanted in a patient with the intent for the patient to be supported for days or weeks with no potential for discharge from the hospital with the device.

## **GUIDELINE NOTE 7, ERYTHROPOIESIS-STIMULATING AGENT (ESA) GUIDELINE**

*Lines 33,66,79,102,103,105,123-*

*125,131,138,144,159,165,166,168,170,181,197,198,206-*

*208,218,220,221,228,229,231,235,243,249,252,275-278,280,287,292,310-*

*312,314,320,339-341,352,356,366,459,622*

A) Indicated for anemia (Hgb < 10gm/dl or Hct < 30%) induced by cancer chemotherapy given within the previous 8 weeks or in the setting of myelodysplasia.

1) Reassessment should be made after 8 weeks of treatment. If no response, treatment should be discontinued. If response is demonstrated, ESAs should be discontinued once the hemoglobin level reaches 10gm/dl, unless a lower hemoglobin level is sufficient to avoid the need for red blood cell (RBC) blood transfusion.

B) Indicated for anemia (Hgb < 10gm/dl or HCT < 30%) associated with HIV/AIDS.

1) An endogenous erythropoietin level < 500 IU/L is required for treatment, and patient may not be receiving zidovudine (AZT) > 4200 mg/week.

2) Reassessment should be made after 8 weeks. If no response, treatment should be discontinued. If response is demonstrated, ~~ESAs should be titrated to maintain a level between 10 and 12~~ the lowest ESA dose sufficient to reduce the need for RBC transfusions should be used, and the Hgb should not exceed 11gm/dl.

C) Indicated for anemia (Hgb < 10 gm/dl or HCT <30%) associated with chronic renal failure, with or without dialysis.

1) Reassessment should be made after 8 weeks. If no response, treatment should be discontinued. If response is demonstrated, ~~ESAs should be titrated to maintain a level between 11 and 12~~ the lowest ESA dose sufficient to reduce the need for RBC transfusions should be used, and the Hgb should not exceed 11gm/dl. In those not on dialysis, the Hgb level should not exceed 10gm/dl.

## MINUTES

Health Technology Assessment Subcommittee  
Meridian Park Community Health Education Center  
19300 SW 65th Avenue, Tualatin, OR  
April 23, 2012, 1:00-4:00pm

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**Members Present:** Alissa Craft, DO, MBA; James MacKay, MD; Gerald Ahmann, MD (via phone); George Waldmann, MD, Ed Toggert, MD (via phone).

**Members Absent:** none

**Staff Present:** Darren Coffman; Wally Shaffer, MD, MPH; Dave Lenar.

**Also Attending:** Alison Little, MD (CEBP); Shannon Vandergriff (CEBP); Anna Thompson (Medtronic); Dena Searce (Medtronic); Joanie Cosgrove (Medtronic); Mike Bolen (Medtronic); Jeff Christensen (Jazz Pharmaceuticals); Chris Arapiff (Medtronic); Laura Modjeski (Pac/West Communications); Richard Kosasad.

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### I. CALL TO ORDER

Alissa Craft called the meeting of the Health Technology Assessment Subcommittee (HTAS) to order at 1:05 pm.

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### 2. REVIEW OF MARCH MINUTES

No changes were made to the March minutes.

**Minutes approved 5-0.**

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### 3. REVIEW OF THE COVERAGE GUIDANCE AND PUBLIC INPUT PROCESS

Darren Coffman presented a review of the coverage guidance process including timelines for public input and posting of notices. He noted the discrepancy between a 30-day public comment period and fewer than 30 days between subcommittee meetings would mean an elongated process for completing coverage guidances.

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### 4. REVIEW DRAFT COVERAGE GUIDANCE

#### A. LUMBAR DISCOGRAPHY

Wally Shaffer presented the evidence summary for lumbar discography and the draft coverage guidance was discussed. Expert written testimony, at the request of the subcommittee, was accepted from Dr. Don Ross, a neurosurgeon at OHSU. Dr. Ross outlined his reasons and supporting evidence for not recommending the use of discography, including the possibility of accelerated degenerative changes due to the

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procedure. There was discussion about the meaning of “uncomplicated lumbar degenerative disc disease” and how that is differentiated from “complicated lumbar degenerative disc disease.” It was decided to leave out any mention of “uncomplicated” in the coverage guidance.

Action

- 1) Adopt revised draft coverage guidance:  
**Lumbar discography should not be a covered service for patients with low back pain.**

A motion was made to approve and seconded. **Motion approved 5-0.**

#### B. VERTEBROPLASTY, SACROPLASTY, AND KYPHOPLASTY

Wally Shaffer presented the evidence summary for vertebroplasty, sacroplasty, and kyphoplasty and the draft coverage guidance was discussed. There was discussion about the immediate versus long term benefits of kyphoplasty. Some members felt that even though there may not be long term benefits, the immediate pain relief could justify covering the procedure. Members discussed the fact that there have been over 100 studies published regarding these procedures since the publication of the Washington HTA. The members felt there was sufficient evidence about the use of these procedures in treating malignancy related fractures, but did not have enough evidence to make a conclusion about their use in osteoporotic compression fractures or if there was any benefit for certain subpopulations.

Action

- 1) Adopt revised draft coverage guidance:  
**Vertebroplasty, sacroplasty, and kyphoplasty should not be covered for routine osteoporotic compression fractures.**

A motion was made to approve and seconded. **Motion approved 5-0.**

#### C. ARTIFICIAL DISCS

Wally Shaffer presented the evidence summary on artificial discs (ADs) and the draft coverage guidance was discussed. Members discussed whether there were age limitations for cervical ADs and how much of the FDA approved indications to include in this and subsequent coverage guidances. Dr. MacKay raised concerns about durability, especially for load bearing lumbar ADs, and noted that there was not clear evidence.

Action

- 1) Adopt draft coverage guidance with the following revision:  
**“...Reconstruction of a single disc following single level discectomy...”**

A motion was made to approve and seconded. **Motion approved 4-1.**

#### D. HIP RESURFACING

Wally Shaffer presented the evidence summary for hip resurfacing and the draft coverage guidance was discussed. Members were mainly concerned with the age of the Washington HTA and more recent evidence concerning the safety of metal-on-metal joint replacements. Wally Shaffer noted that the FDA was concerned enough with metal-on-metal safety that they added contraindications to the use of hip resurfacing specifically aimed at reducing complications from metal-on-metal. Members discussed if they would be able to rescind a coverage approval recommendation if a review of the metal-on-metal hip resurfacing evidence showed safety risks.

##### Action

- 1) Adopt draft coverage guidance as written.
- 2) Request the Center for Evidence-based Practice to evaluate any new evidence on the safety of metal-on-metal hip resurfacing.

A motion was made to approve and seconded. **Motion approved 5-0.**

#### 5. PUBLIC COMMENT

Prior to a vote on the coverage guidance for vertebroplasty, sacroplasty, and kyphoplasty, public comment was received from Dena Scearce, a representative of Medtronic. She commented that the Washington HTA report which the subcommittee was basing their decision on was out of date given the numerous studies published since the HTA's release. She also raised concerns about the studies used in the HTA, noting that some of the studies used a mix of procedures to draw conclusions instead of using a single type of procedure. It was also commented that the Washington coverage decision was positive and all commercial payers in Oregon currently cover these procedures.

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#### 6. ADJOURNMENT

The meeting was adjourned at 3:10pm. The next meeting is scheduled for May 21, 2012 from 1:00-4:00 pm in Room 117B of the Meridian Park Hospital Community Health Education Center in Tualatin.

**HTAS Coverage Guidance  
Summary**

Oregon Health Evidence Review Commission  
June 14, 2012



**Coverage Guidance**

For HERC review and approval:

- MRI for Breast Cancer Screening



2



## MRI for Breast Cancer Screening

### HERC Coverage Guidance

- Breast MRI should not be covered for screening for breast cancer.

## MRI for Breast Cancer Screening

### Evidence Summary

- Adding yearly screening with MRI to mammographic (+/- US +/- clinical breast exam) screening in women at high risk of breast cancer will increase detection of breast cancer.
- The increase in cancer detection is offset by a higher rate of false positive tests.
- Changes in care will occur in some women who undergo MRI testing (additional biopsies, etc).
- No RCTs have assessed the effect of adding MRI to conventional breast cancer screening on mortality rates.

## HEALTH EVIDENCE REVIEW COMMISSION (HERC)

### **DRAFT** COVERAGE GUIDANCE: MRI FOR BREAST CANCER SCREENING

DATE: XX/XX/XXXX

#### HERC COVERAGE GUIDANCE

Breast MRI should not be covered for screening for breast cancer.

#### RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

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

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

#### EVIDENCE SOURCE

Washington State Health Care Authority Health Technology Assessment Program. (2010). *HTA Report: Breast MRI in diagnosis and treatment of cancer in women at high risk*. Olympia, WA: Health Technology Assessment Program. Retrieved from [http://www.hta.hca.wa.gov/documents/breast\\_mri\\_072310\\_final.pdf](http://www.hta.hca.wa.gov/documents/breast_mri_072310_final.pdf)

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

## SUMMARY OF EVIDENCE

### **Clinical Background**

In 2009, an estimated 192,370 cases and 40,170 deaths occurred in women with breast cancer. In 2002, the United States Preventive Services Task Force found adequate evidence of film mammography's sensitivity and specificity and evidence of mammography's effectiveness in decreasing breast cancer mortality in women at average risk and concluded that film mammography was the standard for detecting breast cancer in women at average risk of developing breast cancer. In 2007, the American Cancer Society (ACS) issued guidelines recommending that women at high risk of developing breast cancer be screened with MRI. The ACS recommends annual mammography and MRI screening for women starting at age 30 if their lifetime risk is approximately 20% to 25%. Women with *BRCA1* mutations are estimated to have a 65% risk by age 70 years for developing breast cancer; the corresponding risk for *BRCA2* mutations is 45%.

### **Evidence Review**

#### *Diagnostic Accuracy*

Adding yearly screening with MRI to mammographic (+/- US +/- clinical breast exam) screening in women at high risk of breast cancer (family history of breast cancer,  $\geq$  approximately 20% lifetime risk of breast cancer, known *BRCA1/2* carriers and/or previous history of breast cancer) will increase detection of breast cancer. Increased breast cancer detection will also occur in women with increased breast density or fibroglandular breast tissue. The increase in cancer detection of approximately 2 to 5 breast cancers per 100 screenings is offset by a higher rate of false positive tests.

#### *Changes in Treatment*

Changes in care, such as recall of patients, subsequent benign breast biopsies and possibly unnecessarily more extensive breast tissue resections and unnecessary mastectomies will occur in some women who undergo MRI testing. Approximately 11 additional benign biopsies will occur per 100 screenings, and many women will undergo more extensive breast resection surgery (up to 44% change in treatment plans). The evidence regarding the effect of adding MRI to mammographic screening on incomplete cancer excision rates or breast cancer recurrence rates is inconclusive. No RCTs have assessed the effect of adding MRI to conventional breast cancer screening on mortality rates.

#### *Safety*

Gadolinium-based MRI contrast agents appear to be safe. There is no evidence of adverse events associated with MRI radiation exposure. We found no evidence that breast implants increase the risk of developing breast cancer. The evidence is

insufficient to conclude that false-positive breast cancer screening or testing results lead to clinically meaningful negative psychological outcomes.

#### *Technical and Provider Issues in MRI Testing*

The evidence is insufficient to establish technical MRI specifications or provider qualifications.

#### *Cost and Cost-effectiveness*

The evidence suggests that adding MRI to mammographic breast cancer screening in women at high risk of developing breast cancer will increase the detection of breast cancers, lead to false positive tests with increased diagnostic and therapeutic interventions and costs, and may increase the number of women who undergo unnecessary mastectomies. However, accurately estimating cost-effectiveness may not be possible because RCTs evaluating the mortality reduction with screening or testing women at high-risk for breast cancer have not been conducted. QALYs gained by adding MRI to mammographic breast cancer screening vary greatly depending upon assumptions about sensitivity of MRI, yearly cancer risk, the number and frequency of diagnostic tests, the type and costs of therapeutic interventions, risk of recurrence, development of cancer in the contralateral breast and mortality assumptions.

[\[Evidence Source\]](#)

### **Overall Summary**

While screening for breast cancer with MRI has been shown to increase the detection of breast cancer when compared to screening with mammography alone, there is no evidence of a benefit on morbidity or mortality, and there is the possibility of overdiagnosis associated with harm.

### **PROCEDURE**

MRI of the Breast

### **DIAGNOSES**

Screening for breast cancer

## APPLICABLE CODES

<b>CODES</b>	<b>DESCRIPTION</b>
<b>ICD-9 Codes</b>	
V10.3	Personal history of malignant neoplasm, breast
V16.3	Family history of malignant neoplasm, breast
V76.10	Special screening for malignant neoplasms, breast, unspecified
V76.19	Special screening for malignant neoplasms, breast, other screening breast examination
V84.01	Genetic susceptibility to malignant neoplasm of breast
<b>ICD-9 Volume 3 (procedure codes)</b>	
None	
<b>CPT Codes</b>	
77058	MRI breast, with or without contrast, unilateral
77059	MRI breast, with or without contrast, bilateral
<b>HCPCS Codes</b>	
C8903	Magnetic resonance imaging with contrast, breast; unilateral
C8904	Magnetic resonance imaging without contrast, breast; unilateral
C8905	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral
C8906	Magnetic resonance imaging with contrast, breast; bilateral
C8907	Magnetic resonance imaging without contrast, breast; bilateral
C8908	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral

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.

## MINUTES

Evidence-based Guidelines Subcommittee

Meridian Park Hospital  
Community Health Education Center, Room 117 B&C  
19300 SW 65th Avenue, Tualatin, OR 97062  
May 3, 2012  
2:00pm - 5:00pm

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**Members Present:** Steve Marks, MD, Vice-Chair Presiding; Wiley Chan, MD, Chair; Vern Saboe, DC; Beth Westbrook, PsyD; Irene Crosswell, RPh; Leda Garside, RN (arrived after roll call); Som Saha, MD, MPH (arrived after roll call).

**Members Absent:** Eric Stecker, MD.

**Staff Present:** Darren Coffman; Cat Livingston, MD, MPH; Dave Lenar.

**Also Attending:** Alison Little, MD and Shannon Vandegriff (CEbP); Jessie Little (ASU); Paul Nielsen (MedImmune); Kathy Kirk (OPMC).

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### CALL TO ORDER

Steve Marks called the meeting of the Evidence-based Guideline Subcommittee (EbGS) to order at 2:12 pm (after quorum achieved) and updated the agenda. Marks indicated a topic slated for today's discussion - nonpharmacologic interventions for treatment-resistant depression - will be addressed at the June meeting. In addition, some topics listed for next month's discussion, 1) early childhood caries treatment: stainless steel crowns vs other, 2) laser based treatment of venous disease and 3) evaluation and management of low backpain – pharmacologic interventions, will not be discussed in June.

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### REVIEW OF MARCH MINUTES

**Motion: Approve minutes as written. Motion carries: 5-0 (Absent – Garside, Saha).**

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### DIRECTOR UPDATES

Darren Coffman presented a revised [coverage guidance process](#). The new trusted sources that have been approved by HERC were reviewed. If possible, topics with public reports will be prioritized higher. The 30-day posting process was reviewed, as well as the 2-month time span between meetings the 30-day posting requires, so that public comment can be brought back to the subcommittee to review. Coffman reviewed the process for responding to studies that are submitted as part of public comment.

Coffman discussed the overall timeline of subcommittee's work. This subcommittee will now meet every other month. This new schedule will allow us to discuss topics continuously between meetings, incorporating a 30-day comment period. Meetings will be held in August, October and December. The September and November meetings are cancelled.

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## **REVIEW OF THE PERCUTANEOUS INTERVENTIONS FOR LOW BACK PAIN GUIDELINE**

Alison Little reviewed major points of the draft guideline included in the meeting materials ([pages 25-47](#)). There was no discussion.

**Motion: To approve the guideline as written. Motion carries: 7-0**

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### **COVERAGE GUIDANCE PUBLIC COMMENT:**

#### ***Nonpharmacological Treatments of Low Back Pain***

Marks began a discussion about the approach to the public comment process. Wiley Chan mentioned it would be interesting to know why seemingly strong studies were rejected by trusted sources if it were easily identifiable. Som Saha affirmed the importance of not dismissing concerns about excluded studies. However, it was noted the HERC process is about evaluating guidelines that are already determined to be of high quality. The members agreed the trusted sources accomplish their work through a very well accepted method. If interested parties have a problem with how the guideline is developed, that should be addressed with the guideline makers themselves; there are not the resources nor is it efficient for the EbGS or staff to dig into primary sources. Knowledge of which specific studies have been used and cited is clearly listed and readily available.

There was a discussion about the role of the subcommittee in evaluating evidence excluded from the source report. The members agree if the studies have already been considered by a trusted source, the subcommittee will not evaluate further details about those studies. Further, if the evidence is already examined by a systematic review and/or trusted source, the Center for Evidence-based Policy (CEbP) does not need to reevaluate. If there is a review of systematic reviews, no searching is necessary. If source document has references included, then CEbP will check to see if those studies were included or excluded. HERC policy is to use systematic reviews or highly quality guidelines and to re-evaluate studies previously assessed for inclusion or exclusion by the systematic review is not warranted.

Little reviewed the public comments ([pages 62-70](#)) and the [CeBP's recommended responses](#). No changes were recommended to be made to the draft coverage guidance on Low Back Pain: Non-Pharmacologic/Non-Invasive Interventions after review of the public comments.

**Motion: To approve the coverage guidance as written and forward to HERC. Motion carries: 7-0.**

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## REVIEW OF NEW DRAFT COVERAGE GUIDANCES

### ***Diagnosis and Treatment of Pediatric ADHD*** ([pages 71-79](#))

Livingston began the discussion, stating the term “preschoolers” should be replaced with the phrase “[children under 6](#)” with disruptive behavior disorders (including those at risk for ADHD), and parent behavior training should be covered as first-line therapy. It was suggested there may be a need to determine which subtypes of parent behavior trainings are more efficacious and if the elements of parent behavior training are known, whether those should be specified. Saha stated details such as to length, duration and frequency of trainings should be determined by the health plan’s coverage implementation teams and should not be included in the guidance.

The evidence suggests psychostimulant medication should be considered as a second line of therapy, weighing the benefits and harms to determine if it is appropriate for an individual child. Additional changes suggested included the following: For children ages [6 and over](#) with ADHD, psychostimulants alone or psychostimulants with [specific](#) behavioral treatment are considered first-line therapy and should be covered.

#### **Action**

- Change language to replace “preschoolers” with the statement “children 5 and under”
- Add into draft coverage guidance “specific\* parent behavior treatment” : \*Parent behavior therapies with evidence to support them include a), b), c),...x).

**Motion: To conditionally approve the ADHD draft coverage guidance for public comment pending the ability to identify the parent behavior training therapies with supporting evidence. Motion carries: 7-0.**

### ***Advanced Imaging for Low Back Pain*** ([pages 89-95](#))

Livingston reiterated the proposed coverage guidance stemming from the recently approved HERC guideline. There was little substantial discussion.

#### **Action**

- Add red flags Table B (and add an asterix) into coverage guidance document
- Define persistent as (>1 month duration)

**Motion: To approve the Advanced Imaging for Low Back Pain draft coverage guidance for public comment as amended. Motion carries: 7-0.**

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## NEXT MONTHS TOPICS

- Review public comment and finalize coverage guidances on:
  - Knee arthroscopy for osteoarthritis
  - Femoracetabular impingement syndrome surgery
  - Elective induction of labor
  - Ultrasound in pregnancy
  - Indications for planned cesarean section

- New Draft Coverage Guidance Topics
  - Red flags and imaging in headache
  - Imaging in dementia
  - Nonpharmacologic interventions for treatment-resistant depression

### ***Clarification about Studies with Insufficient Evidence***

Livingston asked for a clarification about how the subcommittee views making recommendations based on studies when there is insufficient evidence. Saha pointed out there are many standardly practiced interventions which are never studied or are impossible to study with randomized trials. Marks agreed, stating lack of evidence does not necessarily mean lack of efficacy.

Chan held that if the subcommittee's charge is to give guidance on maximal cost-effective care and the studies cannot prove that fact, then we are unable to estimate cost-benefit and should not pay for it; the burden of proof is on the proponent of the intervention. Others wondered about factoring in provider and patient preferences, supposing it depends on the topic and if it is even possible to conduct randomized controlled trials. For example, it is *not* feasible to do a study of the efficacy for labor induction for pre-eclamptic pregnant women; however, low back pain studies are possible.

