



# **Health Evidence Review Commission**

**January 10, 2013**

**Meridian Park Hospital  
Community Health Education Center, Room 117B&C  
19300 SW 65th Avenue, Tualatin, OR 97062**



## AGENDA

### HEALTH EVIDENCE REVIEW COMMISSION

Meridian Park Room 117

January 10, 2013

1:30-4:30 pm

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

#	Time	Item	Presenter	Action Item
1	1:30 PM	Call to Order	Alissa Craft	
2	1:35 PM	Approval of Minutes ( 10/11/12)	Alissa Craft	X
3	1:40 PM	Director's Report	Darren Coffman	
4	1:50 PM	Value-based Benefits Subcommittee Report <ul style="list-style-type: none"> <li>• Approval of April 1, 2013 Prioritized List</li> </ul>	Lisa Dodson Ariel Smits Cat Livingston	X
5	2:15 PM	HERC Rule on Evidence-based Report Development	Darren Coffman Alissa Craft Wiley Chan	
6	2:45 PM	Coverage Guidance Process <ul style="list-style-type: none"> <li>• Public input</li> </ul>	Cat Livingston Alissa Craft Darren Coffman	X
7	3:45 PM	Health Technology Assessment Subcommittee Report <ul style="list-style-type: none"> <li>• Brief account of completion of VKS</li> </ul>	Alissa Craft Wally Shaffer Alison Little	
8	3:55 PM	Evidence-based Guidelines Subcommittee Report	Wiley Chan Cat Livingston Alison Little	
9	4:10 PM	Current and Future Topics	Cat Livingston	
10	4:15 PM	Next Steps <ul style="list-style-type: none"> <li>• Schedule next meeting – March 14, 2013 Meridian Park Room 117 B&amp;C</li> </ul>	Alissa Craft	
11	4:20 PM	Public Comment		
12	4:30 PM	Adjournment	Alissa Craft	

## Minutes

HEALTH EVIDENCE REVIEW COMMISSION  
Meridian Park Hospital  
Community Health Education Center Room 117B&C  
Tualatin, OR 97062  
October 11, 2012

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**Members Present:** Alissa Craft, DO, MBA, Vice-Chair (Chair Pro-tem); Lisa Dodson, MD; James Tyack, DMD; Beth Westbrook, PsyD; Leda Garside, RN; Kathryn Weit; Mark Gibson; Wiley Chan, MD; Vern Saboe, DC; Irene Crosswell, RPH; Gerald Ahmann, MD.

**Members Absent:** Som Saha, MD, MPH, Chair.

**Staff Present:** Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Wally Shaffer, MD; Jason Gingerich; Dorothy Allen.

**Also Attending:** Denise Taray, DMAP; Alison Little, MD, MPH, Shannon Vandegriff, and Heidi Kriz, OHSU CeBP; Joanie Cosgrove, Medtronic; Neal Mills, MD, MBA, ODS Health; Peter Heeckt, MD, Vinod Dasa, MD\*, Shirley Berens\*, Abby Anderson and Colin McMiller, Bioventus; Margaret Eastman\*, Sanofi; Sean Gallah, Ed Troll and David Dahdal\*, Ferring; Raymond North, MD\*; Doug Doglass, MD\*; Russ Riggs, MD\*, Reflex Clinic; Chris Kirk, MD, OHP Medical Directors; Ann Demaree, RN; Ellen Lowe, OAHHS.

*\*Indicated interest in giving public testimony*

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### Call to Order

Alissa Craft, Vice-Chair of the Health Evidence Review Commission (HERC), called the meeting to order. Role was called.

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### Approval of Minutes

**MOTION: To approve the minutes of the August 9, 2012 meeting as presented.**  
**CARRIES 11-0.**

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### Director's Report

#### *Staff addition and recognition*

Ariel Smits was recognized as having achieved 5-years of state service. Jason Gingerich was welcomed back to the staff, this time as a policy analyst. Darren Coffman clarified his new role.

#### *Meeting time amended*

A few months ago, the meeting time was pushed forward an hour, causing some issue for members who travel longer distances. Coffman suggested changing it to 1:30-4:30 pm to see if that would provide relief. Others indicated a potential problem with the time change. The members agreed to try the new start time for the next meeting.

### *Subcommittee membership*

Dr. Susan Williams, an orthopedic surgeon from Roseburg, was nominated and accepted as a subcommittee member for VbBS. Coffman noted Dr. Ed Toggart has resigned from HTAS and Dr. Timothy Keenen (previously appointed) now has a schedule that allows him to participate.

### *Rules Advisory Committee*

Coffman gave an update on the development of administrative rules. There is a requirement to convene a Rules Advisory Committee consisting of representatives who are impacted by our process including members from subcommittees, industry, advocacy associations, key stakeholders, etc.

This process will help ensure policy consistencies on reviewed topics, revision schedules, and public comment issues. This process will also define when and how additional expertise outside of seated subcommittee members is incorporated.

HERC leadership will coordinate with staff to manage membership and hope to convene a meeting in mid-November of approximately 3 hours. Dr. Chan expressed interest in participating.

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## **Policies**

### *Coverage Recommendations Algorithm & Guidance Development Framework Principles* [Handout](#)

Livingston explained how the algorithm was developed and the intended use when vetting evidence for guidelines and coverage guidance topics. It helps answer the question of what to do when there are different levels of evidence among the trusted sources.

There has been feedback from OHP Medical Directors who expressed they are looking to this body to make the hard decisions on coverage guidance issues. Accordingly, EbGS nuanced the algorithm to minimize areas of indecisiveness. This is seen to be a working document.

Livingston mentioned an area in need of clarification is to define what is meant by the statement "Treatment is prevalent."

Members agreed this is a useful working document; they would like additional discussion and time to digest the information.

OHP Medical Directors have expressed an interest in this Commission making coverage recommendations on topics where there more controversy. Dr. Chan stated his opinion that doing so would take a full guideline development team to manage. Coffman mentioned HERC budget currently has funding for two evidence-based guideline reviews and two health technology reviews per year.

Considering the new framework, Livingston shared the EbGS members felt a different decision might have been made for coverage guidance of Femoroacetabular Impingement Syndrome Surgery ([page 17](#)), which was previously tabled. The new algorithm does not allow for tabling a subject. OHP Medical Directors have asked for direction. Should this topic move back to subcommittee for further review?

**MOTION: Return FIA to EbGS for further review. CARRIES: 11-0.**

*Public Testimony and Materials Submission*

Criteria for Topic Review on the Placement of Services on the Prioritized List for the Health Evidence Review Commission ([page 24](#)): Additional language recommended (in blue) amending the criteria for rare clinical conditions.