Consensus from the members was that if there are current proven interventions that work, then new therapies which do not have sufficient evidence should not be recommended for coverage. It becomes much more of an issue if there are no known effective treatments. At that point, a shared decision making process should occur.

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### **CONFIRMATION OF NEXT MEETING**

The next meeting is scheduled for June 7, 2012 from 2:00- 5:00 pm in Room 117B&C of the Meridian Park Hospital Health Education Center in Tualatin.

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### **PUBLIC COMMENT**

There was no public comment.

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### **ADJOURNMENT**

The meeting was adjourned at 3:53 pm.

# EbGS Coverage Guidance Summaries

Oregon Health Evidence Review Commission  
June 14, 2012



## Coverage Guidance

For HERC review and approval:

- Knee Arthroscopy for Osteoarthritis
- Routine Ultrasound in Pregnancy
- Induction of Labor
- Indications for Planned Cesarean Section
- Low Back Pain: Non-pharmacologic/Non-invasive Interventions
- Low Back Pain: Pharmacologic Interventions (also reviewed by P&T committee)



2



## Knee Arthroscopy for Osteoarthritis

### **HERC COVERAGE GUIDANCE**

- In the absence of other appropriate indications, arthroscopic lavage and debridement of knee osteoarthritis (or osteoarthrosis) should not be covered.

## Knee Arthroscopy for Osteoarthritis

### **Evidence Summary**

- There is no evidence that neither arthroscopic lavage nor debridement improves pain or functional outcomes in patients with osteoarthritis of the knee.

## Routine Ultrasound in Labor

### HERC COVERAGE GUIDANCE

- Routine ultrasound for average risk pregnant women should be covered only:
  - Once in the first trimester for the purpose of identifying fetal aneuploidy or anomaly (between 11 and 13 weeks of gestation) and/or dating confirmation. In some instances, if a patient's LMP is truly unknown, a dating ultrasound may be indicated prior to an aneuploidy screen.
  - Once for the purpose of anatomy screening after 18 weeks gestation.
- Only *one type* of routine prenatal ultrasound should be covered in a single day (*i.e., transvaginal or abdominal*).

## Routine Ultrasound in Labor

### Evidence Summary

- The accuracy of ultrasound is variable, and it may be helpful in monitoring some high-risk pregnancies.
- In the case of identified fetal anomalies, ultrasound can alter pregnancy management. Otherwise, ultrasound does not change treatment plans, alter delivery modes or improve health outcomes in low-risk pregnancies.

# Induction of Labor

## **HERC COVERAGE GUIDANCE**

- Induction of labor *should be* covered for the following indications:
  - Gestational age beyond 41 0/7 weeks
  - Prelabor rupture of membranes at term
  - Diabetes, pre-existing and gestational
- Induction of labor *should not* be covered for:
  - Macrosomia (in the absence of maternal diabetes)
  - Elective purposes (without a medical or obstetrical indication)
  - Breech
- For those indications for which there is insufficient evidence of clear benefit over harm, coverage may be based on an individualized treatment plan taking into account maternal and infant health.

# Induction of Labor

## **Evidence Summary**

- Elective induction of labor (EIOL) likely increases the risk of Cesarean section in nulliparous women, and possibly in multiparous women.
- EIOL increases the risk of operative delivery.
- EIOL at <39 weeks increases the risk of NICU admission for infants.
- EIOL has strong evidence of net benefit for gestational age over 41 weeks and prelabor rupture of membranes.
- Evidence of net harm for EIOL for macrosomia.
- A number of indications for EIOL have insufficient evidence of net benefit or harm.
- Conflicting recommendations on severe intrauterine growth restriction, maternal diabetes and history of precipitous labor, although the latter likely reflects differences in the health care delivery system.

## Indications for Planned Cesarean Section

### **HERC COVERAGE GUIDANCE**

- Planned cesarean section (CS) should be covered for:
  - Breech presentation (if external cephalic version unsuccessful or contraindicated; and vaginal breech delivery is unavailable, undesired, or contraindicated)
  - Partial or complete placenta previa
  - Morbidly adherent placenta
  - Human immunodeficiency virus (HIV) positive mothers who are not receiving anti-retroviral therapy, are receiving anti-retroviral therapy and have a viral load of 400 copies per ml or more, or who are co-infected with Hepatitis C
  - Primary herpes simplex virus infection in the third trimester
  - Twin pregnancy (if the presenting twin is not vertex)

## Indications for Planned Cesarean Section

### **HERC COVERAGE GUIDANCE (cont.)**

- Planned CS should not be covered for:
  - Preterm birth
  - Small for gestational age
  - Suspected cephalopelvic disproportion
  - Maternal Hepatitis B infection
  - Maternal Hepatitis C infection
  - Elective (without obstetrical or medical indication)
- For prior cesarean delivery and other conditions for which there is insufficient evidence of clear benefit over harms, coverage may be based on an individualized treatment plan.

## Indications for Planned Cesarean Section

### Evidence Summary

- Elective CS is likely associated with longer hospital stays, increased NICU admissions and increased neonatal respiratory problems.
- While maternal urinary or fecal incontinence is less likely in the short term, there is no difference in longer term follow up.
- There is insufficient evidence to fully evaluate the benefits and risks of CS on maternal request, and given that the risks of placenta previa and accreta rise with each CS, CS on maternal request is not recommended for women desiring several children.
- VBAC is a reasonable and safe choice for the majority of women with prior cesarean.
- Emerging evidence of serious harms relating to multiple cesareans.

## Indications for Planned Cesarean Section

### Evidence Summary (cont.)

- Planned CS recommended for the following indications:
  - breech presentation,
  - twin pregnancy (if the presenting twin is not cephalic),
  - placenta previa and accreta,
  - HIV positive mothers in some circumstances and primary herpes simplex virus infection in the third trimester, and
  - obesity with high estimated fetal weight and HSV recurrence at birth.
- Insufficient evidence for all other indications.
- Planned CS without an evidence-based indication may increase neonatal and maternal harms, increase costs, and result in unnecessary procedures.

## Low Back Pain: Non-pharmacologic/ Non-invasive Interventions

### HERC Coverage Guidance

For pain  $\leq$  4 weeks, self-care is recommended, and for those who do not improve with self-care, spinal manipulation should be covered.

For pain  $>$  4 weeks duration, the following treatments may be covered:

- Acupuncture
- Cognitive-behavioral therapy
- Exercise therapy
- Intensive interdisciplinary rehabilitation
- Massage therapy
- Progressive relaxation
- Spinal manipulation
- Yoga (viniyoga)

The following should NOT be covered for low back pain:

- Continuous or intermittent traction
- Transcutaneous electrical nerve stimulation

## Low Back Pain: Non-pharmacologic/ Non-invasive Interventions

### Evidence Summary

#### Effective Non-pharmacologic Interventions

For acute low back pain (duration  $<$ 4 weeks):

- Spinal manipulation

For subacute (duration  $>$ 4 to 8 weeks) low back pain:

- Intensive interdisciplinary rehabilitation
- Functional restoration with CBT

For chronic low back pain:

- Acupuncture
- Exercise therapy
- Massage therapy
- Viniyoga-style yoga
- Cognitive-behavioral therapy or progressive relaxation
- Spinal manipulation
- Intensive interdisciplinary rehabilitation.

#### Non-pharmacologic Interventions that are NOT effective

- Transcutaneous electrical nerve stimulation
- Intermittent or continuous traction

## Low Back Pain: Pharmacologic Interventions

### HERC Coverage Guidance

Pharmacologic interventions for low back pain should be covered as follows:

- Acute low back pain
  - Initial pharmacologic therapy should be acetaminophen or non-steroidal anti-inflammatory medications (NSAIDs) and/or skeletal muscle relaxants.
  - Second line agents include benzodiazepines and opioids
- Chronic low back pain (>1 month)
  - First line: acetaminophen or NSAIDs, tricyclic antidepressants
  - Second line: benzodiazepines and opioids
  - Skeletal muscle relaxants should not be covered for chronic low back pain
- For acute exacerbations of chronic low back pain, the herbal therapies of devil's claw, willow bark, and capsicum may be covered.
- Given the risk profile of opiates and benzodiazepines, there should be a risk assessment prior to initiating therapy, and clear documentation of functional benefit should be required for ongoing prescription coverage.
- Systemic steroids should NOT be covered for low back pain.

## Low Back Pain: Pharmacologic Interventions

### Evidence Summary

- NSAIDs, opioids, tramadol, skeletal muscle relaxants, antidepressants and antiepileptics, have been shown to have moderate, primarily short-term benefits for patients with low back pain.
- Each class of medication is associated with unique trade-offs involving benefits, risks, and costs.
- For most patients, first-line medications are acetaminophen or NSAIDs.
- Systemic corticosteroids are ineffective.
- Several herbal therapies demonstrate small to moderate benefit.

## HEALTH EVIDENCE REVIEW COMMISSION (HERC)

### **DRAFT COVERAGE GUIDANCE: KNEE ARTHROSCOPY FOR OSTEOARTHRITIS**

DATE: XX/XX/XXXX

#### HERC COVERAGE GUIDANCE

In the absence of other appropriate indications, arthroscopic lavage and debridement of knee osteoarthritis (or osteoarthrosis) should not be covered.

#### RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

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

Coverage guidance development follows to translate the evidence review to a policy decision. In addition to an evidence-based guideline developed by the Evidence-based Guideline Subcommittee and a health technology assessment developed by the Health Technology Assessment Subcommittee, coverage guidance may utilize an existing evidence report produced in the last 5 years by the Agency for Healthcare Research and Quality, the Medicaid Evidence-based Decisions Project or the Washington Health Technology Assessment Program.

#### EVIDENCE SOURCE

Washington State Health Care Authority Health Technology Assessment Program. (2008). HTA evidence report: Arthroscopic surgery of the knee for osteoarthritis. Retrieved from [http://www.hta.hca.wa.gov/documents/ka\\_final.pdf](http://www.hta.hca.wa.gov/documents/ka_final.pdf)

National Institute for Health and Clinical Excellence. (2007). Arthroscopic knee washout, with or without debridement, for the treatment of osteoarthritis: Guidance. London: NICE. Retrieved from <http://guidance.nice.org.uk/IPG230/Guidance/pdf/English>

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

## SUMMARY OF EVIDENCE

### **Clinical Background**

Osteoarthritis (OA) is a common orthopedic condition characterized by articular degeneration within a joint that is estimated to affect approximately 27 million people in the United States. The diagnosis of osteoarthritis of the knee is commonly based on a combination of symptoms and physical findings such as knee pain or stiffness and radiographic findings. Patients with knee osteoarthritis and symptoms that are refractory to medical management may receive arthroscopic interventions for diagnosis or treatment. Interventions such as debridement and lavage of the knee are carried out with the goal of delaying knee replacement arthroplasty. Although orthopedic guidelines list joint lavage and arthroscopic debridement as treatment options, their roles in managing OA of the knee remain controversial. In 1998, it was estimated that 650,000 knee arthroscopies were performed yearly (Moseley 2002). Arthroscopies are considered by many to be minimally invasive procedures, but clinically significant adverse events have been reported.

### **Evidence Review**

The Washington HTA report utilized the 2007 systematic review conducted by AHRQ (Samson 2007) as the primary evidence base. That report stated that the evidence is insufficient to conclude that arthroscopy and lavage or debridement results in pain reduction or improved function for patients with osteoarthritis of the knee. Neither arthroscopic lavage nor debridement has been found to be superior to sham arthroscopy in well-designed and conducted randomized controlled trials (RCTs). A search of the literature identified no new studies since the AHRQ Publication that met inclusion criteria. Only one study (Moseley 2002), was included in the review, which evaluated the Knee-Specific-Pain Score (KSPS) at two years along with other measures of pain and function and determined that they did not include a clinically meaningful difference between either the debridement group and placebo or the lavage group and placebo group.

The WA HTA reported limited information on adverse effects from RCTs that evaluated arthroscopy with lavage and debridement for knee OA, primarily because the trials focused on efficacy and did not formally measure safety events. Observational data, however, provided useful indicators about safety concerns, including the following:

- Mortality has been reported to be from 0.1% to 0.5% ;
- A 0.3% rate of stroke or myocardial infarction has been reported;
- A hemarthrosis rate of nearly 25% was reported in one case series;
- Reports of infection have ranged from 0.5% to 2%;
- DVT has been reported to be from 0.6% to 17.9% in patients undergoing arthroscopy for any reason (not specifically for OA of the knee).

An economic model was provided by The Medical Advisory Secretariat Ministry of Health and Long-term Care, Toronto. The authors were unable to conduct a full economic analysis because effectiveness was not demonstrated in the literature.

[\[Evidence Source\]](#)

### Overall Summary

There is no evidence that neither arthroscopic lavage nor debridement improves pain or functional outcomes in patients with osteoarthritis of the knee.

### PROCEDURE

Arthroscopy of the Knee

### DIAGNOSES

Osteoarthritis of the knee

### APPLICABLE CODES

<b>CODES</b>	<b>DESCRIPTION</b>
<b>ICD-9 Diagnosis Codes</b>	
715.06	Osteoarthrosis, generalized, of lower leg
715.16	Osteoarthrosis, localized, primary of lower leg
715.26	Osteoarthrosis, localized, secondary, of lower leg
715.36	Osteoarthrosis, localized, not specified as primary or secondary, of lower leg
715.86	Osteoarthrosis, involving more than one site but not specified as generalized, of lower leg
715.96	Osteoarthrosis, unspecified as localized or generalized, of lower leg
716.66	Unspecified monoarthritis, lower leg
<b>CPT codes</b>	
29866	Arthroscopy, knee, surgical; osteochondral autograft(s) (eg, mosaicplasty) (includes harvesting of the autograft[s])
29867	osteochondral allograft (eg, mosaicplasty)
29868	meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral
29871	Arthroscopy, knee, surgical; for infection, lavage and drainage
29873	with lateral release
29874	for removal of loose body or foreign body (eg, osteochondritis dissecans fragmentation, chondral fragmentation)
29875	synovectomy, limited (eg, plica or shelf resection) (separate procedure)

<b>CODES</b>	<b>DESCRIPTION</b>
29876	synovectomy, major, 2 or more compartments (eg, medial or lateral)
29877	debridement/shaving of articular cartilage (chondroplasty)
29879	abrasion arthroplasty (includes chondroplasty where necessary) or multiple drilling or microfracture
29880	with meniscectomy (medial AND lateral, including any meniscal shaving)
29881	with meniscectomy (medial OR lateral, including any meniscal shaving)
29882	with meniscus repair (medial OR lateral)
29883	with meniscus repair (medial AND lateral)
29884	with lysis of adhesions, with or without manipulation (separate procedure)
29885	drilling for osteochondritis dissecans with bone grafting, with or without internal fixation (including debridement of base of lesion)
29886	drilling for intact osteochondritis dissecans lesion
29887	drilling for intact osteochondritis dissecans lesion with internal fixation
29888	Arthroscopically aided anterior cruciate ligament repair/augmentation or reconstruction
29889	Arthroscopically aided posterior cruciate ligament repair/augmentation or reconstruction

Note: Inclusion on this list does not guarantee coverage

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.

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## HEALTH EVIDENCE REVIEW COMMISSION (HERC)

### **DRAFT** COVERAGE GUIDANCE: ROUTINE ULTRASOUND IN PREGNANCY

DATE: XX/XX/XXXX

#### HERC COVERAGE GUIDANCE

Routine ultrasound for average risk pregnant women should be covered only:

- Once in the first trimester for the purpose of identifying fetal aneuploidy or anomaly (between 11 and 13 weeks of gestation) and/or dating confirmation. In some instances, if a patient's LMP is truly unknown, a dating ultrasound may be indicated prior to an aneuploidy screen.
- Once for the purpose of anatomy screening after 18 weeks gestation

Only one type of routine prenatal ultrasound should be covered in a single day (*i.e., transvaginal or abdominal*).

#### RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

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

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

## EVIDENCE SOURCE

Washington State Health Care Authority Health Technology Assessment Program. (2010). Ultrasonography (ultrasound) in pregnancy: Health technology assessment. Retrieved from [http://www.hta.hca.wa.gov/documents/final\\_report\\_ultrasound.pdf](http://www.hta.hca.wa.gov/documents/final_report_ultrasound.pdf)

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

## SUMMARY OF EVIDENCE

### **Clinical Background**

Ultrasound (US) is used in prenatal care as a diagnostic tool for monitoring fetal development and maternal health outcomes. During the first trimester (6 days of gestation up to 13 weeks) an US may be performed for a variety of reasons, including estimation of gestational age diagnosis, evaluation of multiple gestations, or measurement of markers for fetal aneuploidy (abnormal chromosome number). In the second trimester (between 16 weeks and 22 weeks), US is performed to assess anatomical fetal growth and development (fetal anatomical survey), screen for markers for fetal aneuploidy, estimate fetal weight, detect and evaluate gynecological abnormalities, and detect fetal anatomical abnormalities. In the United States, routine US is not typically performed in the third trimester unless the pregnancy is considered a high-risk pregnancy or a specific indication has developed.

Although high-risk pregnancies are not precisely defined, they include such conditions as age  $\geq 35$  years at delivery, diabetes mellitus, asthma, hypertension, previous pregnancy loss, preeclampsia, fetal intrauterine growth restriction (IUGR), premature rupture of membranes, multiple pregnancy, preterm labor, and postterm pregnancy. All of these conditions may require US to monitor either fetal or maternal well-being. In addition, assessment of cervical length by transvaginal ultrasound (TVU) has been tested as a screening method for women at risk of preterm labor. If short cervix is confirmed, the clinician can administer treatment to delay birth and to prevent perinatal respiratory distress.

### **Evidence Review**

Accuracy: The literature suggests that US has variable accuracy, depending on the target condition. As a screening tool, it is often combined with other tests. Sensitivities of 40% to 99% have been reported, but information about specificity, positive predictive value, and negative predictive value is limited. Evidence addressing the differential accuracy of transabdominal vs. transvaginal US was not identified.

Effectiveness in High-Risk Pregnancy: The evidence provides some support for the use of Doppler US to monitor high-risk patients (which conditions are considered high risk are not specified). The use of TVU to identify patients in need of prophylactic treatment because of imminent risk of preterm birth is also supported by the evidence, but the use of TVU surveillance in women with a history of preterm birth is not.

Effectiveness in Low-Risk Pregnancy, Early Screening: Routine US in early pregnancy (< 24 weeks) does not change patient management, substantially alter delivery modes, or improve health outcomes, at least not in high-resource settings. Routine US doubles the rate of abortion for fetal anomaly, but the estimated absolute increase is 0.10 percentage point.

Effectiveness in Low-Risk Pregnancy, Late Screening: Evidence has not shown routine US in late pregnancy (> 24 weeks) to change patient management, affect delivery mode, or improve health outcomes.

Safety: Evidence for major outcomes has shown US to be a reasonably safe procedure with no serious short-term adverse effects. There is no association between US and childhood cancers, and no impact on developmental outcomes after birth with the exception of an increase in the risk of non-right-handedness in boys.

Differential Effectiveness and Safety: Routine US performed between 14 weeks and 24 weeks (second trimester) is most likely to detect multiple births and to reduce the frequency of induction of labor, compared with US at other gestational ages. However, there is no differential effect by gestational age on perinatal mortality.

[\[Evidence Source\]](#)

### Overall Summary

The accuracy of ultrasound is variable, and it may be helpful in monitoring some high-risk pregnancies. In the case of identified fetal anomalies, ultrasound can alter pregnancy management. Otherwise, ultrasound does not change treatment plans, alter delivery modes or improve health outcomes in low-risk pregnancies.

### PROCEDURE

Obstetrical ultrasound

### DIAGNOSES

Pregnancy

### APPLICABLE CODES

CODES	DESCRIPTION
<b>ICD-9 Diagnosis Codes</b>	
V22	<b>Normal pregnancy</b> V22.0. Supervision of normal first pregnancy V22.1 Supervision of other normal pregnancy V22.2 Pregnant state, incidental
V23	<b>Supervision of high-risk pregnancy</b> V23.0 Pregnancy with history of V23.1 Pregnancy with history of trophoblastic disease

CODES	DESCRIPTION
<b>ICD-9 Diagnosis Codes</b>	
	V23.2 Pregnancy with history of abortion V23.3 Grand multiparity V23.4 Pregnancy with other poor obstetric history V23.41 Pregnancy with history of pre-term labor V23.49 Pregnancy with other poor obstetric history V23.5 Pregnancy with other poor reproductive history V23.7 Insufficient prenatal care V23.8 Other high-risk pregnancy V23.81 Elderly primigravida V23.82 Elderly multigravida V23.83 Young primigravida V23.84 Young multigravida V23.85 Pregnancy resulting from assisted reproductive technology V23.86 Pregnancy with history of in utero procedure during previous pregnancy V23.89 Other high-risk pregnancy V23.9 Unspecified high-risk pregnancy
640	<b>Hemorrhage in early pregnancy</b> 640.0 Threatened abortion 640.8 Other specified hemorrhage in early pregnancy 640.9 Unspecified hemorrhage in early pregnancy
641	<b>Antepartum hemorrhage, abruptio placentae, and placenta previa</b> 641.0 Placenta previa without hemorrhage 641.1 Hemorrhage from placenta previa 641.2 Premature separation of placenta 641.3 Antepartum hemorrhage associated with coagulation defects 641.8 Other antepartum hemorrhage 641.9 Unspecified antepartum hemorrhage
642	<b>Hypertension complicating pregnancy, childbirth, and the puerperium</b> 642.0 Benign essential hypertension complicating pregnancy, childbirth, and the puerperium 642.1 Hypertension secondary to renal disease, complicating pregnancy, childbirth, and the puerperium 642.2 Other pre-existing hypertension complicating pregnancy, childbirth, and the puerperium 642.3 Transient hypertension of pregnancy 642.4 Mild or unspecified pre-eclampsia 642.5 Severe pre-eclampsia 642.6 Eclampsia 642.7 Pre-eclampsia or eclampsia superimposed on pre-existing hypertension 642.9 Unspecified hypertension complicating pregnancy, childbirth, or the puerperium
643	<b>Excessive vomiting in pregnancy</b> 643.0 Mild hyperemesis gravidarum 643.1 Hyperemesis gravidarum with metabolic disturbance 643.2 Late vomiting of pregnancy 643.8 Other vomiting complicating pregnancy 643.9 Unspecified vomiting of pregnancy
644	<b>Early or threatened labor</b> 644.0 Threatened premature labor

CODES	DESCRIPTION
<b>ICD-9 Diagnosis Codes</b>	
	644.1 Other threatened labor 644.2 Early onset of delivery
645	<b>Late pregnancy</b> 645.1 Post term pregnancy 645.2 Prolonged pregnancy
646	<b>Other complications of pregnancy, not elsewhere classified</b> 646.0 Papyraceous fetus 646.1 Edema or excessive weight gain in pregnancy, without mention of hypertension 646.2 Unspecified renal disease in pregnancy, without mention of hypertension 646.3 Recurrent pregnancy loss 646.4 Peripheral neuritis in pregnancy 646.5 Asymptomatic bacteriuria in pregnancy 646.6 Infections of genitourinary tract in pregnancy 646.7 Liver disorders in pregnancy 646.8 Other specified complications of pregnancy 646.9 Unspecified complication of pregnancy
647	<b>Infectious and parasitic conditions in the mother classifiable elsewhere, but complicating pregnancy, childbirth, or the puerperium</b> 647.0 Syphilis 647.1 Gonorrhea 647.2 Other venereal diseases 647.3 Tuberculosis 647.4 Malaria 647.5 Rubella 647.6 Other viral diseases 647.8 Other specified infectious and parasitic diseases 647.9 Unspecified infection or infestation
648	<b>Other current conditions in the mother classifiable elsewhere, but complicating pregnancy, childbirth, or the puerperium</b> 648.0 Diabetes mellitus 648.1 Thyroid dysfunction 648.2 Anemia 648.3 Drug dependence 648.4 Mental disorders 648.5 Congenital cardiovascular disorders 648.6 Other cardiovascular diseases 648.7 Bone and joint disorders of back, pelvis, and lower limbs 648.8 Abnormal glucose tolerance 648.9 Other current conditions classifiable elsewhere
649	<b>Other conditions or status of the mother complicating pregnancy, childbirth, or the puerperium</b> 649.0 Tobacco use disorder complicating pregnancy, childbirth, or the puerperium 649.1 Obesity complicating pregnancy, childbirth, or the puerperium 649.2 Bariatric surgery status complicating pregnancy, childbirth, or the puerperium 649.3 Coagulation defects complicating pregnancy, childbirth, or the puerperium 649.4 Epilepsy complicating pregnancy, childbirth, or the puerperium 649.5 Spotting complicating pregnancy 649.6 Uterine size date discrepancy

CODES	DESCRIPTION
<b>ICD-9 Diagnosis Codes</b>	
	649.7 Cervical shortening
651	<b>Multiple gestation</b> 651.0 Twin pregnancy 651.1 Triplet pregnancy 651.2 Quadruplet pregnancy 651.3 Twin pregnancy with fetal loss and retention of one fetus 651.4 Triplet pregnancy with fetal loss and retention of one or more fetus(es) 651.5 Quadruplet pregnancy with fetal loss and retention of one or more fetus(es) 651.6 Other multiple pregnancy with fetal loss and retention of one or more fetus(es) 651.7 Multiple gestation following (elective) fetal reduction 651.8 Other specified multiple gestation 651.9 Unspecified multiple gestation
652	<b>Malposition and malpresentation of fetus</b> 652.0 Unstable lie 652.1 Breech or other malpresentation successfully converted to cephalic presentation 652.2 Breech presentation without mention of version 652.3 Transverse or oblique presentation 652.4 Face or brow presentation 652.5 High head at term 652.6 Multiple gestation with malpresentation of one fetus or more 652.7 Prolapsed arm 652.8 Other specified malposition or malpresentation 652.9 Unspecified malposition or malpresentation
653	<b>Disproportion</b> 653.0 Major abnormality of bony pelvis, not further specified 653.1 Generally contracted pelvis 653.2 Inlet contraction of pelvis 653.3 Outlet contraction of pelvis 653.4 Fetopelvic disproportion 653.5 Unusually large fetus causing disproportion 653.6 Hydrocephalic fetus causing disproportion 653.7 Other fetal abnormality causing disproportion 653.8 Disproportion of other origin 653.9 Unspecified disproportion
654	<b>Abnormality of organs and soft tissues of pelvis</b> 654.0 Congenital abnormalities of uterus 654.1 Tumors of body of uterus 654.2 Previous cesarean delivery 654.3 Retroverted and incarcerated gravid uterus 654.4 Other abnormalities in shape or position of gravid uterus and of neighboring structures 654.5 Cervical incompetence 654.6 Other congenital or acquired abnormality of cervix 654.7 Congenital or acquired abnormality of vagina 654.8 Congenital or acquired abnormality of vulva 654.9 Other and unspecified
655	<b>Known or suspected fetal abnormality affecting management of mother</b>

CODES	DESCRIPTION
<b>ICD-9 Diagnosis Codes</b>	
	655.0 Central nervous system malformation in fetus 655.1 Chromosomal abnormality in fetus 655.2 Hereditary disease in family possibly affecting fetus 655.3 Suspected damage to fetus from viral disease in the mother 655.4 Suspected damage to fetus from other disease in the mother 655.5 Suspected damage to fetus from drugs 655.6 Suspected damage to fetus from radiation 655.7 Decreased fetal movements 655.8 Other known or suspected fetal abnormality, not elsewhere classified 655.9 Unspecified
656	<b>Other known or suspected fetal and placental problems affecting management of mother</b> 656.0 Fetal-maternal hemorrhage 656.1 Rhesus isoimmunization 656.2 Isoimmunization from other and unspecified blood-group incompatibility 656.3 Fetal distress 656.4 Intrauterine death 656.5 Poor fetal growth 656.6 Excessive fetal growth 656.7 Other placental conditions 656.8 Other specified fetal and placental problems 656.9 Unspecified fetal and placental problem
657	Polyhydramnios
658.0	Oligohydramnios
659.4	Grand multiparity
659.5	Elderly primigravida
659.6	Elderly multigravida
659.7	Abnormality in fetal heart rate or rhythm
678	<b>Other fetal conditions</b> 678.0 Fetal hematologic conditions 678.1 Fetal conjoined twins
679	<b>Complications of in utero procedures</b> 679.0 Maternal complications from in utero procedure 679.1 Fetal complications from in utero procedure
<b>ICD-9 Volume 3 (procedure codes)</b>	
None	

CODES	DESCRIPTION
<b>CPT Codes</b>	
76801	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester (< 14 weeks 0 days), transabdominal approach; single or first gestation
76802	each additional gestation (+76801)
76805	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (≥ 14 weeks 0 days), transabdominal approach; single

CODES	DESCRIPTION
<b>CPT Codes</b>	
	or first gestation
76810	each additional gestation (+76805)
76811	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach; single or first gestation
76812	each additional gestation (+76811)
76813	Ultrasound, pregnant uterus, real time with image documentation, first trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach; single or first gestation
76814	each additional gestation (+76813)
76815	Ultrasound, pregnant uterus, real time with image documentation, limited (eg, fetal heart beat, placental location, fetal position and/or qualitative amniotic fluid volume), 1 or more fetuses
76816	Ultrasound, pregnant uterus, real time with image documentation, follow-up (eg, re-evaluation of fetal size by measuring standard growth parameters and amniotic fluid volume, re-evaluation of organ system(s) suspected or confirmed to be abnormal on a previous scan), transabdominal approach, per fetus
76817	Ultrasound, pregnant uterus, real time with image documentation, transvaginal
76818	Fetal biophysical profile; with non-stress testing
76819	without non-stress testing
<b>HCPCS Codes</b>	
None	

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## HEALTH EVIDENCE REVIEW COMMISSION (HERC)

### DRAFT COVERAGE GUIDANCE: INDUCTION OF LABOR

DATE: XX/XX/XXXX

#### HERC COVERAGE GUIDANCE

Induction of labor *should be* covered for the following indications:

- Gestational age beyond 41 0/7 weeks
- Prelabor rupture of membranes at term
- Diabetes, pre-existing and gestational

Induction of labor *should not be* covered for:

- Macrosomia (in the absence of maternal diabetes)
- Elective purposes (without a medical or obstetrical indication)
- Breech

For those indications for which there is insufficient evidence of clear benefit over harm\*, coverage may be based on an individualized treatment plan taking into account maternal and infant health.

\*There was insufficient evidence for the following indications that were evaluated in the literature: preterm, prelabor rupture of membranes; cholestasis of pregnancy; mild and severe preeclampsia; eclampsia; suspected IUGR (preterm and term); gastroschisis; twin gestation; oligohydramnios; placental abruption; chorioamnionitis; maternal medical conditions (e.g., renal disease, chronic pulmonary disease, chronic hypertension, cardiac disease, antiphospholipid syndrome); gestational hypertension; fetal compromise (e.g., severe fetal growth restriction, isoimmunization, oligohydramnios); fetal demise

#### RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

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

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

## EVIDENCE SOURCE

King, V., Pilliod, R., & Little, A. (2010). *Rapid review: Elective induction of labor*. Portland: Center for Evidence-based Policy. Available at: <http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/index.cfm>

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

## SUMMARY OF EVIDENCE

### **Clinical Background**

The use of induction of labor (IOL) in the U.S. doubled between 1990 and 2006. Rates of labor induction vary substantially from state to state, from a low of 13.2% (California) to a high of 35.2% (Utah). The rate of increase in medically indicated IOL has been slower than the overall increase, suggesting that the increase in elective inductions has been more rapid. The increase in the overall use of induction is likely multifactorial. There appear to have been shifts in the threshold for induction at earlier gestations with both medically indicated and elective IOL. The practices and preferences of individual physicians also have an effect on the use of IOL and the subsequent risk of cesarean delivery. Women's requests may also contribute to increased demand for elective induction of labor (EIOL).

### **Evidence Review**

Systematic reviews of randomized controlled trials find either a slight increase in cesarean delivery or no effect with EIOL, but there is some evidence of increased risk of operative vaginal delivery. Observational studies using spontaneous labor control groups find increased risk of cesarean delivery for nulliparous women with number needed to harm (NNH) of 4 to 10. Multiparous women may also have an increased risk of cesarean delivery with a NNH of 62 based on one study. Cesarean delivery is increased particularly among nulliparous women who have a low Bishop score (a measure of readiness for labor) at the time of EIOL and receive preinduction cervical ripening. Infants face an increased risk of admission to a neonatal intensive care unit

(NICU) if their mothers undergo EIOL prior to 39 weeks of gestation. The length of active labor may be shorter with EIOL, although the total time spent on a labor and delivery unit or in the hospital may be greater. Most commonly cited indications for IOL are not well supported by evidence.

### Evidence-supported indications and contraindications

#### ***Indications with net benefit***

The only indications for induction of labor supported by strong evidence of net benefit are gestational age beyond 41 weeks and prelabor rupture of membranes at term.

#### ***Indications with net harm***

The only indication for which there is evidence of harm is suspected macrosomia, for which there is no evidence of improved fetal outcomes, but an increase in the risk of cesarean section.

#### ***Indications with insufficient evidence***

The other indications for induction of labor that were considered in the evidence report but have insufficient evidence to make strong recommendations include the following:

- Preterm, prelabor rupture of membranes
- Cholestasis of pregnancy
- Mild and severe preeclampsia
- Eclampsia
- Suspected IUGR (preterm and term)
- Gastroschisis
- Twin gestation
- Oligohydramnios
- Gestational diabetes treated with insulin
- Maternal cardiac disease

Quality improvement programs targeted at eliminating inappropriate EIOL can be effective at reducing cesarean delivery outcomes, particularly for nulliparous women with a low Bishop score.

#### **Recommendations from Others**

The *American College of Obstetrics and Gynecology (ACOG)* identifies the specific indications for induction of labor, including but not limited to the conditions listed below:

- Premature rupture of membranes
- Eclampsia, preeclampsia, gestational hypertension
- Fetal compromise (severe IUGR, isoimmunization, oligohydramnios)
- Placental abruption

- Chorioamnionitis
- Maternal medical conditions (eg. diabetes, renal disease, chronic pulmonary disease, chronic hypertension, cardiac disease, antiphospholipid syndrome)
- Fetal compromise (eg, severe fetal growth restriction, isoimmunization, oligohydramnios)
- Post-term pregnancy
- Logistical reasons (risk for rapid labor, distance from hospital)

In addition, for patients with gestational diabetes, they state the following:

No good evidence to support routine delivery before 40 weeks of gestation. There are no data to support a policy of cesarean delivery purely on the basis of GDM. It would appear reasonable to recommend that patients with GDM be counseled regarding possible cesarean delivery without labor when the estimated fetal weight is 4,500 g or greater.

For patients with pregestational diabetes, they state:

Early delivery may be indicated in some patients with vasculopathy, nephropathy, poor glucose control, or a prior stillbirth. In contrast, patients with well-controlled diabetes may be allowed to progress to their expected date of delivery as long as antenatal testing remains reassuring. Expectant management beyond the estimated due date generally is not recommended. Cesarean delivery may be considered if the estimated fetal weight is greater than 4,500 g in women with diabetes. Induction of labor in pregnancies with a fetus with suspected macrosomia has not been found to reduce birth trauma and may increase the cesarean delivery rate.

For suspected fetal macrosomia, they state:

Recent large cohort and case–control studies demonstrate the safety of allowing a trial of labor for estimated birth weights of more than 4,000 g. Despite the poor predictive value of an estimated fetal weight beyond 5,000 g and a lack of evidence supporting cesarean delivery at any estimated fetal weight, most, but not all, authors agree that consideration should be given to cesarean delivery in this situation.

For breech presentation, they state:

Mode of delivery should depend on the experience of the healthcare provider. Cesarean will be the preferred mode for most physicians. Planned vaginal delivery may be reasonable. (No comment regarding induction)

The *National Institute for Clinical Excellence (NICE)* has the following recommendations regarding induction of labor:

Induction of labor should be offered in the following circumstances:

- Post-term pregnancy
- Preterm, prelabor rupture of membranes after 34 weeks
- Prelabor rupture of membranes at term after 24 hours
- Maternal diabetes, any type (after 38 completed weeks gestation)

Induction of labor should not be routinely offered in the following circumstances:

- Maternal request
- Breech presentation
- Severe IUGR
- History of precipitous labor
- Suspected macrosomia

Induction of labor may be offered depending on the desires of the patient in the following circumstances:

- Fetal demise

Indications for which there are contradictory recommendations between ACOG and NICE are the following:

- Severe IUGR
- History of precipitous labor
- Maternal diabetes (after 38 completed weeks gestation)

### **Overall Summary**

EIOL likely increases the risk of Cesarean section in nulliparous women, and possibly in multiparous women. It also increases the risk of operative delivery. EIOL at less than 39 weeks increases the risk of NICU admission for infants. EIOL has strong evidence of net benefit for gestational age over 41 weeks and prelabor rupture of membranes, while EIOL for macrosomia is the only indication for which there is evidence of net harm. There are a number of indications for EIOL for which there is insufficient evidence of net benefit or harm. Indications for which there is conflicting recommendations include the severe IUGR, maternal diabetes and history of precipitous labor, although the latter likely reflects differences in the health care delivery system.

[\[Evidence Source\]](#)

## **PROCEDURE**

Elective Induction of Labor

## DIAGNOSES

Pregnancy

## APPLICABLE CODES

<b>CODES</b>	<b>DESCRIPTION</b>
<b>ICD-9 Diagnosis Codes</b>	
650	Normal delivery
659.0	Failed mechanical induction
659.1	Failed medical or unspecified induction
V22.0	Supervision of normal first pregnancy
V22.1	Supervision of other normal pregnancy
V22.2	Pregnant state, incidental
V30	Single liveborn
V39	Liveborn unspecified whether single twin or multiple
<b>ICD-10 Diagnosis Codes</b>	
O80	Single spontaneous delivery
Z34.0	Supervision of normal first pregnancy
Z34.8	Supervision of other normal pregnancy
Z34.9	Supervision of normal pregnancy, unspecified
<b>ICD-9 Volume 3 (procedure codes)</b>	
<b>Other procedures inducing or assisting delivery</b>	
73.0	Artificial rupture of membranes
73.1	Other surgical induction of labor: Induction by cervical dilation
73.4	Medical induction of labor
<b>Forceps, vacuum, and breech delivery</b>	
72.0 – 72.9	Forceps, vacuum, and breech delivery
<b>Cesarean section and removal of fetus</b>	
74.0 – 74.4, 74.9	Cesarean section and removal of fetus
<b>CPT Codes</b>	
<b>Dilation</b>	
57800	Dilation of cervical canal, instrumental (separate procedure)
59200	Insertion of cervical dilator (e.g., laminaria, prostaglandin) (separate procedure)
<b>Infusions</b>	
96365	Intravenous infusion for therapy, prophylaxis, or diagnosis; initial, up to 1 hour
96366	Intravenous infusion for therapy, prophylaxis, or diagnosis; each additional hour
96367	Each additional sequential infusion up to 1 hour
96368	Concurrent infusion
<b>Care associated with vaginal delivery</b>	
59400	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care
59409	Vaginal delivery only, with or without postpartum care
59610	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery
59612,	Vaginal delivery only, after previous cesarean delivery

59614	
<b>Care associated with Cesarean</b>	
59510	Routine Obstetric care including antepartum care, Cesarean delivery, and postpartum care
59514	Cesarean Delivery only
59515	Cesarean Delivery only, including postpartum care59618: Routine Obstetric care including antepartum care, Cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery
59620	Cesarean Delivery only, following attempted vaginal delivery after previous Cesarean delivery.
59622	Cesarean Delivery only, following attempted vaginal delivery after previous Cesarean delivery. Including postpartum care
<b>HCPCS Level II Codes</b>	
J2590	Pitocin 10 units. [NOTE: Appears in a listing of “Drugs Administered Other Than Oral Method J0000-J9999.”]
S0191	Misoprostol, oral, 200 mcg [NOTE: Appears in a listing of Temporary National Codes (Non-Medicare), S0012-S9999)

Note: Inclusion on this list does not guarantee coverage

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.

## HEALTH EVIDENCE REVIEW COMMISSION (HERC)

### DRAFT COVERAGE GUIDANCE: INDICATIONS FOR PLANNED CESAREAN SECTION

DATE: XX/XX/XXXX

#### HERC COVERAGE GUIDANCE

Planned cesarean section (CS) should be covered for:

- Breech presentation (if external cephalic version unsuccessful or contraindicated; and vaginal breech delivery is unavailable, undesired, or contraindicated)
- Partial or complete placenta previa
- Morbidly adherent placenta
- Human immunodeficiency virus (HIV) positive mothers who are not receiving anti-retroviral therapy, are receiving anti-retroviral therapy and have a viral load of 400 copies per ml or more, or who are co-infected with Hepatitis C
- Primary herpes simplex virus infection in the third trimester
- Twin pregnancy (if the presenting twin is not vertex)

Planned CS should not be covered for:

- Preterm birth
- Small for gestational age
- Suspected cephalopelvic disproportion
- Maternal Hepatitis B infection
- Maternal Hepatitis C infection
- Elective (without obstetrical or medical indication)

For prior cesarean delivery and other conditions for which there is insufficient evidence\* of clear benefit over harms, coverage may be based on an individualized treatment plan.