**MOTION: To adopt the proposed topic review policy as written. Carries 11-0.**

Health Evidence Review Commission Policy on Acceptance of Testimony and Guidelines for Speakers & Presenters ([page 26](#)):

Additional language recommended (in red) to guide public comment received 7-days prior to a meeting. This is related to the HERC Coverage Guidance Process policy ([page 27-28](#)): Additional language recommended (in red) in response to coverage guidance public comments submitted outside the 30-day public comment window. Gibson expressed concern about public comment forwarded to members the week before the meeting and wonders if some might see that as an advantage, where staff cannot review and analyze those comments. He would like to see individuals attend meetings to give oral testimony. Members discussed only accepting written comments during the 30-day public comment period. Staff will work with leadership to wordsmith and bring back for review in January.

**MOTION: To return the proposed policies for additional staff work. Carries 11-0.**

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**Subcommittee Reports**

Value-based Benefits Subcommittee (VbBS) Report (HERC meeting materials [pages 31-98](#))

Ariel Smits, Cat Livingston and Lisa Dodson reported the VbBS had met earlier in the day, October 11<sup>th</sup>. Each helped to summarize a number of topics discussed.

Recommendations for interim changes were reviewed, adjusting the Prioritized List into compliance with the previously HERC-approved coverage guidances on the following topics ([pages 72-90](#)) (Full text can be found in the [10/11/12 VbBS minutes, Attachment B](#)):

- Artificial Disc Replacement to be included as an alternative to fusion when certain criteria are met
- Non-Pharmacologic Interventions For Treatment-Resistant Depression
  - Discussion to disambiguate language, ensuring “anti-depressant” is used rather than “pharmacologic” treatments
  - Add repetitive transcranial magnetic stimulation and electroconvulsive therapy options only after failure of at least two antidepressants
- Neuroimaging In Dementia: new guideline added to include neuroimaging only for ruling out reversible causes of dementia
- Advanced Imaging For Low Back Pain (incorporated into existing Diagnostic Guideline D4): limits advanced imaging to only patients with certain red-flag conditions

- Elective Induction of Labor (incorporated into existing Guideline Note 85): clarified noncoverage of elective induction of labor prior to 41 weeks except in certain cases such as maternal diabetes, prelabor rupture of membranes, etc

**MOTION: To accept the VbBS recommendations as stated to adjust the Prioritized list to incorporate the five coverage guidances presented to be effective 4/1/13. Carries: 11-0.**

*Additional review:*

Neuroimaging for Headache coverage guidance is currently HERC-approved; some red-flag features might lead to inappropriate imaging. Staff recommends returning this coverage guidance to subcommittee for additional review.

**MOTION: To return Neuroimaging for Headache coverage guidance to EbGS for additional review. CARRIES: 11-0.**

VbBS recommendations for other interim changes, effective 4/1/13 include:

- Coding recommendations:
  - Add codes for peripheral neuropathies to covered nerve disorder lines
  - Add spinal arthrodesis codes to lines that had some, but not all, of the spinal arthrodesis codes
  - Add acupuncture and cognitive behavioral therapy to the low back pain lines and delete spinal traction coverage
  - Add artificial disc replacement codes to the covered and the uncovered spinal conditions lines
  - Recommend DMAP add electromyography to the Diagnostic List
  - Add transcranial magnetic stimulation coverage to the major depression line
  - Add procedures for the treatment of congenital dislocation of the hip
- Guideline notes recommendations:
  - Guideline Note 7, Erythropoiesis-Stimulating Agent (ESA) – Amend to require reassessment of ESA use at 12 rather than 8 weeks of therapy for patients with renal insufficiency.
  - Guideline Note 37, Disorders of Spine With Neurologic Impairment – Clarify the definition of radiculopathy, edit lines/diagnoses.
  - Guideline Note 47, Urinary Incontinence – Modify to remove electrical stimulation as a possible modality as a requirement to be tried prior to surgery.
  - Guideline Note 92, Acupuncture – Revise to allow coverage for low back pain for 12 visits and for tension headache.
  - New Guideline Note 100, Smoking and Spinal Fusion – This guideline allows coverage of non-emergent spinal fusion only for non-smoking patients.
    - Brief discussion of discrimination to smokers; though smoking cessation is covered; this guideline is for non-emergent conditions only. Smits notes this language has been reviewed by several area spine surgeons.
    - Public comment from Dr. Vinod Dasa, a Louisiana State University Health Sciences Center orthopedic surgeon (total joint) with no declared conflicts: He expressed concern that this proposed guideline moves the decision making away from the surgeon. Another point to consider is the development of technology to augment fusion which may make exclusion

for smoking obsolete. He urged caution about making blanket statements which limit a physician's ability to care appropriately for their patient.

Recommendations for the biennial list (10/1/14) include ([pages 90-96](#)):

- ICD-10-CM conversion recommendations:
  - Add codes for foreign body in GI tract to a covered line with a guideline specifying when these codes are on the covered line and when on the uncovered lines
  - Add albinism codes to the precancerous skin condition line; add oculocutaneous albinism codes to an ophthalmology line

**MOTION: To accept the other coding and guideline VbBS recommendations as stated. See the [VbBS minutes of 10/11/12](#) for a full description. Carries: 11-0.**

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

Wally Shaffer explained there is one coverage guidance from this subcommittee being proposed today (overview in the meeting materials on [pages 104-107](#)).

#### *HTAS Coverage Guidance Recommendation:*

- **Viscosupplementation for Osteoarthritis of the Knee ([page 108](#))**

The 30-day public comment period on the draft guideline closed May 30, 2012. Public comments were received and considered. This technology is an injection therapy for knee arthritis. The intent of this technology is to find a treatment that is between conservative care (with anti-inflammatory medications) and knee replacement surgery. There is an extensive body of evidence that shows effectiveness is marginal.

Several individuals representing patients, providers and product manufacturers gave public comment, all in supported of coverage for this procedure. Commission members discussed these comments but also mentioned most patients see no benefit or experience harm from these procedures, and that the evidence considered shows a benefit which may not be clinically significant.

Public comments (see \* above for individuals who provided comments) focused on several areas:

- Personal testimonies from physicians and patients with reports of successful viscosupplementation treatment urge coverage of the procedure.
- Testimony raising concerns about the quality of the evidence used in the noncoverage determination. Concerns included inclusion of inappropriately selected patients in the studies, known as selection bias.
- Testimony that analgesics are insufficient or contraindicated for some patients. Steroids have adverse effects. The only other alternative is knee replacement, which is more expensive and more invasive.
- Testimonies observing other similar bodies and other payers have decided to cover the procedure.