\*There was insufficient evidence for the following indications that were evaluated in the literature: twin pregnancy (if the presenting twin is vertex); herpes simplex virus recurrence at birth; body mass index over 50; HIV positive mothers on highly active anti-retroviral therapy with a viral load less than 400 copies/ml, or on any anti-retroviral therapy with a viral load of less than 50 copies/ml; macrosomia (estimated fetal weight >4500g if diabetic, or >5000g if obese)

## RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

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

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

## EVIDENCE SOURCES

Cunningham, F.G., Bangdiwala, S., Brown, S.S., Dean, T.M., Frederiksen, M., Rowland Hogue, C.J., et al. (2010). National Institutes of Health Consensus Development Conference Statement: Vaginal birth after cesarean: New insights. March 8-10, 2010. *Obstetrics & Gynecology*, 115(6), 1279–1295. Retrieved from [http://consensus.nih.gov/2010/images/vbac/vbac\\_statement.pdf](http://consensus.nih.gov/2010/images/vbac/vbac_statement.pdf)

Guise, J-M., Eden, K., Emeis, C., Denman, M.A., Marshall, N., Fu, R, et al. (2010). *Vaginal birth after cesarean: New insights. Evidence Report/Technology Assessment No.191. (Prepared by the Oregon Health & Science University Evidence-based Practice Center under Contract No. 290-2007-10057-I). AHRQ Publication No. 10-E003.* Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from <http://www.ncbi.nlm.nih.gov/books/NBK44571/>

National Institute for Health and Clinical Excellence, & National Collaborating Centre for Women's and Children's Health. (2008). *Diabetes in pregnancy: Management of diabetes and its complications from preconception to the postnatal period.* London, UK: Royal College of Obstetricians and Gynaecologists Press. Retrieved from <http://www.nice.org.uk/guidance/CG63>

National Institute for Health and Clinical Excellence, & National Collaborating Centre for Women's and Children's Health. (2011). *Caesarean section. (Clinical guideline 132).* London, UK: Royal College of Obstetricians and Gynaecologists Press. Retrieved from <http://guidance.nice.org.uk/CG132>

NIH State-of-the-Science Conference Statement on Cesarean Delivery on Maternal Request. *NIH Consens Sci Statements*. 2006. Mar 27-29; 23(1) 1–29. Retrieved from <http://consensus.nih.gov/2006/cesareanstatement.pdf>

Risser, A., & King, V. (2010). *Rapid review: Elective cesarean section*. Portland: Center for Evidence-based Policy. Retrieved from [http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/upload/Elective-Delivery-Elective-Cesarean\\_PUBLIC\\_Rapid-Review\\_Final\\_12\\_1\\_10.pdf](http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/upload/Elective-Delivery-Elective-Cesarean_PUBLIC_Rapid-Review_Final_12_1_10.pdf)

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

## SUMMARY OF EVIDENCE

### **Clinical Background**

According to the National Center for Health Statistics, the national rate of CS reached 32.8 percent of all live births in 2010. The largest contributions to this rising rate are an increase in primary cesareans to a rate of 20.6 percent in 2004 and a steep decline in the rate of vaginal birth after cesarean (VBAC) from 28.3% in 1996 to 9.2% in 2004. Over ninety percent of women who have had a CS will deliver by repeat cesarean. This increase is not well explained by changes in the population risk profile. There is interest in understanding the factors underlying this increase and to understand to what extent primary planned CS done without an identifiable medical risk (elective CS) and CS by maternal request contribute to this rate. The best estimate is that between 4% and 18% of primary CS in the United States are elective.

### **Evidence Review**

#### Elective Cesarean Delivery

The literature pertaining to the benefits and harms of cesarean delivery is limited by the lack of randomized trials that compare mode of *intended* delivery. Nearly all of the evidence compares outcomes based on actual delivery mode rather than intended mode of delivery, limiting the conclusions that can be drawn.

The MED report concluded that although much of the evidence is of low quality, the following outcomes are likely associated with elective CS:

- longer hospital stays;
- increased Neonatal Intensive Care Unit (NICU) admissions;
- increased neonatal respiratory problems; and
- maternal urinary or fecal incontinence is less likely in the short term, with no difference in longer term follow up.

The differences between an intended vaginal delivery group and an intended cesarean group are less marked for these outcomes at 39 or more weeks of gestation. Elective cesarean delivery likely has no benefit for urinary or fecal continence in the longer term, although immediate postpartum outcomes may favor elective CS. There are important downstream effects to consider in the performance of elective CS, most notably in maternal morbidity due to abnormal placentation. There are some important issues around quality of life such as post partum pain, recovery time, and postpartum mood which are important, but which have not been well studied as they apply to elective CS.

The 2010 MED report draws heavily from the AHRQ systematic review that was commissioned to inform the 2006 National Institute of Health (NIH) State of the Science Consensus Statement on Cesarean Delivery on Maternal Request, as well as the AHRQ review commissioned to inform the 2010 NIH Consensus Development Conference on Vaginal Birth after Cesarean: New Insights. The 2006 NIH consensus statement draws the following conclusions:

- There is insufficient evidence to evaluate fully the benefits and risks of cesarean delivery on maternal request as compared to planned vaginal delivery, and more research is needed.
- Until quality evidence becomes available, any decision to perform a cesarean delivery on maternal request should be carefully individualized and consistent with ethical principles.
- Given that the risks of placenta previa and accreta rise with each cesarean delivery, cesarean delivery on maternal request is not recommended for women desiring several children.
- Cesarean delivery on maternal request should not be performed prior to 39 weeks of gestation because of the significant danger of neonatal respiratory complications.
- Maternal request for cesarean delivery should not be motivated by unavailability of effective pain management. Efforts must be made to assure availability of pain management services for all women.

The majority of planned CS in the United States are performed for women who have a prior history of cesarean birth. The 2010 AHRQ systematic review Vaginal Birth after Cesarean: New Insights concluded the following:

“Each year 1.5 million childbearing women have cesarean deliveries, and this population continues to increase. This report adds stronger evidence that VBAC is a reasonable and safe choice for the majority of women with prior cesarean. Moreover, there is emerging evidence of serious harms relating to multiple cesareans. Relatively unexamined contextual factors such as medical liability, economics, hospital structure, and staffing may need to be addressed to prioritize VBAC services. There is still no evidence to inform patients, clinicians, or policy-makers about the outcomes of *intended* route of delivery because the evidence is based largely on the actual route of delivery.

This inception cohort is the equivalent of intention to treat for randomized controlled trials and this gap in information is critical.”

This AHRQ systematic review contributed to the evidence presented to a NIH Consensus Conference. The 2010 NIH Consensus Development Conference on Vaginal Birth after Cesarean: New Insights found the following:

*Maternal Benefits of a trial of labor*

- Women who have a trial of labor, regardless of ultimate mode of delivery, are at decreased risk of maternal mortality compared to elective repeat cesarean delivery. (Evidence grade: high)
- There is an association between cesarean delivery and abnormal placental position and growth in subsequent pregnancies and the risk of having abnormal placental position and growth increases with increasing number of cesarean deliveries. Overall, the major benefit of trial of labor is the 74 percent likelihood of VBAC and avoidance of multiple cesarean deliveries. The following health outcomes occur less frequently in women who have a VBAC (i.e. a successful trial of labor) (Evidence grade: moderate):
  - The incidence of placenta previa (placenta covering the cervix) significantly increases in women with each additional cesarean delivery
  - The incidence of placenta accreta, increta, and percreta (growth of the placenta into or through the uterine muscle) increases with the number of cesarean deliveries.
  - There does not appear to be an increased incidence of placental abruption (i.e., premature separation of the normally implanted placenta from the uterus) with increasing number of cesarean deliveries, although the risk is increased when women who have one prior cesarean delivery are compared to women who have not had a cesarean delivery.
- The overall risk of hysterectomy is statistically similar for trial of labor compared with elective repeat cesarean delivery (157 versus 280 per 100,000 respectively) and may be less in women at term. Limited evidence suggests that the risk of hysterectomy increases with induction of labor, high-risk pregnancy, and increasing number of cesarean deliveries (Evidence grade: moderate)
- The risk of blood transfusion is not significantly different for trial of labor or elective repeat cesarean delivery (900 versus 1,200 per 100,000). Factors that increase this risk include induction of labor with no prior vaginal delivery, high-risk pregnancy, and an increased number of prior cesarean deliveries.(Evidence grade: moderate)

- There is shorter hospitalization overall for trial of labor compared to elective repeat cesarean delivery. This benefit does not pertain to morbidly obese women. A single study suggests lower rates of deep venous thrombosis (DVT) in women undergoing trial of labor compared with elective repeat cesarean delivery (Evidence grade: low)

#### *Maternal Harms of a trial of labor*

- There is a clear increased risk of uterine rupture in women who have a trial of labor compared to elective repeat cesarean delivery. (Evidence grade: Moderate). Low grade evidence finds the following:
  - Women with classical and low vertical uterine scars have an increased risk of rupture when compared to women who had a low transverse uterine incision
  - Induction of labor has been associated with uterine rupture.
  - Increasing number of prior cesarean deliveries may increase risks of uterine rupture
  - A prior vaginal birth (before or after the previous cesarean delivery) decreases the risk of uterine rupture to approximately
- The evidence is insufficient to address a woman's perceptions of her birth experience, initial parent-infant interactions, ability to perform activities of daily living or initiate breastfeeding, association with other conditions such as chronic pain, ectopic pregnancy, stillbirth, infertility, complications related to subsequent surgery, pelvic floor function, rates of infection or surgical injury.

#### *Neonatal effects of a trial of labor*

- Studies of perinatal mortality (death between 20 weeks of gestation and 28 days of life) are of moderate quality and show that the perinatal mortality rate is increased for trial of labor (Evidence grade: moderate)
- Studies of fetal mortality (deaths in utero at 20 weeks of gestation or greater) suggest a higher death rate in trial of labor (Evidence grade: low)
- The evidence on hypoxic ischemic encephalopathy is unclear. The NIH Consensus Conference, noting a recent large observational study that found a significantly higher incidence of hypoxic ischemic encephalopathy in trial of labor compared with elective repeat cesarean delivery, rated the evidence grade on this finding as low, while the AHRQ SR rated it as insufficient.
- The evidence is insufficient to address respiratory sequelae, sepsis, birth trauma, breastfeeding and mother-infant bonding.

## Indications for Cesarean Section

The 2010 MED report relied on the guideline and systematic review conducted by the National Institute for Clinical Excellence (NICE) published in 2004 to determine the indications for planned cesarean section, but noted that this guideline would be updated in 2011. The updated guideline was published in November 2011

(<http://www.nice.org.uk/nicemedia/live/13620/57162/57162.pdf>). The 2011 NICE guideline identified one small study (N= 357), published after the 2004 guideline, that compared primiparous women planning a CS in the absence of medical indication to those planning a vaginal birth. That study found the following outcomes in the planned CS group:

- Longer maternal hospital stays
- Better “birth experience” at 2 days and 3 months
- Worse “uncomplicated breast feeding” at 3 months
- Lower likelihood of plans for another child at 3 months

There were no statistically significant differences between groups in the following outcomes:

- Resumption of coitus at 3 months
- Depression
- NICU care

The quality of the evidence was rated very low, however, the guideline authors recommend that “For women requesting a CS, if after discussion and offer of support (including perinatal mental health support for women with anxiety about childbirth), a vaginal birth is still not an acceptable option, offer a planned CS. “

## Indications for Cesarean Delivery

The 2011 NICE guideline recommends planned CS for the following indications:

- Breech presentation (if external cephalic version unsuccessful or contraindicated)
- Twin pregnancy, if the presenting twin is not cephalic
- Partial or complete placenta previa
- Morbidly adherent placenta
- HIV positive mothers who are not receiving anti-retroviral therapy, are receiving anti-retroviral therapy and have a viral load of 400 copies per ml or more, or who are co-infected with Hepatitis C
- Primary herpes simplex virus infection in the third trimester

The 2011 NICE guideline does not recommend planned cesarean, either because of insufficient evidence, or because there is a balance of trade offs between clinical benefits and harms or net health benefits and resource use, for the following indications:

- Twin pregnancy, if the presenting twin is cephalic
- Preterm birth
- Small for gestational age
- Suspected cephalopelvic disproportion
- HIV positive mothers on highly active anti-retroviral therapy with a viral load less than 400 copies/ml, or on any anti-retroviral therapy with a viral load of less than 50 copies/ml
- Maternal Hepatitis B infection
- Maternal Hepatitis C infection
- HSV recurrence at birth
- Body mass index over 50
- Prior CS delivery

In addition, the NICE guidance on Diabetes in Pregnancy (2008) recommends that pregnant women with diabetes who have a normally grown fetus should be offered elective birth through induction of labor, or by elective caesarean section if indicated, after 38 completed weeks.

### **Recommendations from Others**

The American College of Obstetrics and Gynecology (ACOG) does not list specific indications for cesarean section, but some of their documents suggest when it is appropriate. When a guideline or bulletin exists, their recommendations do not contradict the NICE recommendations presented above, with two exceptions. For women with herpes simplex virus who have active genital lesions or prodromal symptoms, ACOG recommends CS. In addition, they state that CS should be considered for obese women with an estimated fetal weight of more than 5000 grams, or more than 4500 grams for patients with diabetes (whether obese or not). For patients with gestational diabetes, they state that there is “no good evidence to support routine delivery before 40 weeks of gestation. There are no data to support a policy of cesarean delivery purely on the basis of GDM. It would appear reasonable to recommend that patients with GDM be counseled regarding possible cesarean delivery without labor when the estimated fetal weight is 4,500 g or greater”. For pregestational diabetics, they state that “early delivery may be indicated in some patients with vasculopathy, nephropathy, poor glucose control, or a prior stillbirth. In contrast, patients with well-controlled diabetes may be allowed to progress to their expected date of delivery as long as antenatal testing remains reassuring. Expectant management beyond the

estimated due date generally is not recommended. Cesarean delivery may be considered if the estimated fetal weight is greater than 4,500 g in women with diabetes.”

### Overall Summary

Elective CS is likely associated with longer hospital stays, increased NICU admissions and increased neonatal respiratory problems. While maternal urinary or fecal incontinence is less likely in the short term, there is no difference in longer term follow up. A 2006 NIH consensus statement concludes that there is insufficient evidence to fully evaluate the benefits and risks of cesarean delivery on maternal request, and given that the risks of placenta previa and accreta rise with each cesarean delivery, cesarean delivery on maternal request is not recommended for women desiring several children. The majority of planned CS in the US are performed for women who have a prior history of Cesarean birth. A 2010 AHRQ systematic review reports stronger evidence that VBAC is a reasonable and safe choice for the majority of women with prior cesarean, and that there is emerging evidence of serious harms relating to multiple cesareans. The 2011 NICE guideline recommends planned CS only for breech presentation, twin pregnancy (if the presenting twin is not cephalic), placenta previa and accreta, HIV positive mothers in some circumstances and primary herpes simplex virus infection in the third trimester. These indications are supported by ACOG, and in addition, ACOG considers obesity with high estimated fetal weight and HSV recurrence at birth additional indications for planned CS. For all other indications, the evidence is insufficient to recommend cesarean section. Planned cesareans without an evidence-based indication may increase neonatal and maternal harms, increase costs, and result in unnecessary procedures.

### PROCEDURE

Cesarean Section

### DIAGNOSES

Pregnancy

### APPLICABLE CODES

<b>CODES</b>	<b>DESCRIPTION</b>
<b>ICD 9 Codes</b>	
V22.0	Supervision of normal first pregnancy
V22.1	Supervision of other normal pregnancy
V22.2	Pregnant state, incidental
V30	Single liveborn
V39	Liveborn unspecified whether single twin or multiple
<b>ICD 9 Volume 3 (procedure codes)</b>	

74.0	Classical cesarean section
74.1	Low cervical caesarean section
74.4	Cesarean section of other specified type
<b>ICD 10 Codes</b>	
O82	Single delivery by caesarean section
O82.0	Delivery by elective caesarean section
O82.2	Delivery by caesarean hysterectomy
O82.8	Other single delivery by caesarean section
O82.9	Delivery by caesarean section, unspecified
<b>CPT Codes</b>	
Elective Cesarean	
59510	Routine Obstetric care including antepartum care, Cesarean delivery, and postpartum care
59514	Cesarean Delivery only
59515	Cesarean Delivery only, including postpartum care
Nonelective Cesarean	
59618	Routine Obstetric care including antepartum care, Cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery
59620	Cesarean Delivery only, following attempted vaginal delivery after previous Cesarean delivery.
59622	Cesarean Delivery only, following attempted vaginal delivery after previous Cesarean delivery. Including postpartum care
Vaginal Delivery	
59400	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care
59409, 59410	Vaginal delivery only, with and without postpartum care
59610	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery
59612, 59614	Vaginal delivery only, after previous cesarean delivery; with or without postpartum care
<b>HCPCS Codes</b>	
None	

Note: Inclusion on this list does not guarantee coverage

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## HEALTH EVIDENCE REVIEW COMMISSION (HERC)

### **DRAFT COVERAGE GUIDANCE: LOW BACK PAIN: NON-PHARMACOLOGIC/NON-INVASIVE INTERVENTIONS\***

DATE: XX/XX/XXXX

#### HERC COVERAGE GUIDANCE

For pain  $\leq$  4 weeks, self-care is recommended, and for those who do not improve with self-care, spinal manipulation should be covered.

For pain  $>$  4 weeks duration, the following treatments may be covered:

- Acupuncture
- Cognitive-behavioral therapy
- Exercise therapy
- Intensive interdisciplinary rehabilitation
- Massage therapy
- Progressive relaxation
- Spinal manipulation
- Yoga (viniyoga)

The following should NOT be covered for low back pain:

- Continuous or intermittent traction
- Transcutaneous electrical nerve stimulation

\*Coverage guidance for pharmacologic interventions, imaging, percutaneous interventions and surgery for low back pain will be addressed in subsequent documents.

#### RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

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

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

## EVIDENCE SOURCES

Livingston, C., King, V., Little, A., Pettinari, C., Thielke, A., & Gordon, C. (2011). *State of Oregon Evidence-based Clinical Guidelines Project. Evaluation and management of low back pain: A clinical practice guideline based on the joint practice guideline of the American College of Physicians and the American Pain Society (Diagnosis and treatment of low back pain)*. Salem: Office for Oregon Health Policy and Research. Available at: <http://www.oregon.gov/OHA/OHPR/HERC/Evidence-Based-Guidelines.shtml>

Chou, R., Huffman, L. *Nonpharmacologic Therapies for Acute and Chronic Low Back Pain: A Review of the Evidence for an American Pain Society/American College of Physicians Clinical Practice Guideline*. *Ann Intern Med*. 2007; 147; 492-504. Available at: <http://www.annals.org/content/147/7/492.full.pdf+html>

Chou R., Qaseem, A., Snow, V., Casey, D., Cross, J.T., Jr., Shekelle, P., Owens, D.K.; Clinical Efficacy Assessment Subcommittee of the American College of Physicians; American College of Physicians; American Pain Society Low Back Pain Guidelines Panel. *Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society*. *Annals of Internal Med*. 2007; 147(7); 478-491. Available at: <http://www.annals.org/content/147/7/478.long>

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

## SUMMARY OF EVIDENCE

### **Clinical Background**

Low back pain is the fifth most common reason for all physician visits in the United States. Approximately one quarter of U.S. adults reported having low back pain lasting at least 1 whole day in the past 3 months, and 7.6% reported at least 1 episode of severe acute low back pain within a 1-year period. Low back pain is also very costly: Total incremental direct health care costs attributable to low back pain in the U.S. were estimated at \$26.3 billion in 1998. In addition, indirect costs related to days lost from work are substantial, with approximately 2% of the U.S. work force compensated for back injuries each year.

Many patients have self-limited episodes of acute low back pain and do not seek medical care. Among those who do seek medical care, pain, disability, and return to work typically improve rapidly in the first month. However, up to one third of patients report persistent back pain of at least moderate intensity 1 year after an acute episode, and 1 in 5 report substantial limitations in activity. Approximately 5% of the people with back pain disability account for 75% of the costs associated with low back pain.

Many options are available for evaluation and management of low back pain. However, there has been little consensus, either within or between specialties, on appropriate clinical evaluation and management of low back pain. Numerous studies show unexplained, large variations in use of diagnostic tests and treatments. Despite wide variations in practice, patients seem to experience broadly similar outcomes, although costs of care can differ substantially among and within specialties.