**MOTION: To approve the report of the Health Technology Assessment Subcommittee including the coverage guidance on viscosupplementation. Carries 11-0.**

## Approved Coverage Guidance:

### [HERC COVERAGE GUIDANCE](#)

Viscosupplementation should not be covered for the treatment of pain associated with Osteoarthritis (OA) of the knee.

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

Wiley Chan, EbGS Chair, and Livingston explained there are two coverage guidances being proposed today (overview of the two available in the meeting materials on [pages 131-139](#)).

- **Percutaneous Interventions for Low Back Pain** ([page 140](#))

The 30-day public comment period on the draft guideline closed September 7, 2012.

Epidural steroid injection is a minimally invasive procedure employed to relieve neck, arm, back, and leg pain caused by inflamed spinal nerves and herniated discs.

For radiculopathy due to herniated lumbar disc, evidence on benefits of epidural steroid injection is mixed, with some trials finding moderate short-term benefits and others finding no differences. There is no convincing evidence that epidural steroids are associated with long-term benefits and most trials found no reduction in rates of subsequent surgery.

For nonradicular low back pain, there is no convincing evidence that show steroid injections or other interventional therapies to be effective. There is consistent evidence that facet joint steroid injection, prolotherapy and intradiscal steroid injections are no more effective than sham therapies.

- **Management of Chronic Otitis Media with Effusion in Children** ([page 155](#))

The 30-day public comment period on the draft guideline closed September 7, 2012.

This coverage guidance recommendation is for a procedure where a small plastic or metal tube is placed within the tympanic membrane to equalize the pressure behind the eardrum and to allow for adequate drainage of any fluid within the middle ear space (effusion).

The evidence shows a likely decrease in duration of middle ear effusion that provides a short-term improvement in hearing that dissipates by 12 months. There are no clear risk factors that identify children who should have PE (pressure-equalization) tubes placed. Watchful waiting for 3 to 6 months is an appropriate initial step in the management of OME. There is no evidence that antihistamines, decongestants or nasal steroids are effective treatments.

Also considered was adenoidectomy, which may improve middle ear effusions at six months but does not lead to significant improvements in hearing or in recurrent acute otitis media. Autoinflation may have some benefits in terms of resolution of effusion,

while oral steroids and antibiotics show short-term benefit but longer term improvement is either not sustained or is uncertain.

Livingston shared some discussion the EbGS members had over the wording change from “should” to “may” be covered; they questioned if that ambiguity could lead to increased confusion and testing. Given the OHP Medical Director’s recent request for more solid guidance, Dodson wondered if the perceived ambiguity in this guidance might present an issue. Coffman responded medial directors have reviewed the language proposed and found it acceptable. Members agree the wording change is intended to help guide health plans when making a decision for individual coverage.

**MOTION: To accept the report of the Evidence-based Guidelines Subcommittee, including the recommended coverage guidances on percutaneous interventions for low back pain and the management of chronic otitis media in children. Carries 11-0.**

### Approved Coverage Guidances

#### HERC COVERAGE GUIDANCE

For radicular low back pain, Epidural steroid injections should be covered for patients with persistent radiculopathy due to herniated lumbar disc; 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. If an epidural steroid injection does not offer benefit, repeated injections should not be covered.

Epidural steroid injections should NOT be covered for central spinal canal stenosis.

For radicular low back pain, the following treatments should NOT be covered:

- coblation nucleoplasty
- radiofrequency denervation

For nonradicular low back pain, the following treatments should NOT be covered:

- facet joint corticosteroid injection
- prolotherapy
- intradiscal corticosteroid injection
- local injections (including trigger point injections)
- botulinum toxin injection
- epidural steroid injection
- intradiscal electrothermal therapy (IDET)
- medial branch block
- radiofrequency denervation
- sacroiliac joint steroid injection
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation

## HERC COVERAGE GUIDANCE

Antibiotic and other medication therapy (including antihistamines, decongestants, and nasal steroids) should not be covered for children with otitis media with effusion (OME) (without another appropriate diagnosis).

There should be a 3 to 6 month watchful waiting period after diagnosis of otitis media with effusion, and if documented persistent hearing loss is greater than or equal to 25dB in the better hearing ear, referral for tympanostomy surgery may be covered, given short, but not long-term, improvement in hearing.

Formal audiometry should be covered for children with chronic OME present for 3 months or longer. Children with language delay, learning problems, or significant hearing loss should have hearing testing covered initially upon diagnosis. Children with chronic OME who are not at risk for language or developmental delay should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

Adenoidectomy should not be covered at the time of the first pressure equalization tube insertion.

Patients with craniofacial anomalies, Down's syndrome, cleft palate, and patients with speech and language delay along with hearing loss should have coverage based on an individualized treatment plan.

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### **Coverage Guidance Discussion**

Additional discussion centered on what type of coverage guidance recommendations HERC expects from EbGS and HTAS. Some options:

- Strictly about the evidence
- Reflect coverage for a baseline benefits package
- Something else

Chan said he has observed there usually are graded recommendations; a weak recommendation would state "may" while a strong recommendation, one that most individuals would want/need and provide good outcome and performance metrics, would employ phrases like "should" or "must." Perhaps weak recommendations should be excluded under basic benefit packages.

Craft and others expressed concern about how a guidance of "may" would be implemented.

Shaffer shared, in OHP there are three factors for decision making, in order of importance:

- Where does the condition fall on the Prioritized List, above or below the funding line?
- Does the condition pair with the treatment?
- Are there guideline notes?

Coffman noted the phrasing "may" could be seen as useful for VbBS, as the Legislature determines coverage while HERC (through VbBS) determines priority. Stronger language could be seen as a mandate for coverage.

Kirk commented it could be employed to determine levels of cost-sharing in a commercial plan/value based benefit design. Westbrook contended the phrasing could lead to appropriate physician-patient decision-making. Livingston suggested creating a value judgment of marginal benefit which could also drive cost-sharing. Dodson felt we should determine whether the treatment/technology is effective enough in the aggregate that we should devote resources to it.

Members agree it makes sense to have subcommittees answer key questions that are up for interpretation. Coffman suggested a “consumer reports” type of visual layout of the criteria.

**MOTION: To have staff and HERC leadership review the methodology by which EbGS and HTAS submit reports to HERC for consideration and attempt to place them into a more formulaic methodology. CARRIES: 11-0.**

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### Trusted Sources List ([pages 165-190](#))

Livingston reviewed two potential additions to the Commission’s list of trusted sources:

- Institute for Clinical and Economic Review (ICER) ([pages 169-182](#))
  - Reviews look predominantly at cost effectiveness
  - Potential for unique information
  - Trusted vendor for the Washington HTA program (current trusted source)
  - Receive funding from and have an advisory board that includes industry
    - Have well developed policies on the role of the advisory board
- Choosing Wisely® ([pages 183-188](#))
  - National campaign started by the American Board of Internal Medicine
  - Charged specialty societies to self-identify 5 tests or procedures commonly used in their field, whose necessity should be questioned and discussed
  - Part of a multi-year effort to help physicians be better stewards of finite health care resources

Chan expressed unease at naming Choosing Wisely® a “trusted” source, because of the selection methodology. Livingston stated it may be used when no other source is available— noting the quality (or lack) of evidence. The information is useful but it would not be regarded as *good evidence* in all cases.

Coffman suggested we might include in under the section currently dedicated to guidelines where sources employ variable methods, though the language would need to be nuanced.

**MOTION: To accept Institute for Clinical and Economic Review (ICER) as a trusted source. CARRIES: 11-0.**

**MOTION: To accept Choosing Wisely® as a source with variable methods which is searched in the process of developing guidelines/coverage guidances/health technology assessments and topics for consideration. CARRIES: 11-0.**

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## **Prioritization Review and Next Topics**

Given the discussion on coverage guidance today (and the formation of an ad hoc group to discuss the direction), EbGS and HTAS should continue to meet but refrain from developing any final guidance recommendations.

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## **Public Comment**

There was no further public comment at this time.

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## **Adjournment**

Meeting was adjourned at 5:07 pm. Next meeting will be from 1:30-4:30 pm on Thursday, January 10, 2013 at the Meridian Park Hospital Health Education Center in Conf. Room 117 B&C.

DRAFT

# **Value-based Benefit Subcommittee Report**

**Value-based Benefits Subcommittee Recommendations Summary  
For Presentation to:  
Health Evidence Review Commission on October 11, 2012**

*For specific coding recommendations and guideline wording, please see the text of the  
(10/11/12) VbBS minutes.*

**CODE MOVEMENT**

- Spinal arthrodesis codes were added to lines that had some, but not all, of the spinal arthrodesis codes
- Acupuncture and cognitive behavioral therapy were added to the low back pain lines
- Spinal traction was removed from the low back pain lines
- Artificial disc replacement was added to the covered and the uncovered spinal conditions lines
- Electromyography was recommended to be moved from the Ancillary to the Diagnostic List
- Transcranial magnetic stimulation was added to the major depression line
- A series of straightforward code changes were accepted
- Injections into the labyrinth were added for treatment of Meniere's disease
- Several procedures were added for the treatment of congenital dislocation of the hip

**ITEMS CONSIDERED BUT NO CHANGES MADE**

- An unspecified ICD-9 code for toe walking was considered for movement from an uncovered line to a covered dysfunction line; however, a more specific code for tendon contractures was found to pair with the desired treatment and was felt to represent more appropriate coding
- A guideline for neuroimaging in headache was considered, but will be revisited in December

**GUIDELINE CHANGES**

A series of guidelines were revised to ensure consistency between the Prioritized List and HERC-approved coverage guidances

- DIAGNOSTIC GUIDELINE D4, ADVANCED IMAGING FOR LOW BACK PAIN was changed to include the imaging recommendation table included in the HERC low back pain evidence-based guideline
- GUIDELINE NOTE 85, ELECTIVE INDUCTION OF LABOR. The Guideline Note was clarified to indicate that elective induction of labor is not covered for elective induction of labor prior to 41 weeks except in the cases of maternal diabetes, prelabor rupture of membranes, or other medical or obstetrical indications.

Other guideline notes were revised:

- GUIDELINE NOTE 7, ERYTHROPOIESIS-STIMULATING AGENT (ESA) GUIDELINE. The Guideline Note was changed to require reassessment of ESA use at 12 rather than 8 weeks of therapy for patients with renal insufficiency.

- GUIDELINE NOTE 37 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT was modified to clarify the definition of radiculopathy and which lines contained which diagnoses
- GUIDELINE NOTE 47, URINARY INCONTINENCE. The Guideline Note was modified to not include electrical stimulation as a possible modality that could be required to be tried prior to surgery.
- GUIDELINE NOTE 92, ACUPUNCTURE was revised to allow coverage for low back pain for 12 visits and for tension headache

New guidelines were adopted:

- GUIDELINE NOTE XXX, SMOKING AND SPINAL FUSION. This guideline allows coverage of spinal fusion only for non-smoking patients.
- GUIDELINE NOTE XXX, FOREIGN BODIES IN THE GI TRACT was adopted to specify that hazardous foreign bodies would be covered on a higher line, nonhazardous bodies on a lower line

A series of new guidelines were adopted to ensure consistency between the Prioritized List and HERC-approved coverage guidances

- GUIDELINE NOTE XXX, ARTIFICIAL DISC REPLACEMENT was adopted which details when artificial disc replacement would potentially be covered.
- GUIDELINE NOTE XXX, NON-PHARMACOLOGIC INTERVENTIONS FOR TREATMENT-RESISTANT DEPRESSION was adopted to require trials of two antidepressant medications prior to ECT or repetitive transcranial magnetic stimulation
- DIAGNOSTIC GUIDELINE XXX, NEUROIMAGING IN DEMENTIA was adopted specifying when neuroimaging is covered for the work up of dementia

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

- Various ICD-10 codes for peripheral neuropathies were moved from an uncovered sprain/strain line to covered nerve disorder lines
- Foreign body codes were added to a covered line with a guideline specifying when these codes are on the upper covered and when on the lowered uncovered lines
- Albinism codes were added to the precancerous skin condition line; certain albinism codes involving conditions of the eyes were also added to an ophthalmology line

**VALUE-BASED BENEFITS SUBCOMMITTEE**  
**Meridian Park Health Education Center**  
**October 11, 2012**  
**8:30 AM – 1:30 PM**

**Members Present:** Lisa Dodson, MD, Chair; Kevin Olson, MD, Vice-chair; Chris Kirk, MD; James Tyack, DMD; Mark Gibson; Laura Ocker, Lac; David Pollack, MD; Irene Crowell, RPh (by phone)

**Members Absent:** None

**Staff Present:** Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Jason Gingerich; Dorothy Allen

**Also Attending:** Denise Taray (DMAP); Kathy Kirk, Oregon Pain Management Commission

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

The meeting was called to order at 8:30 am and roll was called. Minutes from the August 9, 2012 VbBS meeting were reviewed and approved as submitted.