## **Evidence Review**

**Recommendation 1:** *Clinicians should provide patients with evidence-based information on low back pain with regard to their expected course, advise patients to remain active, and provide information about effective self-care options (strong recommendation, moderate-quality evidence).*

Clinicians should inform all patients of the generally favorable prognosis of acute low back pain with or without sciatica, including a high likelihood for substantial improvement in the first month. General advice on self-management for nonspecific low back pain should include recommendations to remain active, which is more effective than resting in bed for patients with acute or subacute low back pain. Self-care education books based on evidence-based guidelines, such as *The Back Book* are recommended because they are an inexpensive and efficient method for supplementing clinician-provided back information and advice and are similar or only slightly inferior in effectiveness to such costlier interventions as supervised exercise therapy, acupuncture, massage, and spinal manipulation.

[\[Evidence source\]](#)

**Recommendation 2:** *For patients who do not improve with self-care options, clinicians should consider the addition of nonpharmacologic therapy with proven benefits—for acute low back pain, spinal manipulation; for chronic or subacute low back pain, intensive interdisciplinary rehabilitation, exercise therapy, acupuncture, massage therapy, spinal manipulation, yoga, cognitive-behavioral therapy, or progressive relaxation (weak recommendation, moderate-quality evidence).*

For acute low back pain (duration <4 weeks), spinal manipulation administered by providers with appropriate training is associated with small to moderate short-term benefits. Supervised exercise therapy and home exercise regimens are not effective for acute low back pain, and the optimal time to start exercise therapy after the onset of symptoms is unclear. For subacute (duration >4 to 8 weeks) low back pain, intensive interdisciplinary rehabilitation (defined as an intervention that includes a physician consultation coordinated with a psychological, physical therapy, social, or vocational intervention) is moderately effective, and functional restoration with a cognitive-behavioral component reduces work absenteeism due to low back pain in occupational settings. For chronic low back pain, moderately effective nonpharmacologic therapies include acupuncture, exercise therapy, massage therapy, Viniyoga-style yoga, cognitive-behavioral therapy or progressive relaxation, spinal manipulation, and intensive interdisciplinary rehabilitation. Transcutaneous electrical nerve stimulation and intermittent or continuous traction (in patients with or without sciatica) have not been proven effective for chronic low back pain.

[\[Evidence source\]](#)

### **Overall Summary**

Non-pharmacologic treatments that have been shown to be effective for LBP include spinal manipulation, intensive interdisciplinary rehabilitation, exercise therapy, acupuncture, massage therapy, yoga, cognitive-behavioral therapy and progressive relaxation. Transcutaneous electrical nerve stimulation and intermittent or continuous traction have not been proven effective in the treatment of chronic LBP.

### **PROCEDURES**

Acupuncture  
Cognitive-behavioral therapy  
Continuous or intermittent traction  
Exercise therapy  
Intensive interdisciplinary rehabilitation  
Massage therapy  
Progressive relaxation  
Spinal manipulation  
Transcutaneous electrical nerve stimulation  
Viniyoga-style yoga

### **DIAGNOSES**

Low back pain

## APPLICABLE CODES

CODES	DESCRIPTION
<b>ICD-9 Diagnosis Codes</b>	
170.2	Tumor lumbosacral region primary
198.5	Tumor lumbosacral region secondary
344.60	Cauda equine syndrome
720.1	Spinal enthesopathy
720.2	Sacroiliitis, not elsewhere classified
721.3	Lumbosacral spondylosis without myelopathy
721.42	Spondylosis with myelopathy, lumbar region
721.5	Kissing spine
721.6	Ankylosing vertebral hyperostosis
721.7	Traumatic spondylopathy
721.8	Other allied disorders of spine
721.9	Spondylosis of unspecified site
722.1	Displacement of thoracic or lumbar intervertebral disc without myelopathy
722.2	Displacement of intervertebral disc, site unspecified, without myelopathy
722.32	Schmorl's nodes, lumbar region
722.39	Schmorl's nodes, other region
722.5	Degeneration of thoracic or lumbar intervertebral disc
722.6	Degeneration of intervertebral disc, site unspecified
722.70	Intervertebral disc disorder with myelopathy, unspecified region
722.72	Intervertebral disc disorder with myelopathy, thoracic region
722.73	Intervertebral disc disorder with myelopathy, lumbar region
722.80	Postlaminectomy syndrome, unspecified region
722.82	Postlaminectomy syndrome, thoracic region
722.83	Postlaminectomy syndrome, lumbar region
722.90	Other and unspecified disc disorder, unspecified region
722.92	Other and unspecified disc disorder, thoracic region
722.93	Other and unspecified disc disorder, lumbar region
724	Other and unspecified disorders of back
724.0	Spinal stenosis other than cervical
724.00	Spinal stenosis, unspecified region
724.01	Spinal stenosis, thoracic region
724.02	Spinal stenosis, lumbar region, without neurogenic claudication
724.03	Spinal stenosis, lumbar region, with neurogenic claudication
724.09	Spinal stenosis, other region
724.1	Pain in thoracic spine
724.2	Lumbago
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.5	Backache, unspecified
724.6	Disorders of sacrum
724.7	Disorders of coccyx
724.70	Unspecified disorder of coccyx
724.71	Hypermobility of coccyx
724.79	Other disorders of coccyx
724.8	Other symptoms referable to back

<b>CODES</b>	<b>DESCRIPTION</b>
724.9	Other unspecified back disorders
730.2	Unspecified osteomyelitis
732.0	Juvenile osteochondrosis of spine
733.0	Osteoporosis
737.2	Lordosis (acquired)
737.30	Scoliosis [and kyphoscoliosis], idiopathic
737.39	Other kyphoscoliosis and scoliosis
737.4	Curvature of spine associated with other conditions
737.8	Other curvatures of spine
737.9	Unspecified curvature of spine
738.4	Acquired spondylolisthesis
738.5	Other acquired deformity of back or spine
739.2	Nonallopathic lesions, thoracic region
739.3	Nonallopathic lesions, lumbar region
739.4	Nonallopathic lesions, sacral region
754.2	Congenital musculoskeletal deformities of spine
756.1	Congenital anomalies of spine
846	Sprains and strains of sacroiliac region
847.1	Sprain of thoracic
847.2	Sprain of lumbar
847.3	Sprain of sacrum
847.4	Sprain of coccyx
847.9	Sprain of unspecified site of back
<b>ICD-9 Volume 3 (procedure codes)</b>	
None	
<b>CPT</b>	
<b>Spinal Manipulation</b>	
98925	Osteopathic manipulative treatment (OMT); 1-2 body regions involved
98926	3-4 body regions involved
98927	5-6 body regions involved
98928	7-8 body regions involved
98929	9-10 body regions involved
98940	Chiropractic manipulative treatment (CMT); spinal, 1-2 regions
98941	spinal, 3-4 regions
98942	spinal, 5 regions
98943	extraspinal, 1 or more regions
<b>Acupuncture</b>	
97810	Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
+97811	without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)
97813	with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
+97814	with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)
<b>Cognitive Behavioral Therapy</b>	
90804	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in

<b>CODES</b>	<b>DESCRIPTION</b>
	an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient
90805	with medical evaluation and management services
90806	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient
90807	with medical evaluation and management services
90808	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient
90809	with medical evaluation and management services
90810	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient
90811	with medical evaluation and management services
90812	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient
90813	with medical evaluation and management services
90814	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient
90815	with medical evaluation and management services
90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy)
97001	Physical therapy evaluation
97002	Physical therapy re-evaluation
97012	Traction, mechanical
97014	Electrical stimulation (unattended)
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
97112	neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
97116	gait training (includes stair climbing)
97124	massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)
97140	Manual therapy techniques (eg, mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes
97150	Therapeutic procedure(s), group (2 or more individuals) (Group therapy procedures involve constant attendance of the physician or therapist, but by definition do not require one-on-one patient contact by the physician or therapist)
97530	Therapeutic activities, direct (one-on-one) patient contact by the provider (use of dynamic activities to improve functional performance), each 15 minutes
<b>HCPCS Level II Codes</b>	
E0830	Ambulatory traction device, all types, each
E0941	Gravity assisted traction device, any type
H0002	Behavioral health screening to determine eligibility for admission to treatment

CODES	DESCRIPTION
	program
H0004	Behavioral health counseling and therapy, per 15 minutes
H0031	Mental health assessment, by nonphysician
H0032	Mental health service plan development by nonphysician
H2000	Comprehensive multidisciplinary evaluation
H2001	Rehabilitation program, per ½ day
S9451	Exercise classes, nonphysician provider, per session

Note: Inclusion on this list does not guarantee coverage

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.

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## HEALTH EVIDENCE REVIEW COMMISSION (HERC)

### **DRAFT COVERAGE GUIDANCE: LOW BACK PAIN: PHARMACOLOGIC INTERVENTIONS\***

DATE: XX/XX/XXXX

#### HERC COVERAGE GUIDANCE

Pharmacologic interventions for low back pain should be covered as follows:

Acute low back pain

- Initial pharmacologic therapy should be acetaminophen or non-steroidal anti-inflammatory medications (NSAIDs) and/or skeletal muscle relaxants.
- Second line agents include benzodiazepines and opioids

Chronic low back pain (>1 month)

- First line: acetaminophen or NSAIDs, tricyclic antidepressants
- Second line: benzodiazepines and opioids
- Skeletal muscle relaxants should not be covered for chronic low back pain

For acute exacerbations of chronic low back pain, the herbal therapies of devil's claw, willow bark, and capsicum may be covered.

Given the risk profile of opiates and benzodiazepines, there should be a risk assessment prior to initiating therapy, and clear documentation of functional benefit should be required for ongoing prescription coverage.

Systemic steroids should NOT be covered for low back pain.

\*Coverage guidance for non-pharmacologic interventions, imaging, percutaneous interventions and surgery for low back pain will be addressed in subsequent documents.

#### RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

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

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

## EVIDENCE SOURCES

Livingston, C., King, V., Little, A., Pettinari, C., Thielke, A., & Gordon, C. (2011). *State of Oregon Evidence-based Clinical Guidelines Project. Evaluation and management of low back pain: A clinical practice guideline based on the joint practice guideline of the American College of Physicians and the American Pain Society (Diagnosis and treatment of low back pain)*. Salem: Office for Oregon Health Policy and Research. Available at: <http://www.oregon.gov/OHA/OHPR/HERC/Evidence-Based-Guidelines.shtml>

Chou, R., Huffman, L. *Medications for Acute and Chronic Low Back Pain: A Review of the Evidence for an American Pain Society/American College of Physicians Clinical Practice Guideline*. Ann Intern Med. 2007; 147; 505-514. Available at: <http://www.annals.org/content/147/7/505.full.pdf+html>

Chou R., Qaseem, A., Snow, V., Casey, D., Cross, J.T., Jr., Shekelle, P., Owens, D.K.; Clinical Efficacy Assessment Subcommittee of the American College of Physicians; American College of Physicians; American Pain Society Low Back Pain Guidelines Panel. *Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society*. Annals of Internal Med. 2007; 147(7); 478-491. Available at: <http://www.annals.org/content/147/7/478.long>

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

## SUMMARY OF EVIDENCE

### **Clinical Background**

Low back pain is the fifth most common reason for all physician visits in the United States. Approximately one quarter of U.S. adults reported having low back pain lasting at least 1 whole day in the past 3 months, and 7.6% reported at least 1 episode of severe acute low back pain within a 1-year period. Low back pain is also very costly: Total incremental direct health care costs attributable to low back pain in the U.S. were estimated at \$26.3 billion in 1998. In addition, indirect costs related to days lost from

work are substantial, with approximately 2% of the U.S. work force compensated for back injuries each year.

Many patients have self-limited episodes of acute low back pain and do not seek medical care. Among those who do seek medical care, pain, disability, and return to work typically improve rapidly in the first month. However, up to one third of patients report persistent back pain of at least moderate intensity 1 year after an acute episode, and 1 in 5 report substantial limitations in activity. Approximately 5% of the people with back pain disability account for 75% of the costs associated with low back pain.

Many options are available for evaluation and management of low back pain. However, there has been little consensus, either within or between specialties, on appropriate clinical evaluation and management of low back pain. Numerous studies show unexplained, large variations in use of diagnostic tests and treatments. Despite wide variations in practice, patients seem to experience broadly similar outcomes, although costs of care can differ substantially among and within specialties.

### **Evidence Review**

**Recommendation 1:** *For patients with low back pain, clinicians should consider the use of medications with proven benefits in conjunction with back care information and self-care. Clinicians should assess severity of baseline pain and functional deficits, potential benefits, risks, and relative lack of long-term efficacy and safety data before initiating therapy (strong recommendation, moderate-quality evidence). For most patients, first-line medication options are acetaminophen or nonsteroidal anti-inflammatory drugs.*

Medications in several classes have been shown to have moderate, primarily short-term benefits for patients with low back pain. Each class of medication is associated with unique trade-offs involving benefits, risks, and costs. For example, acetaminophen is a slightly weaker analgesic than NSAIDs but is a reasonable first-line option for treatment of acute or chronic low back pain because of a more favorable safety profile and low cost. Nonselective NSAIDs are associated with well-known gastrointestinal and renovascular risks, and there is an association between exposure to cyclooxygenase-2–selective or most nonselective NSAIDs and increased risk for myocardial infarction. Opioid analgesics or tramadol are an option when used judiciously in patients with acute or chronic low back pain who have severe, disabling pain that is not controlled (or is unlikely to be controlled) with acetaminophen and NSAIDs. Because of substantial risks, including aberrant drug-related behaviors with long-term use in patients vulnerable or potentially vulnerable to abuse or addiction, potential benefits and harms of opioid analgesics should be carefully weighed before starting therapy. Failure to respond to a time-limited course of opioids should lead to reassessment and consideration of alternative therapies or referral for further evaluation.

For skeletal muscle relaxants, although the antispasticity drug tizanidine has been well studied for low back pain, there is little evidence for the efficacy of baclofen or dantrolene, the other FDA-approved drugs for the treatment of spasticity. Other medications in the skeletal muscle relaxant class are an option for short-term relief of acute low back pain, but all are associated with central nervous system adverse effects (primarily sedation). Tricyclic antidepressants are an option for pain relief in patients with chronic low back pain and no contraindications to this class of medications. Antidepressants in the selective serotonin reuptake inhibitor class and trazodone have not been shown to be effective for low back pain, and serotonin–norepinephrine reuptake inhibitors (duloxetine and venlafaxine) have not yet been evaluated for low back pain.

Gabapentin is associated with small, short-term benefits in patients with radiculopathy and has not been directly compared with other medications or treatments. There is insufficient evidence to recommend for or against other antiepileptic drugs for back pain with or without radiculopathy. For acute or chronic low back pain, benzodiazepines seem similarly effective to skeletal muscle relaxants for short-term pain relief but are also associated with risks for abuse, addiction, and tolerance. Herbal therapies, such as devil's claw, willow bark, and capsicum, seem to be safe options for acute exacerbations of chronic low back pain, but benefits range from small to moderate. Systemic corticosteroids are not recommended for treatment of low back pain with or without sciatica, because they have not been shown to be more effective than placebo.

[\[Evidence source\]](#)

### **Overall Summary**

Medications in several classes, including NSAIDs, opioids, tramadol, skeletal muscle relaxants, antidepressants and antiepileptics, have been shown to have moderate, primarily short-term benefits for patients with low back pain. Each class of medication is associated with unique trade-offs involving benefits, risks, and costs. For most patients, first-line medications are acetaminophen or NSAIDs. Systemic corticosteroids are ineffective. Several herbal therapies demonstrate small to moderate benefit.

### **PROCEDURES**

Pharmacologic therapy

### **DIAGNOSES**

Low back pain

## APPLICABLE CODES

CODES	DESCRIPTION
<b>ICD-9 Diagnosis Codes</b>	
170.2	Tumor lumbosacral region primary
198.5	Tumor lumbosacral region secondary
344.60	Cauda equine syndrome
720.1	Spinal enthesopathy
720.2	Sacroiliitis, not elsewhere classified
721.3	Lumbosacral spondylosis without myelopathy
721.42	Spondylosis with myelopathy, lumbar region
721.5	Kissing spine
721.6	Ankylosing vertebral hyperostosis
721.7	Traumatic spondylopathy
721.8	Other allied disorders of spine
721.9	Spondylosis of unspecified site
722.1	Displacement of thoracic or lumbar intervertebral disc without myelopathy
722.2	Displacement of intervertebral disc, site unspecified, without myelopathy
722.32	Schmorl's nodes, lumbar region
722.39	Schmorl's nodes, other region
722.5	Degeneration of thoracic or lumbar intervertebral disc
722.6	Degeneration of intervertebral disc, site unspecified
722.70	Intervertebral disc disorder with myelopathy, unspecified region
722.72	Intervertebral disc disorder with myelopathy, thoracic region
722.73	Intervertebral disc disorder with myelopathy, lumbar region
722.80	Postlaminectomy syndrome, unspecified region
722.82	Postlaminectomy syndrome, thoracic region
722.83	Postlaminectomy syndrome, lumbar region
722.90	Other and unspecified disc disorder, unspecified region
722.92	Other and unspecified disc disorder, thoracic region
722.93	Other and unspecified disc disorder, lumbar region
724	Other and unspecified disorders of back
724.0	Spinal stenosis other than cervical
724.00	Spinal stenosis, unspecified region
724.01	Spinal stenosis, thoracic region
724.02	Spinal stenosis, lumbar region, without neurogenic claudication
724.03	Spinal stenosis, lumbar region, with neurogenic claudication
724.09	Spinal stenosis, other region
724.1	Pain in thoracic spine
724.2	Lumbago
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.5	Backache, unspecified
724.6	Disorders of sacrum
724.7	Disorders of coccyx
724.70	Unspecified disorder of coccyx
724.71	Hypermobility of coccyx

<b>CODES</b>	<b>DESCRIPTION</b>
724.79	Other disorders of coccyx
724.8	Other symptoms referable to back
724.9	Other unspecified back disorders
730.2	Unspecified osteomyelitis
732.0	Juvenile osteochondrosis of spine
733.0	Osteoporosis
737.2	Lordosis (acquired)
737.30	Scoliosis [and kyphoscoliosis], idiopathic
737.39	Other kyphoscoliosis and scoliosis
737.4	Curvature of spine associated with other conditions
737.8	Other curvatures of spine
737.9	Unspecified curvature of spine
738.4	Acquired spondylolisthesis
738.5	Other acquired deformity of back or spine
739.2	Nonallopathic lesions, thoracic region
739.3	Nonallopathic lesions, lumbar region
739.4	Nonallopathic lesions, sacral region
754.2	Congenital musculoskeletal deformities of spine
756.1	Congenital anomalies of spine
846	Sprains and strains of sacroiliac region
847.1	Sprain of thoracic
847.2	Sprain of lumbar
847.3	Sprain of sacrum
847.4	Sprain of coccyx
847.9	Sprain of unspecified site of back
<b>ICD-9 Volume 3 (procedure codes)</b>	
None	
<b>CPT Codes</b>	
None	
<b>HCPCS Level II Codes</b>	
J7506	Prednisone, oral, per 5 mg
J7509	Methylprednisolone, oral, per 4 mg
J7510	Prednisolone, oral, per 5 mg

Note: Inclusion on this list does not guarantee coverage

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# Percutaneous Interventions for Low Back Pain

Oregon Health Evidence Review Commission  
June 14, 2012



## Background

- Direction to develop guidelines comes from “Oregon’s Action Plan for Health” released in December 2010
  - Eight foundational strategies
  - One strategy is to set standards for safe and effective care
    - “Identify and develop ten sets of Oregon-based best practice guidelines and standards”
- Work completed by Guideline Development Group (GDG), consisting of representatives of
  - Oregon Health Authority
  - Oregon Healthcare Leadership Council
  - Oregon Corporation for Healthcare Quality
  - Technical support from Center for Evidence-based Policy



## Background

- One of the first 10 Guidelines chosen to be developed
- Criteria for choosing topics:
  - Areas of high utilization
  - Areas of high cost
  - Areas with high variation
  - Good evidence available to support optimal practice
- Other related topics include:
  - Evaluation and Management of Low Back Pain
  - Advanced Imaging for Low Back Pain
  - Spinal Fusion (now on hold)

## Guideline Methods

- Methods: 17 databases searched for candidate guidelines with the following characteristics:
  - evidence-based, that is, guideline recommendations are based on systematic reviews of the literature,
  - address the use of percutaneous interventions in adults with chronic back pain,
  - published in English and,
  - freely available to the public.

## Guideline Methods

Methods cont.