ACTION: HERC staff will post the approved minutes on the website as soon as possible.

An orthopedic surgeon from Roseburg has expressed interest in joining the VbBS/HERC. The HERC has been looking for surgical expertise in a member. The subcommittee had no objections to having the HERC consider her for VbBS membership. She will likely be joining the VbBS for the December meeting.

Coffman discussed having a possible new timeline for dealing with new CPT codes. These codes are expected to be published in September rather than late October. The VbBS may take these codes up in November (starting in 2013) and publish a new List on January 1<sup>st</sup> to allow the new codes to be incorporated into the List in a timely fashion. The downside of this proposal would be to have a longer time between Lists (January 1 and October 1 rather than April 1 and October 1). Kirk reported that the plans did not have an issue with the delayed code publication to date. HERC staff will continue to examine this possible change and update the subcommittee.

Smits presented a HERC staff request for input from the subcommittee for dealing with treatments with low effectiveness and high cost. Two options would be a specific guideline for each new class of treatment or a general guideline outlining general coverage guidance. Gibson thought that a set of principles for coverage would be useful. Ocker suggested that some of these treatments should still be brought to the committee to review. Coffman mentioned that previous discussions with the HSC had brought up issues about having an absolute number (QALY threshold) in a guideline. Kirk urged staff to consider the guideline note method as these notes have been very useful for the plans and in the legal process.

➤ **Topic: Mononeuritis and other peripheral neuropathies**

**Discussion:** Livingston introduced a summary document with suggested placement changes for ICD-10 codes for peripheral neuropathies on the 2014 list. It was clarified the new acute peripheral nerve injury line included surgical treatment only. There was minimal discussion and changes were approved as proposed.

**Actions:**

- 1) G57.10-G57.13 moved from line 638 to lines 535 and 557
- 2) G57.20-G57.22 moved from line 638 to lines 450 (new line on October 1, 2014 List), 535 and 557.
- 3) G57.40-G57.42 moved from line 557 to line 441
- 4) G58.8-G58.9 moved from line 638 to lines 535 and 557
- 5) DMAP advised to move G59 from line 638 to the Excluded File

➤ **Topic: Toe walking**

**Discussion:** Smits introduced a summary regarding coverage of toe walking. Kirk brought up that most toe-walking self resolves and therefore does not need to be covered. Pollack was concerned about the cases in which kids have an underlying medical condition which results in the toe walking, such as cerebral palsy. In CP and other cases, there are true ligament contractures. The group felt that ligament contractures should be covered, but not toe walking per se. Smits noted that 727.18 (ligament contracture) was on line 318 and paired with the tendon lengthening CPT code requested for treatment of toe walking. The decision was that 727.18 could be used to code for this condition when surgery is required. Providers may need to be educated that this pairing exists on line 318. Toe walking (ICD-9 739.79) was not added to line 318.

**Actions:** No changes made to the Prioritized List

➤ **Topic: Erythropoiesis stimulating guideline revision**

**Discussion:** Livingston introduced a summary document regarding suggested changes to the erythropoiesis stimulating agents (ESAs) guideline. There was some discussion about use of ESAs for conditions not currently included in the guideline, such as anemia resulting from treatment including multiple medications for hepatitis C. The decision was not to consider adding any indications until specifically requested to review ESAs for a new particular indication. The requested change increasing the reassessment period in renal failure to 12 weeks was accepted.

**Actions:** A revised guideline note was adopted as shown in Attachment A.

➤ **Topic: Radiculopathy and guideline note 37**

**Discussion:** Livingston introduced a summary document with suggested changes to guideline note 37. There was a discussion about adding radiculopathy and members

suggested a language modification could be made for greater clarity. There were clarifying suggestions about which portion of the guideline applied to which line on the Prioritized List.

**Actions:** A revised diagnostic guideline was approved as shown in Attachment A.

➤ **Topic: Guideline for spinal fusion and smoking**

**Discussion:** Smits introduced a summary with a suggested new guideline regarding smoking and spinal fusion. There was some discussion about whether it would be problematic to require testing on the day of surgery. Kirk felt that the guideline as written was implementable and the requirement for testing was not significantly different from the bariatric surgery guideline. There was concern that there was no restriction to not smoke after surgery; however, it was felt that such restrictions would not be feasible. Gibson suggested that, because there are multiple types of surgery which have better outcomes with non-smoking, a more general guideline limiting most types of surgery to non-smokers should be considered. However, it was felt that the evidence reviewed showed decrease efficacy with smoking and spinal fusion; evidence was not reviewed for other types of surgery.

Ocker expressed concern for discrimination with this guideline. She was concerned that smokers may tend to have other characteristics such as poor diet, sedentary lifestyle, etc. She suggested that patient education may be more valuable than a restrictive guideline. Other members agreed that there was a concern about discrimination. However, the general consensus was that the evidence supported this guideline. Additionally, restricting smoking had precedence in other rules such as restricting alcohol use prior to liver transplant. Spinal fusion is generally an elective surgery, which gives patients time to quit smoking. Dodson reminded the subcommittee that OHP covers tobacco cessation treatments, so patients would all have access to these types of services. The group felt that Ocker's concerns about patient education and optimizing lifestyle issues should be brought up again when this guideline was discussed at HERC. The group also added a clause to the guideline specifying that patients have access to tobacco cessation services.

There was discussion that spinal fusion surgery has marginal effectiveness, so any restrictions which improve outcomes are useful. There was also support for having patients have accountability for optimizing their own health outcomes.

DMAP raised concerns about the suggested guideline specifying "non-elective" spinal surgery. There was a question about what the definition of elective was. The subcommittee felt that only emergent indications would require a waiving of the non-smoking guideline and changed that wording in the guideline. Emergent indications were thought to be neurologic conditions which were unstable, such as rapidly progressing neurological deterioration. An emergent indication would be one for which delay in treatment would reasonably be expected to result in permanent serious dysfunction. The decision was to change the language to "emergent" without a specific definition in the guideline. If there is a problem in defining emergent in practice, then DMAP or the health plans can bring this guideline back for further modifications.