- 10 identified (3 rated poor from prior work, 1 not public, remaining 6 assessed for methodological quality)
- Two good quality, one fair quality with good rigor of development examined further
- GDG chose ACP/APS guideline as base because it was most comprehensive
  - Chou, R., Loesser, J.D., Owens, D.K., Rosenquist, R.W., Atlas, S.J., Baisden, J., Carragee, E.J., Grabois, M., Murphy, D.R., Resnick, D.K., Stanos, S.P., Shaffer, W.O., Wall E.M. (2009). Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: An evidence-based clinical practice guideline from the American Pain Society. *Spine* 34:10:1066-1077

## Guideline Recommendations

Guideline includes three main recommendations:

1. *In patients with persistent radiculopathy due to herniated lumbar disc, it is recommended that clinicians discuss risks and benefits of epidural steroid injection as an option (weak recommendation, moderate-quality evidence). It is recommended that shared decision-making regarding epidural steroid injection include a specific discussion about inconsistent evidence showing moderate short-term benefits, and lack of long-term benefits. There is insufficient evidence to adequately evaluate benefits and harms of epidural steroid injection for spinal stenosis.*

## Guideline Recommendations

Guideline includes three main recommendations:

2. *In patients with persistent nonradicular low back pain, facet joint corticosteroid injection, prolotherapy, and intradiscal corticosteroid injection **are not recommended** (strong recommendation, moderate-quality evidence).*
3. *There is insufficient evidence to adequately evaluate benefits of local injections, botulinum toxin injection, epidural steroid injection, intradiscal electrothermal therapy (IDET), therapeutic medial branch block, radiofrequency denervation, sacroiliac joint steroid injection, coblation nucleoplasty, percutaneous intradiscal radiofrequency thermocoagulation .... or other medications for nonradicular low back pain.*

## Table A. Recommendations for Percutaneous Injections of the Spine

- Table A sorts evidence by condition
  - Non-specific LBP
  - Presumed discogenic pain
  - Presumed facet joint pain
  - Presumed sacroiliac joint pain
  - Radiculopathy, including with herniated disc
  - Spinal stenosis
- Addresses 14 different interventions
- Includes net benefit, strength of recommendation, quality of evidence rating

## Peer Review

- Draft guideline peer-reviewed December 2011
- Solicited comments from 22 peer reviewers from following specialties:
  - Anesthesiology
  - Behavioral Health
  - Complementary & Alternative Medicine
  - Family Medicine
  - Internal Medicine
  - Occupational Medicine
  - Orthopedic Surgery
  - Neurosurgery
  - Pain Advocacy
  - Pain Medicine
  - Physical Therapy
  - Physical Medicine & Rehabilitation
  - Radiology
  - Sports Medicine
  - Worker's Compensation
- Responses received from 7
- Comments reviewed by GDG and incorporated as appropriate

## Public Comment & Next Steps

- Draft guideline posted for public comment Feb 17-March 18
- No comments received
- Evidence-based Guideline Subcommittee reviewed and approved May 3
- Now due for final adoption/approval by HERC

# State of Oregon Evidence-based Clinical Guidelines Project

## Percutaneous Interventions for Low Back Pain

A clinical practice guideline based on the 2009 American Pain Society  
Guideline (Interventional Therapies, Surgery, and Interdisciplinary  
Rehabilitation for Low Back Pain)

February 2012

Oregon  
Health  
Authority

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## Suggested Citation

Livingston, C., Little, A., King, V., Pettinari, C., Thielke, A., Pensa, M., Vandegriff, S., & Gordon, C. (2012). *State of Oregon Evidence-based Clinical Guidelines Project. Percutaneous interventions for low back pain: A clinical practice guideline based on the 2009 American Pain Society Guideline (Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain)*. Salem: Office for Oregon Health Policy and Research. Available at: <http://www.oregon.gov/OHA/OHPR/HERC/Evidence-Based-Guidelines.shtml>

This document was prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center) on behalf of the Guideline Development Group and the Office for Oregon Health Policy & Research. This document is intended to help providers, consumers and purchasers of health care in Oregon make informed decisions about health care services. The document is intended as a reference and is provided with the understanding that neither the Center nor the Guideline Development Group are engaged in rendering any clinical, legal, business or other professional advice.

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

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## Objective

This guideline was developed by a collaborative group of public and private partners to provide up-to-date evidence-based guidance on the role of percutaneous interventions in low back pain. The aim of the guideline is to identify evidence-based, appropriate indications for the use of percutaneous interventions in patients with low back pain of any duration, with and without leg pain. This guideline can then be used to create practice standards and coverage guidelines for use across public and private payers. It does not address patients with back pain associated with major trauma, tumor, metabolic disease, inflammatory back disease, fracture, dislocation, major instability or deformity, progressive or severe neurologic deficits, or back pain in children, adolescents or pregnant women. Percutaneous interventions addressed in this guideline include intradiscal, facet joint, sacroiliac joint and epidural steroid injections, prolotherapy, botulinum toxin injections, local injections, medial branch block, radiofrequency denervation, intradiscal electrothermal therapy, percutaneous intradiscal radiofrequency thermocoagulation and coblation nucleoplasty.

Additional evidence concerning other elements of evaluation as well as recommendations for management of low back pain can be found in the State of Oregon Evidence-based Clinical Guidelines:

- Evaluation and Management of Low Back Pain<sup>1</sup>
- Advanced Imaging for Low Back Pain<sup>2</sup>

## Background

In June 2009, the Oregon legislature passed health reform legislation HB 2009, which created the Oregon Health Policy Board and charged it with creating a comprehensive health reform plan for our state. In December 2010, the Board released *Oregon's Action Plan for Health*, which lays out "strategies that reflect the urgency of the health care crisis and a timeline for actions that will lead Oregon to a more affordable, world-class health care system." They outlined eight foundational strategies, one of which is to "set standards for safe and effective care." To accomplish this, the plan directs the state to "Identify and develop 10 sets of Oregon-based best practice guidelines and standards that can be uniformly applied across public and private health care to drive down costs and reduce unnecessary care." This work is being conducted by the Oregon Health Services Commission and the Oregon Health Resources Commission in close collaboration with providers, the Center for Evidence-Based Policy, and other key stakeholders.<sup>3</sup>

## Development of this guideline:

This guideline was developed by a Guideline Development Group (GDG) consisting of representatives from the State of Oregon Health Authority, the Oregon Healthcare Leadership Council, and the Oregon Corporation for Healthcare Quality with support from clinical evidence specialists from the Center for

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<sup>1</sup> Livingston, C., King, V., Little, A., Pettinari, C., Thielke, A., & Gordon, C. (2011). *State of Oregon Evidence-based Clinical Guidelines Project. Evaluation and management of low back pain: A clinical practice guideline based on the joint practice guideline of the American College of Physicians and the American Pain Society (Diagnosis and treatment of low back pain)*. Salem: Office for Oregon Health Policy and Research.

<sup>2</sup> Livingston, C., Little, A., King, V., Pettinari, C., Thielke, A., Vandegriff, S., & Gordon, C. (2012). *State of Oregon Evidence-based Clinical Guidelines Project. Advanced imaging for low back pain: A clinical practice guideline based on the joint practice guideline of the American College of Physicians and the American Pain Society (Diagnosis and treatment of low back pain)*. Salem: Office for Oregon Health Policy & Research.

<sup>3</sup> Effective January 1, 2012, House Bill 2100 (2011) terminates the Health Services Commission and Health Resources Commission and transfers their duties related to evidence-based guideline development to a new Health Evidence Review Commission.

Evidence-based Policy. The Center provided expertise in the process of guideline development and undertook analysis and appraisal to support the development of this guideline.

### **Methods:**

The GDG developed this guideline using the ADAPTÉ<sup>4</sup> framework which is a systematic approach to the endorsement or modification of guideline(s) produced in one cultural context or organizational setting for application in another context. Guideline adaptation is used as an alternative to wholly new guideline development, which can be time consuming, expensive and an inefficient use of resources, when existing quality guidelines are available.

The process for developing this guideline began by searching 17 different databases and other sources for guidelines related to percutaneous interventions for chronic back pain (see appendix A). Candidate guidelines were required to satisfy the following requirements:

- to be evidence-based, that is, guideline recommendations are based on systematic reviews of the literature,
- to address the use of percutaneous interventions in adults with chronic back pain,
- to be published in English and,
- to be freely available to the public.

The GDG required that evidence-based recommendations be made on the basis of both the quality and strength of the underlying evidence from any included guideline's systematic reviews. The initial search identified 10 candidate guidelines which met the above stated criteria (Appendix B). Of the original candidate guidelines, three had been rated as poor quality during the development of a previous guideline and one was excluded because it was not publically available. The six remaining guidelines were then assessed for methodologic quality using a modified AGREE (Appraisal of Guidelines Research and Evaluation) II<sup>5</sup> instrument (Appendix C) by two different guideline quality assessors from the Center for Evidence-based Policy. Two of those guidelines were rated good quality, and one was rated fair with good rigor of development of the evidence and recommendations according to the modified AGREE rating tool. These three guidelines were then examined further for scope and clarity of presentation.

Comparison of the APS guideline was made to the other high quality, comprehensive guidelines, which were produced by the National Institute for Health and Clinical Excellence (NICE), and Towards Optimized Practice, Alberta Clinical Guidelines Program. Of the guidelines considered for review, the GDG felt that the APS guideline was the most comprehensive.

After considering guideline scope and specific modalities addressed, the GDG selected the American Pain Society's 2009 guideline "Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: An evidence-based clinical practice guideline from the American Pain Society" as the base guideline, primarily because it had recommendations concerning a broader range of interventions than guidelines from the National Institute for Health and Clinical Evidence (NICE) or from Towards Optimized Practice (TOP). (See Appendix E for procedures addressed in the APS guideline.) The APS guideline in its entirety can be found at the following link:

[http://journals.lww.com/spinejournal/Abstract/2009/05010/Interventional\\_Therapies,\\_Surgery,\\_and.14.aspx](http://journals.lww.com/spinejournal/Abstract/2009/05010/Interventional_Therapies,_Surgery,_and.14.aspx). The

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<sup>4</sup> <http://www.adapte.org/www/>

<sup>5</sup> <http://www.agreecollaboration.org/>

APS guideline is accompanied by a full systematic review on nonsurgical interventional therapies for low back pain in the same journal issue at: <http://www.ampainsoc.org/library/pdf/LBPEvidRev.pdf>.

The APS guideline panel arrived at treatment recommendations by first evaluating the evidence for treatments according to a system adapted from the US Preventive Services Task Force for grading the evidence, then estimating the magnitude of effects, including whether the benefits of the treatment outweigh the harms. (See Appendix D for the APS criteria for arriving at recommendations.)

**Updating:**

The APS guideline was published in 2009. The authors of the guideline were contacted in March 2011 and stated that there had been no new published evidence which would change the recommendations of the guideline and that it was considered current. The GDG recommends that this guideline be reevaluated if the APS issues an updated guideline and at least every two years for currency if the original guideline is not updated.

**Recommendations**

Below are the recommendations of the APS clinical practice guideline followed by discussion of each recommendation.

**Table A. State of Oregon Evidence-based Clinical Guideline Recommendations for Percutaneous Injections of the Spine**

Condition	Intervention	Net Benefit	Recommendation	Strength of Recommendation and Quality of Evidence Rating*
<b>Non-radicular Low Back Pain</b>				
<b>Non-specific Low Back Pain</b>	<ul style="list-style-type: none"> <li>Prolotherapy</li> </ul>	No net benefit	In patients with persistent nonradicular low back pain, <b>clinicians should not</b> provide prolotherapy.	Recommendation: Strong Grade: High-quality evidence
	<ul style="list-style-type: none"> <li>Local injections</li> <li>Botulinum toxin injection</li> <li>Epidural steroid injection</li> <li>Therapeutic medial branch block</li> <li>Radiofrequency denervation</li> <li>Sacroiliac joint steroid injection</li> <li>Coblation nucleoplasty</li> </ul>	Unknown	In patients with persistent nonradicular low back pain, there is insufficient evidence to adequately evaluate the benefits of local injections, botulinum toxic injection, epidural steroid injection, therapeutic medial branch block, radiofrequency denervation, sacroiliac joint steroid injection, or coblation nucleoplasty.	Insufficient evidence to determine net benefits or harms
	<ul style="list-style-type: none"> <li>Intradiscal steroid injection</li> </ul>	No net benefit	In patients with presumed discogenic pain, <b>clinicians should not</b> provide	Recommendation: Strong Grade: High quality-

Condition	Intervention	Net Benefit	Recommendation	Strength of Recommendation and Quality of Evidence Rating*
Presumed discogenic pain			intradiscal steroid injection.	evidence
	<ul style="list-style-type: none"> <li>• Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)</li> <li>• Intradiscal electrothermal therapy (IDET)</li> </ul>	Unknown	In patients with presumed discogenic pain, there is insufficient evidence to adequately evaluate the benefits of PIRFT or IDET	Insufficient evidence to determine net benefits or harms
Presumed facet joint pain	<ul style="list-style-type: none"> <li>• Facet joint steroid injection</li> </ul>	No net benefit	In patients with presumed facet joint pain, <b>clinicians should not</b> provide facet joint steroid injection.	Recommendation: Strong Grade: Moderate-quality evidence
	<ul style="list-style-type: none"> <li>• Radiofrequency denervation</li> </ul>	Unknown	In patients with presumed facet joint pain, there is insufficient evidence to adequately evaluate the benefits of radiofrequency denervation.	Insufficient evidence to determine net benefits or harms
Presumed sacroiliac joint pain	<ul style="list-style-type: none"> <li>• Sacroiliac joint steroid injection</li> </ul>	Unknown	In patients with presumed sacroiliac joint pain, there is insufficient evidence to adequately evaluate the benefits of sacroiliac joint steroid injection.	Insufficient evidence to determine net benefits or harms
<b>Radiculopathy or Spinal Stenosis</b>				
Radiculopathy with herniated lumbar disc	<ul style="list-style-type: none"> <li>• Epidural steroid injection</li> </ul>	<b>Moderate benefit (short-term)</b>	<p>In patients with persistent radiculopathy due to herniated lumbar disc, <b>clinicians should</b> discuss the risks and benefits of epidural steroid injections as an option.</p> <p>It is recommended that Shared decision-making regarding epidural steroid injection includes a specific discussion about inconsistent evidence showing moderate short-term benefits and lack of long-term benefits.</p>	Recommendation: Weak Grade: Moderate-quality evidence
Radiculopathy with herniated	<ul style="list-style-type: none"> <li>• Coblation nucleoplasty</li> </ul>	Unknown	In patients with radiculopathy with herniated lumbar disc, there is	Insufficient evidence to determine net benefits or

Condition	Intervention	Net Benefit	Recommendation	Strength of Recommendation and Quality of Evidence Rating*
lumbar disc, cont.			insufficient evidence to adequately evaluate the benefits.	harms
Radiculopathy	<ul style="list-style-type: none"> <li>Radiofrequency denervation</li> </ul>	Unknown	In patients with radiculopathy, there is insufficient evidence to adequately evaluate the benefits.	Insufficient evidence to determine net benefits or harms
Symptomatic Spinal Stenosis	<ul style="list-style-type: none"> <li>Epidural steroid injection</li> </ul>	Unknown	In patients with spinal stenosis, there is insufficient evidence to adequately evaluate the benefits.	Insufficient evidence to determine net benefits or harms

\*See Appendix D for complete description of APS and ACP evidence grading methods. Chou, et al. (2009) utilize the US Prevent Services Task Force criteria for rating the strength of recommendation and quality of evidence. Recommendations in this table are modified to fit GRADE terminology for consistency among State of Oregon guidelines.

## Recommendation #1<sup>6</sup> :

### Epidural Steroid Injection for persistent radiculopathy due to herniated lumbar disc

*In patients with persistent radiculopathy due to herniated lumbar disc, it is recommended that clinicians discuss risks and benefits of epidural steroid injection as an option (weak recommendation, moderate-quality evidence). It is recommended that shared decision-making regarding epidural steroid injection include a specific discussion about inconsistent evidence showing moderate short-term benefits, and lack of long-term benefits. There is insufficient evidence to adequately evaluate benefits and harms of epidural steroid injection for spinal stenosis.*

For radiculopathy due to herniated lumbar disc, evidence on benefits of epidural steroid injection is mixed. Although some higher-quality trials (Arden 2005; Bush 1991; Dilke 1973; Wilson-MacDonald 2005) found epidural steroid injection associated with moderate short-term (through up to 6 weeks) benefits in pain or function, others (Carette 1997; Karppinen 2001; Ng 2005) found no differences *versus* placebo injection. Reasons for the discrepancies between trials is uncertain, but could be related to the type of comparator treatment, as trials (Beliveau 1971; Breivik 1976; Bush 1991; Carette 1997; Cuckler 1985; Karppinen 2001; Klenerman 1984; Ng 2005; Rogers 1992; Snoek 1977; Zahaar 1991) that compared an epidural steroid injection to an epidural saline or local anesthetic injection tended to report poorer results than trials (Arden 2005; Dilke 1973; Helliwell 1985; Mathews 1987; Ridley 1988; Wilson-MacDonald 2005) that compared an epidural steroid injection to a soft-tissue (usually interspinous ligament) placebo injection. Regardless of the comparator intervention, there is no convincing evidence that epidural steroids are associated with long-term benefits and most trials (Arden 2005; Carette 1997; Riew 2000; Wilson-MacDonald 2005) found no reduction in rates of subsequent

<sup>6</sup> Extracted and modified from Chou, et. al. (2009)

surgery. Although serious complications following epidural steroid injection are rare in clinical trials, (Arden 2005; Karppinen 2001; Kolsi 2000; Kraemer 1997; Ng 2005) there are case reports of paralysis and infections. (Glaser 2005; Hooten 2006; Huntoon 2004) There is insufficient evidence on clinical outcomes to recommend a specific approach for performing epidural steroid injection (Ackerman 2007; Kolsi 2000; Kraemer 1997; McGregor 2001; Thomas 2003) or on use of fluoroscopic guidance. In addition, insufficient evidence exists to recommend how many epidural injections to perform, though 1 higher-quality trial found that if an initial epidural steroid injection did not result in benefits, additional injections over a 6-week period did not improve outcomes (Arden 2005).

*Epidural steroid injection for the treatment of radiculopathy with herniated lumbar disc is the only percutaneous intervention found to have a net benefit, and the benefit appears to be short-term.*

Decisions regarding use of epidural steroid injection should be based on a shared decision-making process that includes a discussion of the inconsistent evidence for short-term benefit, lack of long-term benefit, potential risks, and costs. Patient preferences and individual factors should also be considered. For example, epidural steroid injection may be a reasonable option for short-term pain relief in patients who are less optimal surgery candidates due to comorbidities. There is insufficient evidence to guide specific recommendations for timing of epidural steroid injection, though most trials enrolled patients with at least subacute (greater than 4 weeks) symptoms.

Evidence on efficacy of epidural steroid injection for spinal stenosis is sparse and shows no clear benefit, though more trials are needed to clarify effects (Cuckler 1985; Fukusaki 1998; Zahaar 1991). Although chymopapain chemonucleolysis ([see glossary, Supplemental Digital Content 1, http://links.lww.com/A840](#)) is effective for radiculopathy due to herniated lumbar disc, (Gibson 2007a, 2007b) it is less effective than discectomy ([see glossary, Supplemental Digital Content 1, http://links.lww.com/A840](#)) and is no longer widely available in the United States, in part due to risk of severe allergic reactions.

## **Recommendation #2<sup>7</sup>:**

### **Facet Joint Injection, Prolotherapy, Intradiscal Corticosteroid Injection**

*In patients with persistent nonradicular low back pain, facet joint corticosteroid injection, prolotherapy, and intradiscal corticosteroid injection **are not recommended** (strong recommendation, moderate-quality evidence).*

Injections and most interventional therapies for nonradicular low back pain target specific areas of the back that are potential sources of pain, including the muscles and soft tissues (botulinum toxin injection, prolotherapy, and local injections [[see glossary, Supplemental Digital Content 1, http://links.lww.com/A840](#)]), facet joints (facet joint steroid injection, therapeutic medial branch block, and radiofrequency denervation [[see glossary, Supplemental Digital Content 1, http://links.lww.com/A840](#)]), degenerated intervertebral discs (intradiscal steroid injection, IDET, [[see glossary, Supplemental Digital Content 1, http://links.lww.com/A840](#)] and related procedures), and sacroiliac joints (sacroiliac joint injection)

There is no convincing evidence from randomized trials that injections and other interventional therapies are effective for nonradicular low back pain. Facet joint steroid injection (Carette 1991; Lilius

<sup>7</sup> Extracted and modified from Chou, et. al. (2009)

1989) prolotherapy (Dagenais 2007) and intradiscal steroid injections (Khot 2004; Simmons 1992) are not recommended because randomized trials consistently found them to be no more effective than sham therapies.