**Actions:**

- 1) A new guideline was adopted as shown in Attachment B.
- 2) Add 22532-22548, 22590-22632 to line 84 DEEP ABSCESSSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS; INTESTINAL PERFORATION
- 3) Add 22532-22548 to line 607 SPINAL DEFORMITY, NOT CLINICALLY SIGNIFICANT

➤ **Topic: Urinary Incontinence Guideline**

**Discussion:** Smits introduced a summary document with suggested changes to the urinary incontinence guideline. There were some questions about whether electrical stimulation was part of physical therapy. Ocker noted that some of the literature showed acupuncture treatments, others showed electrical pads as the therapy. Kirk noted that electrical stimulation was billed in addition to PT. Dodson expressed concern about limiting the modalities used by a PT. Smits pointed out that electrical stimulation (CPT 97014) was currently on the Excluded List, so we are not covering it currently. The subcommittee agreed to not add coverage for this service and to remove reference to this service from the current urinary incontinence guideline.

**Actions:** A revised guideline note was adopted as shown in Attachment A

➤ **Topic: Coverage Guidance for Low Back Pain/Acupuncture Guideline**

**Discussion:** Livingston introduced a summary of changes to the Prioritized List to make it consistent with the HERC coverage guidance for low back pain. There was discussion about adding coverage for low back pain, which has traditionally been below the funding line. However, OHP is currently paying for primary care visits for this diagnosis. Members discussed that as OHP moves toward CCOs, there may be additional incentive to cover services such as yoga. There was some concern about CCOs not being willing to accept the global budget amounts, which would make such coverage less likely. Currently, many patients with back pain are treated by pain clinics, but there is an access issue for both pain clinics and primary care for patients with back pain and narcotic prescriptions. There is an emerging issue of PCPs unwilling to see patients who are taking narcotics at all.

There was some discussion about requiring referrals for acupuncture. Ocker was concerned that this might limit access. Others expressed concern that acupuncturists may not be able to make a diagnosis, which would be required for coverage. Seeing a PCP and getting identified as having a covered diagnosis would be facilitated by requiring referral for acupuncture. There was concern that some PCPs would refuse to refer to acupuncture as they do not feel that it is effective. The subcommittee expressed their intent to not limit acupuncture access, but rather to have a referral to maintain continuity between the PCP and acupuncturist.

Further discussion of the acupuncture guideline centered around the number of visits allowed for low back pain. The decision was 12 visits was a reasonable place to start. Ocker felt that 12 visits was a reasonable number for any chronic pain condition.

The decision was to add coverage for acupuncture and CBT to lines 400 and 562 (the back lines). Spinal traction will no longer be covered per the coverage guidance. A coding specification will be added to these lines to specify that CBT is only covered for certain back pain diagnoses. The acupuncture guideline was modified to reflect coverage for low back pain. An additional modification was made to the acupuncture guideline to allow coverage for tension headaches. HERC staff will work with Ocker to consider other conditions to be added to the acupuncture guideline.

**Actions:**

- 1) Add acupuncture (97810-4) to lines 400 and 562.
- 2) Add cognitive behavioral therapy (90804-15) to lines 400 and 562
- 3) Delete spinal traction (CPT code 97012) from lines 400 and 562
- 4) Add a coding specification to Line 400
  - i. Cognitive behavioral therapy (90804-15) only pairs on Line 400 with the low back diagnoses (M47.26, M47.27, M51.06, M51.07, M51.16, M51.17, M51.26, M51.27, M54.16, M54.17)
- 5) Add a coding specification to Line 562
  - i. Cognitive behavioral therapy (90804-15) only pairs on Line 562 with the low back diagnoses (M47.816, M47.817, M47.896, M47.897, M48.36, M48.37, M51.26, M51.27, M51.36, M51.37, M51.86, M51.87, M54.5, M62.830, S33.5xxA, S33.9xxA, S39.092A, S39.82xA, S39.93xA)
- 6) Acupuncture guideline modified as shown in Attachment A.

➤ **Topic: Coverage Guidance for Artificial Disc Replacement**

**Discussion:** Smits introduced a summary of changes suggested for the Prioritized List to allow agreement with the approved coverage guidance on artificial disc replacement. Livingston reminded the subcommittee that the data showed that artificial disks were non-inferior to spinal fusion. Olson pointed out that the HSC had not adopted coverage of artificial discs due to concern about safety; however, the newer data reviewed to create the coverage guidance appeared to be more reassuring about the safety of this procedure. It was also discussed that this procedure is safer than the alternative of spinal fusion. Dodson wanted the List to match the coverage guidance and the HTAS decision. It was pointed out that the diagnoses suggested to pair with artificial disc replacement were on lines 400 and 562 and the artificial disk CPT codes should be added to both lines. The decision was to adopt the guideline as suggested, with an additional reference to line 562.

**Actions:**

- 1) Adopt a new guideline as shown in Attachment B
- 2) Add artificial disc replacement (CPT 22856-22865) to line 400 and 562

➤ **Topic: Coverage Guidance for Neuroimaging for Low Back Pain**

**Discussion:** Livingston introduced a summary of changes suggested for the Prioritized List to allow agreement with the approved coverage guidance on neuroimaging for low back pain. There was minimal discussion about the guideline. It was pointed out that

electromyography (CPT 96002-4) is used for diagnosis of a variety of conditions. The proposal was to not cover this service for the diagnosis of low back pain; however, the group agreed that it should be covered for diagnosis for other conditions and moved from the Ancillary to the Diagnostic List. The intention is to not cover EMG for diagnosis of low back pain.

**Actions:**

- 1) Advise DMAP to move electromyography (CPT 96002-4) from the Ancillary List to the Diagnostic List
- 2) Diagnostic guideline 4 modified as shown in Attachment A.

**Topic: Coverage Guidance for Nonpharmacologic Interventions for Treatment Resistant Depression**

**Discussion:** Livingston introduced a summary of changes suggested for the Prioritized List to allow agreement with the approved coverage guidance on treatment resistant depression. Pollack expressed ~~concern~~ **dismay** that there was no evidence for treatments such as meditation, psychotherapy, etc. There was some discussion about clarifying what qualifies as two medications for depression. For example, sleep aids should not be considered medications. The medications should be SSRIs, SNRIs, tricyclic antidepressants or similar medications. There was some concern that psychotherapy may not be reasonable to try in certain cases, such as catatonic patients. The group felt that the proposed guideline was reasonable, but changed the title to more closely reflect what was included in the guideline.