Five randomized, placebo-controlled trials evaluated prolotherapy (Gibson 2007a; Huntoon 2004; Klenerman 1984; Malmivaara 2007; Weber 1983). All were included in a higher quality Cochrane review (Willems 2004). Four trials were rated higher quality (Huntoon 2004; Klenerman 1984; Malmivaara 2007; Weber 1983). For chronic nonspecific low back pain, 3 trials (2 higher quality: Klenerman 1984, Malmivaara 2007) found no difference between prolotherapy and either saline or local anesthetic control injections for short-or long-term (up to 24 months) pain or disability (Malmivaara 2007).

### **Recommendation #3<sup>8</sup> :**

#### **Other Interventional Procedures**

*There is insufficient evidence to adequately evaluate benefits of local injections, botulinum toxin injection, epidural steroid injection, intradiscal electrothermal therapy (IDET), therapeutic medial branch block, radiofrequency denervation, sacroiliac joint steroid injection, coblation nucleoplasty, percutaneous intradiscal radiofrequency thermocoagulation .... or other medications for nonradicular low back pain.*

For local injections, there is insufficient evidence to accurately judge benefits because available trials are small, lower-quality, and evaluate heterogeneous populations and interventions (Collee 1991; Garvey 1989; Hameroff 1981; Sonne 1985). Trials of IDET (Freeman 2005; Pauza 2004) and radiofrequency denervation (Leclaire 2001; Nath 2008; van Kleef 1999; van Wijk 2005) reported inconsistent results. There were a small number of higher quality trials, and in the case of radiofrequency denervation, the trials had technical or methodologic shortcomings (Hooten 2005), making it difficult to reach conclusions about benefits. For other interventional therapies, data are limited to 1-2 small placebo-controlled randomized trials (botulinum toxin injection (Foster 2001), epidural steroid injection for nonradicular low back pain (Serrao 1992), PIRFT (Barendse 2001, Ercelen 2003) and sacroiliac joint steroid injection [see glossary, Supplemental Digital Content 1, <http://links.lww.com/A840>] (Luukkainen 2002), or there are no placebo-controlled randomized trials (therapeutic medial branch block, coblation nucleoplasty....or other medications).

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<sup>8</sup> Extracted and modified from Chou, et. al. (2009)

## Appendix A. Sources Searched for Low Back Pain Guidelines

1. British Medical Journal – Clinical Evidence
2. Cochrane Library
3. Agency for Healthcare Research and Quality
4. ECRI
5. Hayes, Inc
6. Veterans Administration – Technology Assessment Program (VA TAP)
7. Blue Cross Blue Shield HTA
8. Centers for Medicare and Medicaid
9. CADTH
10. Washington HTA Program
11. US Preventive Services Task Force
12. ICSI
13. Guidelines.gov
14. American College of Physicians AND American Pain Society
15. American Physical Therapy Association
16. PEDro.org.au (evidence-based physiotherapy database)
17. GIN Guidelines Database

DRAFT

## Appendix B. Low Back Pain Guidelines Identified

### Methods Summary:

Initially, 17 databases and other sources for guidelines related to percutaneous Interventions for low back pain were searched. Candidate guidelines were required to:

- be evidence-based (recommendations based on a full systematic review)
- be comprehensive
- be published in English
- be freely available to the public

Ten candidate guidelines were identified, of which six were sufficiently comprehensive and were assessed by two clinical epidemiologists for methodologic quality using a modified AGREE (Appraisal of Guidelines Research and Evaluation) II<sup>9</sup> instrument.

Candidate guidelines were then assessed considering:

- age
- source
- specific treatment elements addressed
- presentation

The GDG selected the guideline of highest quality and that was most comprehensive. (See guideline text for comprehensive Methods discussion)

### Low Back Pain Guidelines Identified in Search – Selected for Quality Assessment

Armon, C., Argoff, C.E., Samuels, J., Backonja, M.M. (2007). Assessment: Use of epidural steroid injections to treat radicular lumbosacral pain: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology* 68:723-729.

**Overall guideline quality rating: Fair**

Chou, R., Loesser, J.D., Owens, D.K., Rosenquist, R.W., Atlas, S.J., Baisden, J., Carragee, E.J., Grabois, M., Murphy, D.R., Resnick, D.K., Stanos, S.P., Shaffer, W.O., Wall E.M. (2009) Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: An evidence-based clinical practice guideline from the American Pain Society. *Spine* 34:10:1066-1077. – accompanied by:

Chou, R., Atlas, S.J., Stanos, S.P., Rosenquist, R.W. (2009). A review of the evidence for an American Pain Society clinical practice guideline. *Spine* 34:10:1078-1094.

**Overall guideline quality rating: Fair with good rigor of development of evidence and recommendations**

Manchikanti, L., Boswell, M.V., Singh, V., Benyamin, R.M., Fellows, B., Abdi, S., Buenaventura, R.M., Conn, A., Datta, S., Derby, R., Falco, F.J.E., Erhart, S., Diwan, S., Hayek, S.M., Helm II, S., Parr, A.T., Schultz, D.M., Smith, H.S., Wolfer, L. R., Hirsch, J.A. (2009). Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain. *Pain Physician* 12:699-802.

**Overall guideline quality rating: Poor**

National Health and Medical Research Council. Australian Acute Musculoskeletal Pain Guidelines Group. (2003). Evidence-based management of acute musculoskeletal pain. (Website states that status is “current”).

[Chapter 4 of document is on Acute Low Back Pain.]

<http://www.nhmrc.gov.au/files/nhmrc/file/publications/synopses/cp94.pdf>

**Overall guideline quality rating: Fair**

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<sup>9</sup> <http://www.agreecollaboration.org/>

National Institute for Health and Clinical Excellence (NICE). (2009). Low back pain: Early management of persistent non-specific low back pain. London, UK: National Institute for Health and Clinical Excellence. Retrieved September 30, 2010, from <http://www.nice.org.uk/nicemedia/live/11887/44343/44343.pdf>

**Overall guideline quality rating: Good**

Towards Optimized Practice. (2009). Management of low back pain. Edmonton, AB: Towards Optimized Practice Program.

**Overall guideline quality rating: Good**

#### Low Back Pain Guidelines Identified in Search– Not Selected for Quality Assessment

American College of Occupational and Environmental Medicine (ACOEM). (2007). Low back disorders. Occupational medicine practice guidelines: Evaluation and management of common health problems and functional recovery in workers. 2<sup>nd</sup> ed. Elk Grove Village, IL: ACOEM.

**Overall guideline quality rating: Fair**

Institute for Clinical Systems Improvement (ICSI). (2010). Adult low back pain. Fourteenth edition. Bloomington, MN: ICSI.

**Overall guideline quality rating: Poor**

Michigan Quality Improvement Consortium. (2008). Management of acute low back pain. Southfield, MI: Michigan Quality Improvement Consortium.

**Overall guideline quality rating: Poor**

University of Michigan Health System. (2010). Acute low back pain. Ann Arbor, MI: University of Michigan Health System.

**Overall guideline quality rating: Poor**

## Appendix C: Methodology Checklist Adapted from the AGREE II materials

<b>Methodology Checklist: Guidelines</b>				
Guideline citation <i>(Include name of organization, title, year of publication, journal title, pages)</i>				
Guideline Topic:				
Checklist completed by:			Date:	
<b>SECTION 1: PRIMARY CRITERIA</b>				
<b>To what extent is there</b>		<b>Assessment/Comments:</b>		
1.1	<b>RIGOR OF DEVELOPMENT: Evidence</b> <ul style="list-style-type: none"> <li>• Systematic literature search</li> <li>• Study selection criteria clearly described</li> <li>• Quality of individual studies and overall strength of the evidence assessed</li> <li>• Explicit link between evidence &amp; recommendations</li> </ul> <p><i>(If any of the above are missing, rate as poor)</i></p>	GOOD	FAIR	POOR
1.2	<b>RIGOR OF DEVELOPMENT: Recommendations</b> <ul style="list-style-type: none"> <li>• Methods for developing recommendations clearly described</li> <li>• Strengths and limitations of evidence clearly described</li> <li>• Benefits/side effects/risks considered</li> <li>• External review</li> </ul>	GOOD	FAIR	POOR
1.3	<b>EDITORIAL INDEPENDENCE<sup>10</sup></b> <ul style="list-style-type: none"> <li>• Views of funding body have not influenced the content of the guideline</li> <li>• Competing interests of members have been recorded and addressed</li> </ul>	GOOD	FAIR	POOR
<i>If any of three primary criteria are rated poor, the entire guideline should be rated poor.</i>				
<b>SECTION 2: SECONDARY CRITERIA</b>				
2.1	<b>SCOPE AND PURPOSE</b> <ul style="list-style-type: none"> <li>• Objectives described</li> <li>• Health question(s) specifically described</li> <li>• Population (patients, public, etc.) specified</li> </ul>	GOOD	FAIR	POOR

<sup>10</sup> Editorial Independence is a critical domain. However, it is often very poorly reported in guidelines. The assessor should not rate the domain, but write “unable to assess” in the comment section. If the editorial independence is rated as “poor”, indicating a high likelihood of bias, the entire guideline should be assessed as poor.

SECTION 2: SECONDARY CRITERIA, Cont.				
2.2	<b>STAKEHOLDER INVOLVEMENT</b> <ul style="list-style-type: none"> <li>Relevant professional groups represented</li> <li>Views and preferences of target population sought</li> <li>Target users defined</li> </ul>	GOOD	FAIR	POOR
2.3	<b>CLARITY AND PRESENTATION</b> <ul style="list-style-type: none"> <li>Recommendations specific, unambiguous</li> <li>Management options clearly presented</li> <li>Key recommendations identifiable</li> <li>Application tools available</li> <li>Updating procedure specified</li> </ul>	GOOD	FAIR	POOR
2.4	<b>APPLICABILITY</b> <ul style="list-style-type: none"> <li>Provides advice and/or tools on how the recommendation(s) can be put into practice</li> <li>Description of facilitators and barriers to its application</li> <li>Potential resource implications considered</li> <li>Monitoring/audit/review criteria presented</li> </ul>	GOOD	FAIR	POOR
SECTION 3: OVERALL ASSESSMENT OF THE GUIDELINE				
3.1	How well done is this guideline?	GOOD	FAIR	POOR
3.2	Other reviewer comments:			

#### Description of Ratings: Methodology Checklist for Guidelines

The checklist for rating guidelines is organized to emphasize the use of evidence in developing guidelines and the philosophy that “evidence is global, guidelines are local.” This philosophy recognizes the unique situations (e.g., differences in resources, populations) that different organizations may face in developing guidelines for their constituents. The second area of emphasis is transparency. Guideline developers should be clear about how they arrived at a recommendation and to what extent there was potential for bias in their recommendations. For these reasons, rating descriptions are only provided for the primary criteria in section one. There may be variation in how individuals might apply the good, fair, and poor ratings in section two based on their needs, resources, organizations, etc.

#### Section 1. Primary Criteria (rigor of development and editorial independence) ratings:

**Good:** All items listed are present, well described, and well executed (e.g., key research references are included for each recommendation).

**Fair:** All items are present, but may not be well described or well executed.

**Poor:** One or more items are absent or are poorly conducted

## Appendix D. APS Guideline Criteria for Treatment Recommendations

The APS guideline panel arrived at treatment recommendations by first evaluating the evidence for treatments according to a system adapted from the US Preventive Services Task Force for grading the evidence, then estimating the magnitude of effects, including whether the benefits of the treatment outweigh the harms.

The underlying strength of the evidence for each intervention was given a rating of good, fair or poor based on factors such as the quality, quantity, consistency, and generalizability of the evidence (Table 1).

**Table 1. APS Criteria for Grading the Strength of Evidence**

Rating	Strength
Good	Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes (at least 2 consistent, higher-quality trials)
Fair	Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, size, or consistency of included studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes (at least 1 higher-quality trial of sufficient sample size; 2 or more higher-quality trials with some inconsistency; at least 2 consistent, lower-quality trials, or multiple consistent observational studies with no significant methodologic flaws)
Poor	Evidence is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

Depending on the strength of the evidence for an intervention, the APS used the following criteria for making a recommendation.

**Table 2. APS Criteria for making treatment recommendations**

Grade	Criteria for making a recommendation
A	The panel strongly recommends that clinicians consider offering the intervention to eligible patients. The panel found good evidence that the intervention improves health outcomes and concludes that benefits substantially outweigh harms.
B	The panel recommends that clinicians consider offering the intervention to eligible patients. The panel found at least fair evidence that the intervention improves health outcomes and concludes that benefits moderately outweigh harms, or that benefits are small but there are no significant harms, costs, or burdens associated with the intervention.
C	The panel makes no recommendation for or against the intervention. The panel found at least fair evidence that the intervention can improve health outcomes, but concludes that benefits only slightly outweigh harms, or the balance of benefits and harms is too close to justify a general recommendation.
D	The panel recommends against offering the intervention. The panel found at least fair evidence that the intervention is ineffective or that harms outweighs benefits.
I	The panel found insufficient evidence to recommend for or against the intervention. Evidence that the intervention is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

If a recommendation was made, the APS assigned an overall grade of its strength, adapting the grading system of the international Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) working group. Strong recommendations are required to have clear evidence of benefit or harm. Weak recommendations are based on finely balanced benefits, risks and burdens.

**Table 3. ACP Clinical Practice Guidelines Grading System<sup>11</sup>**

Quality of Evidence	Strength of Recommendation	
	Benefits Do or Do Not Clearly Outweigh Risks	Benefits and Risks and Burdens Are Finely Balanced
High	Strong	Weak
Moderate	Strong	Weak
Low	Strong	Weak
Insufficient evidence to determine net benefits or harms		

The ACP/APS guideline panel considered interventions to have “proven” benefit if there was at least fair quality evidence of moderate or substantial benefit (or of small benefit with no significant harms, costs or burdens).

<sup>11</sup> Adapted from the system developed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) workshop by the American College of Physicians.

## Appendix E. Treatments addressed in APS guidelines\*

Treatment	Definitions Procedures are defined according to APS <a href="http://links.lww.com/A840">http://links.lww.com/A840</a>
Prolotherapy (sclerotherapy) Injections	A procedure involving the repeated injection of an irritant chemical into the soft tissues of the back in order to provoke an inflammatory response that will theoretically subsequently lead to strengthening of the soft tissues with decrease in pain and disability. Also referred to as sclerotherapy
Facet joint corticosteroid injections	Injection of corticosteroid into the facet joints.
Therapeutic medial branch block	Injection of local anesthetic with or without corticosteroid in the area of the medial branch of the posterior primary ramus, the primary nerve innervating the intervertebral facet joint. Usually used as a diagnostic procedure to identify facet joint pain, but has also been used as a therapeutic procedure
Intradiscal corticosteroid injections	Injection of corticosteroid into the intervertebral disc.
Radiofrequency denervation	A procedure involving the destruction of nerves using heat generated by a radiofrequency current.
Intradiscal electrothermal therapy (IDET)	A procedure involving the placement of an electrode or catheter into the intervertebral disc annulus or nucleus and applying electrothermal energy to alter adjacent pain receptors or other structures.
Epidural steroid injection	Injection of corticosteroids via a catheter into the space between the dura and the spine. Common approaches for administering epidural steroid injections are through the interlaminar space, via the neuroforamen under fluoroscopic guidance (transforaminal), and through the sacral hiatus at the sacral canal (caudal).
Local injections	Injection of local anesthetic (with or without corticosteroid) into the muscles or soft tissues of the back. Trigger point injections, a type of local injection, involve an injection performed at a tender area, often with a palpable nodule or band.
Sacroiliac joint steroid Injection	Injection of corticosteroid into or around the sacroiliac joint.
Botulinum toxin injection	Injection of botulinum toxin (an antispasmodic) into the muscles of the back.
Chemonucleolysis	Treatment of herniated discs with intradiscal injections of a proteolysis enzyme, most commonly chymopapain (an extract from papaya). Chymopapain acts by digesting the jelly-like inner portion of the disc known as the nucleus pulposus, while at the same time, leaving the outer portion, the annulus fibrosis, essentially intact.
Adhesiolysis and forceful epidural injection	(not defined)
Coblation® nucleoplasty	A procedure involving the use of a bipolar radiofrequency current in order to create a series of channels in an intervertebral disc and reduce the volume of tissue.
Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)	A procedure involving the placement of an electrode or catheter into the intervertebral disc and applying alternating radiofrequency current. Sometimes classified as a variant of intradiscal electrothermal therapy (IDET).

## Appendix F. List of Peer Reviewers

### Invited: Accepted & Reviewed

**Susan Bamberger, PT, MPT, DIP MDT**

Past President

Oregon Physical Therapy Association

**Roger Chou, MD**

Scientific Director

Oregon Evidence-based Practice Center

Division of General Internal Medicine and Geriatrics

Oregon Health & Science University

**Timothy J. Craven, MD, MPH**

Associate Medical Director

Providence Health Plan MCO

**Rick Deyo, MD, MPH**

Kaiser Permanente Professor of Evidence-Based Family Medicine

Director, KL2 Multidisciplinary Clinical Research Career Development Program

Director, OCTRI Community and Practice-based Research Program

Departments of Family Medicine and Internal Medicine

Oregon Health & Science University

**Marc Gosselin, MD**

Associate Professor

Director, Thoracic Imaging

Department of Diagnostic Radiology

Oregon Health & Science University

**Luci Kovacevic, MD, MPH**

Occupational Medicine Physician

Cascade Medical Associates

**David Pass, MD**

Anesthesiologist

Medical Director

Providence Health Plans

**LaVerne A. Saboe, Jr., DC, DACAN, FICC, DABFP, FACO**

Chiropractic Physician

Past president, Chiropractic Association of Oregon

### Invited: Declined/Did Not Respond/Did Not Review

Fourteen additional reviewers were invited but either declined, did not respond, missed the deadline or did not return the review. Areas of professional expertise for invited reviewers included:

Anesthesiology

Behavioral Health

Complementary and Alternative Medicine

Family Medicine

Internal Medicine

Occupational Medicine

Orthopedic Surgery

Neurosurgery

Pain Advocacy

Pain Medicine

Physical Therapy

Physical Medicine and Rehabilitation

Radiology

Sports Medicine

Worker's Compensation

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DRAFT

## Conflict of Interest Summary

Question: What type of conflict of interest disclosure form should HERC and HERC subcommittee members be required to complete?

Question Source: HERC Staff

Issue: At the April 2012 HERC meeting, there was a discussion about the use of conflict of interest disclosure forms. It was decided to base the HERC COI form on the Washington State Health Technology Assessment COI form.

There was a discussion about the role of having speakers identify their conflicts verbally or in written form, and there was concern that the wording of the form required industry representatives to state their salaries, which was felt to be inappropriate.

There was a discussion about the amount of the monies received, and if less than 10,000 dollars truly represented a conflict or not. It was decided that even small amounts received by industry (including pens and wall clocks) could potentially have an effect. Therefore, the \$10,000 dollar minimum was removed.

There was also concern raised about the role of members as representatives of their organizations and whether their primary workplace should be identified as conflictual, when that was part of the decision to have members serve as public officials. There was a leaning to exclude work in a non-profit as contributing to a conflict of interest. Staff and Center discussions afterwards led to a desire to review this decision, and reconsider if primary employment should be a potential conflict and something that is declared.

Clarification that the conflicts relate to health care goods and services needed to be added into the form.

HERC Staff recommendation:

- 1) Review proposed COI form
- 2) Decide about the primary employer issue



## Health Evidence Review Commission

### CONFLICT OF INTEREST FORM

The Oregon Health Authority asks that you complete this Conflict of Interest form to help us in the decision making process for appointments to the Health Evidence Review Commission or any of its subcommittees.

**If you are selected to serve on the Health Evidence Review Commission or its subcommittees, you will be subject to Conflict of Interest disclosure requirements in ORS Chapter 244 as a public official.**

This form is due on an annual basis, although you should update the form with the HERC Commission within 15 days of a material change in the information provided to the Commission. You may wish to retain a copy of this form.

With regard to healthcare goods and services, a potential conflict of interest is considered as:

1. Receipt or potential receipt of anything of monetary value, including but not limited to, salary or other payments for services such as consulting fees or honoraria.
2. Equity interests such as stocks, stock options or other ownership interests, excluding mutual funds and blinded trusts.
3. Status of position as an officer, board member, trustee, owner or employee of a [for-profit](#) company ([not the primary employer](#)) or company or organization representing a company, association or interest group.
4. Loan or debt interest; or intellectual property rights such as patents, copyrights and royalties from such rights.
5. Manufacturer or industry support of research in which you are participating.
6. Any other relationship that could reasonably be considered a financial, intellectual, or professional conflict of interest.
7. Representation: if representing a person or organization, include the organization's name, purpose, and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).