**Actions:**

- 1) Transcranial magnetic stimulation codes 90867 - 90868 were added to Line 9 MAJOR DEPRESSION, RECURRENT; MAJOR DEPRESSION, SINGLE EPISODE, SEVERE
- 2) No change was made to 90869 placement
- 3) A new treatment guideline for nonpharmacologic interventions for treatment resistant depression was adopted for line 9 as shown in Attachment B

➤ **Topic: Coverage Guidance for Neuroimaging for Dementia**

**Discussion:** Livingston introduced a summary of changes suggested for the Prioritized List to allow agreement with the approved coverage guidance on neuroimaging for dementia. The only modification requested to the proposed guideline was to add the reversible causes of dementia that were listed in the coverage guidance to the guideline.

**Actions:**

- 1) A new diagnostic guideline for neuroimaging in dementia was adopted as shown in Attachment B

➤ **Topic: Coverage Guidance for Neuroimaging for Headache**

**Discussion:** Livingston introduced a summary of changes suggested for the Prioritized List to allow agreement with the approved coverage guidance on neuroimaging for headache. DMAP has made HERC staff aware that this guideline is unenforceable. This guideline needs to be reworked and brought back for consideration at the December meeting.

**Actions:**

- 1) HERC staff to rework guideline and bring back to the December meeting

➤ **Topic: Coverage Guidance for Elective Induction of Labor**

**Discussion:** Smits introduced a summary of changes suggested for the Prioritized List to allow agreement with the approved coverage guidance on elective induction of labor. The guideline affected by this coverage guidance was previously reviewed in August. However, HERC staff on review found that the elective induction of labor guideline substantially did not match the coverage guidance. There was some discussion about whether elective induction should be limited prior to 39 weeks or prior to 41 weeks. Elective induction after 39 weeks is standard of care in many Oregon communities. However, there is no evidence that this improves outcomes, and it may cause harm. The group felt that the HERC should challenge community standard, when the evidence supports other practice. The group also felt that the Prioritized List should match HERC guidances.

**Actions:**

- 1) A revised guideline note was adopted as shown in Attachment A

➤ **Topic: ICD-10 Follow Up Foreign Body in the GI Tract**

**Discussion:** Livingston introduced a summary document regarding suggested changes to coverage of treatment of foreign bodies in the GI tract. There was minimal discussion.

**Actions:**

- 1) Duplicate foreign body in GI tract codes currently on the 2014 biennial Prioritized List line 527 (T18.2xxA, T18.3xxA, T18.4xxA, T18.5xxA, T18.8xxA, T18.9xxA) on renamed Line 48 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, [HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION](#)
- 2) Rename Line 527 FOREIGN BODY IN GI TRACT [WITHOUT RISK OF PERFORATION OR OBSTRUCTION](#).
- 3) Adopt a new guideline for lines 48 and 527 as shown in Attachment B for the 2014 biennial list

➤ **Topic: ICD-10 Follow Up Placement of Albinism Codes**

**Discussion:** Livingston introduced a summary document for changes involving albinism codes for the 2014 biennial list. The discussion centered around whether routine skin exams should be covered for persons with this condition. The suggested placement was on the prevention line (line 3); however, the line containing high risk skin conditions (line 257) was considered to be a better place to pair albinism with skin exam CPT codes. Ocular and cutaneous diagnoses would be on both the ophthalmological and the skin lines. Cutaneous only diagnosis codes should only be on line 257.

**Actions:**

1. Place E70.338 and E70.339 (with hematologic abnormality) on Line 329  
DISORDERS OF AMINO-ACID TRANSPORT AND METABOLISM (NON PKU)  
Place oculocutaneous albinism codes (E70.31x and E70.32x) on Line 452  
STRABISMUS; CONGENITAL ANOMALIES OF EYE
2. Place cutaneous albinism codes E70.30, E70.32X, AND E70.39 on line 257  
DERMATOLOGICAL PREMALIGNANT LESIONS AND CARCINOMA IN SITU

➤ **Topic: Straightforward Issues**

**Discussion:** Smits presented a summary of straightforward changes to the Prioritized List. There was a brief discussion about adding cerumen impaction lavage (69210) to several lines or taking off all lines but 526. The group felt that the lavage was needed to treat the hearing loss or to diagnose otitis media and therefore should be on these lines. Uncomplicated cerumen impaction will stay on line 526. There was also discussion about adding PT/OT for treatment of brachial plexus. The group decided to add PT/OT to both lines with brachial plexus codes (lines 493 and 535).

**Actions:**

- 1) Remove 59830 from line 1
- 2) Add 59830 to line 41
- 3) Add 75557-75561, 75565 to line 50
- 4) Add 26665 to line 382
- 5) Add 26785 to line 297
- 6) Add 43262, 43264, 43265, 43268, and 43271 to line 308
- 7) Add 28190 to line 415
- 8) Remove 96920-2 from lines 223, 386, 432, 517, 545, 553, 554 and 568
- 9) Add 61582 to line 320
- 10) Remove 839.40 from line 497
- 11) Add 839.40 to line 551
- 12) Add 77371 to line 466
- 13) Add 19120 to lines 197, 509 and 665
- 14) Advise DMAP to remove 19120 from the Ancillary List
- 15) Remove 11401 and 11402 from line 197
- 16) Remove 11623 from line 197
- 17) Remove 13122, 13132, and 13133 from line 197
- 18) Add 23470 and 23472 to line 208
- 19) Add 27130 to lines 89, 207, 308 and 382

- 20) Add 27495 to line 208
- 21) Add 11043-11047 to line 142
- 22) Add 76801, 76805, and 76815-7 to line 59
- 23) Add 27495 to line 208
- 24) Add 61571 to line 101
- 25) Add 14000 to line 208
- 26) Add 14001 to lines 197, 216, 308, 448
- 27) Add 69210 to lines 383 and 470
- 28) Add 44120, 44121, and 44125 to line 88
- 29) Add 15100 and 15101 to lines 146, 167, 250, and 448
- 30) Add 44130 to line 341
- 31) Add 33530 to line 77
- 32) Add 12021 to line 216
- 33) Add 77418 and 77421 to line 165
- 34) Add 97001-97004, 97110-97124 to line 493 and 535
- 35) Add reference to line 493 and 535 to GUIDELINE NOTE 6, REHABILITATIVE THERAPIES
- 36) Add 92002-92014 to lines 183, 292, 308, 320, and 448
- 37) Add 65430 to line 164
- 38) Add 44125 to lines 35 and 165
- 39) Add 99211-99255 to line 173
- 40) Change the treatment description of line 173 to "Medical and surgical treatment"
- 41) Add 357.2 to line 535
- 42) Add 51705 and 51710 to line 351
- 43) Add 29828 to line 406
- 44) Remove 45378 from line 48
- 45) Advise DMAP to place 45378 on the Diagnostic List