\_\_\_\_\_  
Your Name (Please Print)

\_\_\_\_\_  
(Date signed)

I have no relationships to disclose.

## Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria		
2.	Equity interests such as stocks, stock options or other ownership interests		
3.	Status of position as an officer, board member, trustee, owner		
4.	Loan or intellectual property rights		
5.	Research funding		
6.	Any other relationship*		

\*6. If yes, Provide Description: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		

7. If yes, Provide Name and Funding Sources: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded. The department will evaluate this justification.

**I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.**

X

\_\_\_\_\_

*Signature*

\_\_\_\_\_

*Date*

\_\_\_\_\_

*Print Name*

**Please return by mail, or email or fax to:**

**Health Evidence Review Commission**

**1225 Ferry Street SE, 1<sup>st</sup> Floor**

**Salem, OR 97301 Phone: 503-3731779; Fax: 503-3785511**

**[HERC.info@state.or.us](mailto:HERC.info@state.or.us)**

## DRAFT – May 21, 2012

### POLICY ON USE OF EXPERTS FOR THE HEALTH EVIDENCE REVIEW COMMISSION AND ITS SUBCOMMITTEES

The HERC and its subcommittees have developed policy to define how clinical experts are utilized in the process of developing clinical guidelines, health technology assessments and coverage guidance documents. Those policies are outlined below:

- Clinical experts will only be utilized at the direction of the HERC or its subcommittees
- Expert testimony will only be sought when there are specific technical questions about how to interpret the evidence or apply the evidence to policy decisions
- Testimony will either be provided in writing in advance of the subcommittee meeting, or, depending on availability and topic, an expert may be asked to attend meetings in person
- The clinical expert must identify all conflicts of interest, and the HERC, its subcommittees or staff may determine that the conflicts are substantial enough that the expert should not be used for this purpose
- Experts recommended by industry may not be utilized because they could be significantly conflicted. These include experts who are employed by industry, serve on industry-sponsored speakers bureaus, conduct training and education for industry, and who have had industry-funded research.

In addition to experts utilized by the HERC for the specific purposes outlined above, HERC welcomes additional expert input in the form of public comment.

- Experts are welcome and encouraged to provide public comment during the public comment process
- All public comment should be provided in writing as directed at:  
<http://www.oregon.gov/OHA/OHPR/HERC/Coverage-Guidance.shtml>
- In addition, experts may provide verbal testimony at the HERC/ Subcommittee public meetings, although public comment time in that setting is limited
- In order to encourage such expert input, HERC will specifically solicit comment from the applicable specialty society, if there is one

## **Health Evidence Review Commission Policy on Acceptance of Testimony and Guidelines for Speakers & Presenters**

The Health Evidence Review Commission (HERC) accepts public comment at each public meeting. Any member of the public or group may provide public comment; however, such comment is limited to 5 minutes per topic regardless of the number of persons wishing to speak to that topic and may be limited to the designated time on the posted agenda. Written comment may be submitted to the Commission or its subcommittees at any time.

HERC may solicit expert testimony on topics of interest to the Commission. When requesting such testimony, HERC staff will inform the expert of the meeting date, the time available for testimony and materials that are needed. [HERC's Policy on use of Experts](#)

The Coverage Guidance input process differs from the policy stated here. Details may be found at: <http://www.oregon.gov/OHA/OHPR/HERC/Coverage-Guidance.shtml>

### **Unsolicited Presentations**

Those who wish to bring topics before the Commission are encouraged to collaborate with HERC staff to optimize presentations and requests resulting in more effective and productive discussions.

- All unsolicited scientific information or evidence must be received by HERC staff at least six weeks in advance of any scheduled meeting. This time frame allows staff to review the submitted material, determine if it meets the criteria for review and allows the appropriate length of time for the agenda item to be listed as part of the Commission's mandatory 30-day public notice window.
- Information received outside six weeks will be considered for the subsequent meeting.
- Request must be approved by HERC staff and the relevant Commission/Subcommittee chair.
- Once approved, a maximum of 10 minutes of agenda time will be allotted for presentation of scientific and evidence-based materials, not including any question and answer period.

HERC strives to utilize the best available evidence in decision-making. The hierarchy of evidence is found in Guidelines for Submitted Materials at <http://www.oregon.gov/OHA/OHPR/HERC/docs/Submitted-Materials.pdf>.

## OREGON HERC CLINICAL EVIDENCE SOURCES

### Sources for Technology Assessments or Guidance

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Agency for Healthcare Research and Quality (AHRQ): Effective Healthcare Program

<http://effectivehealthcare.ahrq.gov/>

AHRQ Evidence Reviews

<http://www.ahrq.gov/clinic/epcix.htm>

AHRQ Health Technology Assessments

<http://www.ahrq.gov/clinic/techix.htm>

Blue Cross Blue Shield (BCBS)

<http://www.bcbs.com/blueresources/tec/tec-assessments.html>

Canadian Agency for Drugs and Technologies in Health (CADTH)

<http://www.cadth.ca/index.php/en/hta/reports-publications/search>

Clinical Evidence (BMJ Publishing Group) (*full text by subscription only*)

<http://clinicalevidence.bmj.com>

Cochrane Library - (*subscription only*) (limit to Database of Systematic Reviews, Database of Abstracts of Reviews of Effects (DARE), HTA Database and NHS Economic Evaluation Database)

<http://www.thecochranelibrary.com>

HAYES Inc. (*subscription only*)

<http://www.hayesinc.com/hayes> or [Log in to the MED Clearinghouse for access](#)

Medicaid Evidence-based Decisions (MED) Project (*proprietary reports available to MED members*)

<http://www.medclearinghouse.org>

National Institute for Health and Clinical Evidence (NICE) (England and Wales)

<http://www.nice.org.uk/>

National Institute for Health Research (NIHR) Health Technology Assessment programme

<http://www.hta.ac.uk/>

Veterans Administration (VA)/Department of Defense (DoD) Evidence-based Synthesis Program

<http://www.hsrd.research.va.gov/publications/esp/>

Veterans Administration (VA)/Department of Defense (DoD) Technology Assessment Program

<http://www.va.gov/VATAP/Phase2pubspage.asp>

Washington Health Technology Assessment Program

<http://www.hta.hca.wa.gov/assessments.html>

## Sources for Guidelines or Guidance

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Australian Government National Health and Medical Research Council (NHMRC)  
<http://www.nhmrc.gov.au/publications/subjects/clinical.htm>

Center for Disease Control and Prevention's Advisory Committee on Immunization Practices  
<http://www.cdc.gov/vaccines/recs/acip/default.htm>

Center for Disease Control and Prevention's Community Preventive Services  
<http://www.thecommunityguide.org/index.html>

Evaluation of Genomic Applications in Practice and Prevention (EGAPP)  
<http://www.egappreviews.org/>

National Institute for Health and Clinical Evidence (NICE) (England and Wales)  
<http://www.nice.org.uk/>

New Zealand Guidelines Group  
[http://www.nzgg.org.nz/index.cfm?fuseaction=fuseaction\\_10](http://www.nzgg.org.nz/index.cfm?fuseaction=fuseaction_10)

Scottish Intercollegiate Guidelines Network (SIGN)  
<http://www.sign.ac.uk/guidelines/index.html>

US Preventive Services Task Force (USPSTF)  
<http://www.ahrq.gov/clinic/uspstfix.htm>

Veterans Administration (VA)/Department of Defense (DoD)  
<http://www.healthquality.va.gov/>

The sources listed below have variable methods, but are searched in the process of developing a new guideline. Not all guidelines found in these sources are guaranteed to use high quality methods, and some will not be appropriate for guidance development.

Institute for Clinical Systems Improvement (ICSI)  
[http://www.icsi.org/guidelines\\_and\\_more/](http://www.icsi.org/guidelines_and_more/)

National Guideline Clearinghouse  
<http://www.guidelines.gov/>

In addition, other clinical evidence and guideline sources may be searched as appropriate to the topic. For example, for guideline development on a cardiology topic, guidelines from the American Heart Association and the American College of Cardiology would be searched.

## Future Potential Topics Identified for Evidence-based Guidelines Subcommittee

TOPIC	REPORTS AVAILABLE	STATUS	PRIORITY
<b>CARDIOVASCULAR</b>			
Screening for CAD in asymptomatic patients	USPSTF 2009	Based on Top 5 Annals of Internal Medicine article (National Physicians Alliance work) (2011)	
Using Nontraditional Risk Factors In Coronary Heart Disease Risk Assessment	USPSTF 2009	Based on Top 5 Annals of Internal Medicine article (National Physicians Alliance work) (2011)	
<b>ENT</b>			
Bilateral cochlear implants in children	MED Report 2011 (Summary needed)	Added at Feb 9, 12 mtg	
Pressure equalization tubes in children	MED Report 2010 (Summary needed)	Added at Feb 9, 12 mtg	
Adenotonsillectomy for OSA in children	Cochrane 2011	Added at Feb 9, 12 mtg	
<b>GYNAECOLOGY</b>			
Urinary incontinence (female)	AHRQ Report 2012	Added at Feb 9, 12 mtg	
<b>IMAGING</b>			
Advanced imaging for cardiac disease	NICE CT Scan Report 2012 WA HTA Calcium Scoring Report 2009 Need additional sources	Added at Feb 9, 12 mtg	
Coronary computed tomographic angiography	MED Report 2011 (Summary needed)	Added at Feb 9, 12 mtg	
<b>ONCOLOGY</b>			
Oncotype dx assay	MED Report 2011 (Summary needed)	Added at Feb 9, 12 mtg	
Prophylactic mastectomy	MED Report 2010 (Summary needed)	Added at Feb 9, 12 mtg	
Pap tests for <21 or s/p hysterectomy for benign disease	ACOG (for age), USPSTF 2012 (for hysterectomy)	Based on Top 5 Annals of Internal Medicine article (National Physicians Alliance work) (2011)	
<b>ORAL HEALTH</b>			
Carries Risk Assessment and Topical Flouride Application in Primary Care Settings	MED Report 2009 (Summary needed)	Added at Feb 9, 12 mtg	

Dental Radiographs for diagnosing caries	MED Report 2009 (Summary needed)	Added at Feb 9, 12 mtg	
Early childhood caried Treatment: Stainless Steel Crowns vs Other	MED Report 2010 (Summary needed)	Added at Feb 9, 12 mtg	
Sedation vs Anaesthesia for Pediatric Dental Care	MED Report 2009 (Summary needed)	Added at Feb 9, 12 mtg	
Topical Flouride for Prevention of Caries in Children and Adolescents	MED Report 2009 (Summary needed)	Added at Feb 9, 12 mtg	
<b>MISCELLANEOUS</b>			
Botulinum toxin type A for chronic migraine prophylaxis	MED Report 2011 (Summary needed)	Added at Feb 9, 12 mtg	
Diagnosis of sleep apnea in children	MED Report 2011 (Summary needed)	Added at Feb 9, 12 mtg	
Laser based treatment of venous disease	AHRQ draft report	Added at Feb 9, 12 mtg	Low
Hospital-level Home-based Care Services	MED Report 2012 (Summary needed)	Recent MED Report	
Screening lab work in asymptomatic pts (BMP and urinalysis)	Cited as USPSTF, confirmation pending	Based on Top 5 Annals of Internal Medicine article (National Physicians Alliance work) (2011)	

## Future Potential Topics Identified for Health Technology Assessment Subcommittee

TOPIC	REPORTS AVAILABLE	STATUS	PRIORITY
Upper endoscopy (indications:GERD and Dyspepsia)	WA HTA Report 2012	Added at Feb 9, 12 mtg	
Functional electrical stimulators for spinal cord and head injury, CP and upper motor neuron diseases	MED Report 2010 (Summary needed)	Added at Feb 9, 12 mtg	
Insulin pumps vs multiple daily injections for Type 1 and Type 2 diabetes	MED Report 2009 (Summary needed)	Added at Feb 9, 12 mtg	
Left ventricular assist devices (LVAD)	MED Report 2010 (Summary needed)	Added at Feb 9, 12 mtg	
New radiation therapies for non-intercranial malignancies	MED Report 2011 (Summary needed)	Added at Feb 9, 12 mtg	
	WA HTA: IMRT (Fall 2012) WA HTA: SRS & SBRT (Fall 2012)		
Spinal cord stimulators for chronic pain	<a href="#">NICE HTA Report 2009</a>	Added at Feb 9, 12 mtg	

<b>Vacuum wound closure (negative pressure wound therapy)</b>	AHRQ Report 2009 <a href="#">HRC Report</a>	Added at Feb 9, 12 mtg	
<b>Carotid endarterectomy versus medical management</b>	Cochrane Report 2011	At suggestion of ICD-10 neurology consultant	
<b>Non-surgical Treatment of sleep apnea in children; compared to surgical treatment</b>	On hold due to lack of identified sources	Added at Feb 9, 12 mtg	
<b>DEXA screening for women &lt;65 or men &lt;75 without risk factors</b>	NOF, USPSTF, AACE, ACPM	Based on Top 5 Annals of Internal Medicine article (National Physicians Alliance work) (2011)	
<b>Cough and cold medicines for children</b>	AAP, Cochrane, FDA	Based on Top 5 Annals of Internal Medicine article (National Physicians Alliance work) (2011)	
<b>Antibiotics for sinusitis</b>	Cochrane and Ann IM BMJ 2011 - Sinusitis (acute)	Based on Top 5 Annals of Internal Medicine article (National Physicians Alliance work) (2011)	
<b>Referral for otitis media with effusion</b>	AAP/AAFP Guidelines, NICE	Based on Top 5 Annals of Internal Medicine article (National Physicians Alliance work) (2011)	
<b>Antibiotics for pharyngitis</b>	AHRQ, Cochrane, EE	Based on Top 5 Annals of Internal Medicine article (National Physicians Alliance work) (2011)	
<b>Cost Effectiveness of Bariatric Surgery</b>	MED Report 2012 (Summary needed)	Recent MED Report	
<b>Microarray Genetic Testing for Children with Neurodevelopmental Disabilities</b>	MED Report 2012 (Summary needed)	Recent MED Report	
<b>Robotic surgery</b>	WA HTA Report 2012	Recent WA HTA Report	
<b>Prenatal genetic testing</b>	Source TBD	Suggested by OHP Medical Directors	

## Topics for Development by Evidence-based Guidelines Subcommittee

### GUIDELINE TOPICS COMPLETED

TOPIC	STATUS	REPORTS AVAILABLE	HERC APPROVAL	PRIORITY
Evaluation and Management of Low Back Pain	Completed	<a href="#">HERC Guideline</a>	Approved 1/12/12	
Advanced Imaging for Low Back Pain	Completed	<a href="#">HERC Guideline</a>	Approved 4/12/12	

### COVERAGE GUIDANCES COMPLETED

TOPIC	STATUS	REPORTS AVAILABLE	HERC APPROVAL	PRIORITY

### COVERAGE GUIDANCES CURRENTLY UNDER DEVELOPMENT BY EVIDENCE-BASED GUIDELINES SUBCOMMITTEE

TOPIC	STATUS	REPORTS AVAILABLE	For HERC Review	PRIORITY
Arthroscopic surgery of the knee for Osteoarthritis	30 day public comment period April 23- May 22, 2012	MED Report (Summary needed) <a href="#">WA HTA</a>	June 14, 2012	<i>High</i>
Low Back Pain: Non-Pharmacologic/Non-Invasive Interventions	30 day public comment period completed April 4, 2012	<a href="#">HERC Guideline</a>	August 9, 2012	
Low Back Pain: Pharmacologic Interventions	30 day public comment period completed April 4, 2012; To P&T Committee for comment May 24, 2012	<a href="#">HERC Guideline</a>	October 11, 2012	
Indications for Planned Cesarean Section	30 day public comment period April 24- May 14, 2012	<a href="#">Public MED</a>	August 9, 2012	<i>High</i>
Elective Induction of Labor	30 day public comment period April 23- May 22, 2012	<a href="#">Public MED</a>	June 14, 2012	<i>High</i>
Femoracetabular impingement (FAI) syndrome surgery	30 day public comment period April 23- May 22, 2012	<a href="#">WA HTA</a>	August 9, 2012	<i>High</i>
Ultrasound in Low Risk Pregnancy	30 day public comment period April 23- May 22, 2012	<a href="#">WA HTA</a>	June 14, 2012	<i>High</i>
Nonpharmacologic interventions for treatment resistant depression (including vagus nerve stimulation, electroconvulsive therapy, and repetitive transcranial magnetic stimulation)	Review at EbGS meeting on June 7, 2012	<a href="#">AHRQ</a>	October 11, 2012	<i>High (CBT)</i>
Diagnosis and treatment of pediatric ADHD	30 day public comment period May 5- June 9, 2012	MED (Summary needed) <a href="#">AHRQ</a>	August 9, 2012	<i>Low</i>
Advanced imaging for Low Back Pain	30 day public comment period May 5- June 9, 2012	<a href="#">HERC Guideline</a>	October 11, 2012	
Percutaneous interventions for low back pain	Review at EbGS meeting on June 7, 2012	<a href="#">HERC Guideline</a>	October 11, 2012	
Imaging in dementia	Review at EbGS meeting on June 7, 2012	MED (Summary needed)	October 11, 2012	
Red Flags and imaging in headache	Review at EbGS meeting on June 7, 2012	MED (Summary needed)	October 11, 2012	

## Topics for Development by Health Technology Assessment Subcommittee

### COVERAGE GUIDANCES COMPLETED

TOPIC	STATUS	REPORTS AVAILABLE	HERC APPROVAL	PRIORITY

### COVERAGE GUIDANCES CURRENTLY UNDER DEVELOPMENT BY HEALTH TECHNOLOGY ASSESSMENT SUBCOMMITTEE

TOPIC	STATUS	REPORTS AVAILABLE	For HERC Review	PRIORITY
<b>MRIs for Breast Cancer Screening</b>	30 Public Comment period April 3 - May 2, 2012	<a href="#">WA HTA</a>	June 14, 2012	<i>High</i>
<b>Discography</b>	30 Public Comment period May 1-May 30, 2012	<a href="#">WA HTA</a>	August 9, 2012	<i>High</i>
<b>Hip Resurfacing</b>	30 Public Comment period May 1-May 30, 2012	<a href="#">WA HTA</a>	August 9, 2012	<i>High</i>
<b>Vertebroplasty, Kyphoplasty and Sacroplasty</b>	30 Public Comment period May 1-May 30, 2012	<a href="#">WA HTA</a>	August 9, 2012	<i>High</i>
<b>Artificial Disc Replacement</b>	30 Public Comment period May 1-May 30, 2012	<a href="#">WA HTA</a>	August 9, 2012	<i>Medium</i>
<b>Self Monitoring of Blood Glucose, Type 1 &amp; 2 Diabetes</b>	Review at HTAS June 25, 2012 meeting	MED Report (Summary needed)	October 11, 2012	<i>High</i>
<b>Real Time Continuous Blood Glucose Monitoring, Type 1 Diabetes</b>	Review at HTAS June 25, 2012 meeting	Cochrane Report (Summary needed)	October 11, 2012	<i>Medium</i>
<b>Real Time Continuous Blood Glucose Monitoring, Type 2 Diabetes</b>	Review at HTAS November 26, 2012 meeting	Cochrane Report (Summary needed)	March 14, 2013	<i>Medium</i>
<b>Diagnosis of sleep apnea in adults</b>	Review at HTAS May 21, 2012 meeting	<a href="#">AHRQ report</a> <a href="#">WA HTA</a>	October 11, 2012	<i>Medium</i>
<b>Treatment of sleep apnea in adults</b>	Review at HTAS May 21, 2012 meeting	<a href="#">AHRQ report</a> <a href="#">WA HTA</a>	October 11, 2012	<i>Medium</i>
<b>Viscosupplementation for osteoarthritis of the knee</b>	Review at HTAS May 21, 2012 meeting	<a href="#">Public MED Report (needs updating)</a> <a href="#">WA HTA</a>	October 11, 2012	<i>Medium</i>
<b>Vagus nerve stimulators for epilepsy</b>	Review at HTAS September 24, 2012 meeting	<a href="#">Public MED Report</a> <a href="#">WA HTA</a>	December 13, 2012	<i>Medium</i>
<b>Bone growth stimulators</b>	Review at HTAS September 24, 2012 meeting	<a href="#">Public MED Report</a> <a href="#">WA HTA</a>	December 13, 2012	<i>Low</i>
<b>PET Scan for Cancer</b>	Review at HTAS on September 24, 2012 meeting	MED Report (Summary needed) <a href="#">WA HTA</a>	December 13, 2012	<i>Medium</i>