➤ **Topic: Intratympanic Gentamycin for Meniere's Disease**

**Discussion:** Smits presented a summary document. There was no discussion.

**Actions:**

- 1) Add 69801 (Labyrinthotomy, with perfusion of vestibuloactive drug(s); transcanal) to line 442 MENIERE'S DISEASE

➤ **Topic: Hip Dysplasia Surgical Treatment**

**Discussion:** Smits presented a summary document. There was no discussion.

**Actions:**

- 1) Add 27001-27006 (Open tenotomy, hip) to line 336
- 2) Add 27140-27165 (osteotomy, hip or pelvis) to line 336
- 3) Add 77036 (capsulectomy or capsulotomy, hip) to line 336
- 4) Do not add hip arthroplasty (27130) to line 336

➤ **Topic: Coverage Algorithm**

**Discussion:** Livingston presented a proposed coverage algorithm for discussion. A comment was raised that the burden of proof should be on those advocating the treatment. A discussion of coverage with evidence development ensued, and there were considerations such as less risk or harm, but unknown effectiveness. There was a discussion of standard of care and how to invest public resources and public dollars. The entire side of the algorithm in which there is insufficient or mixed evidence was felt to be risky for recommended coverage. If there is insufficient evidence, how can one know if it is safer and cheaper. The middle avenue on the algorithm should not have coverage.

**Actions:**

- 1) Further discussion of the algorithm is planned for today's HERC meeting

➤ **Public Comment:**

There was no additional public comment received.

➤ **Issues for next meeting:**

- Placement of 2013 CPT codes
- Guideline note 44, menstrual bleeding disorders
- Puberty suppressing medications for gender questioning youth
- Silver nitrate treatment for dental caries
- Neuroimaging for headache

➤ **Next meeting:**

- Scheduled for December 13, 2012, Meridian Park Hospital Health Education Center, Tualatin OR, Room 117B&C, 8:30 AM

# Attachment A

## Revised Guidelines

The following guideline revisions will go into effect on April 1, 2013:

### **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) 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 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~~ 12 weeks. If no response, treatment should be discontinued. If response is demonstrated, 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.

### **GUIDELINE NOTE 37, DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT**

Line: 400

[For the purpose of treatment coverage on Line 400, neurologic impairment or radiculopathy is defined as:](#)

~~Neurologic impairment or radiculopathy is defined as objective evidence of one or more of the following:~~

- A) Abnormal reflexes
- B) Segmental muscle weakness
- C) Segmental sensory loss
- D) EMG or NCV evidence of nerve root impingement
- E) Cauda equina syndrome,
- F) Neurogenic bowel or bladder
- G) Long tract abnormalities

Otherwise, disorders of spine not meeting these criteria (e.g. pain alone) fall on Line 562 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT.

# Attachment A

## Revised Guidelines

### GUIDELINE NOTE 47, URINARY INCONTINENCE

Line 478

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

A) Patient history of (1, 2, and 3):

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

B) Patient's voiding habits

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

- 1) Urethral hypermobility
- 2) Intrinsic sphincter deficiency

D) Diagnostic workup to rule out urgency incontinence

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

F) Nonmalignant cervical cytology, if cervix is present

G) Patient required to have 3 months alternative therapy (e.g., pessaries or physical therapy, including bladder training, pelvic floor exercises, and/or biofeedback, and/or electrical stimulation, as available).

### GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,212,435,563

Line 1 PREGNANCY

Acupuncture (97810-97814) pairs on Line 1 for the following conditions and codes.

*Hyperemesis gravidarum*

ICD-9 codes: 643.00, 643.03, 643.10, 643.11, 643.13

Acupuncture for hyperemesis gravidarum is covered when a diagnosis is made by the maternity care provider and referred for acupuncture treatment. Up to 2 sessions of acupressure/acupuncture are covered.

*Breech presentation*

ICD-9 codes: 652.20, 652.23

Acupuncture (and moxibustion) for breech presentation is covered when a referral with a diagnosis of breech presentation is made by the maternity care provider, the patient is between 33 and 38 weeks gestation, for up to 2 visits.

*Back and pelvic pain of pregnancy*

ICD-9 codes: 648.70, 648.73

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

Line 212 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE

Acupuncture is covered on this line for the treatment of post-stroke depression only.

Treatments may be billed to a maximum of 30 minutes face-to-face time and limited to 15 total sessions, with documentation of meaningful improvement.

# Attachment A

## Revised Guidelines

Line 400 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT

Acupuncture (97810-4) is included on Line 400 only for pairing with disorders of the spine with myelopathy and/or radiculopathy represented by the diagnosis codes M47.26, M47.27, M51.06, M51.07, M51.16, M51.17, M51.26, M51.27, M54.16, M54.17. Acupuncture for the treatment of these conditions is only covered, when referred, for up to 12 sessions.

Line 435 MIGRAINE HEADACHES

Acupuncture pairs on Line 435 for ICD-9 346, when referred, for up to 12 sessions.

Line 562 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT

Acupuncture pairs on Line 562 only with the low back diagnoses (M47.816, M47.817, M47.896, M47.897, M48.36, M48.37, M51.26, M51.27, M51.36, M51.37, M51.86, M51.87, M54.5, M62.830, S33.5xxA, S33.9xxA, S39.092A, S39.82xA, S39.93xA), when referred, for up to 12 sessions.

Line 563 TENSION HEADACHES

Acupuncture is ~~covered for~~ included on Line 563 for treatment of tension headaches ~~on Line 563~~, when referred, for up to 12 sessions.

**DIAGNOSTIC GUIDELINE D4, ~~MRI OF THE SPINE~~ ADVANCED IMAGING FOR LOW BACK PAIN**

In patients with non-specific low back pain and no “red flag” conditions [see Table D.1], imaging is not a covered service; otherwise work up is covered as shown in the table.

Electromyography (CPT 96002-4) is not covered for non-specific low back pain.

~~MRI of the spine is covered in the following situations:~~

- ~~1. Recent onset of major or progressive neurologic deficit (objective evidence of reflex loss, dermatomal muscle weakness, dermatomal sensory loss, EMG or NCV evidence of nerve root impingement), suspected cauda equina syndrome (loss of bowel or bladder control or saddle anesthesia), or neurogenic claudication in patients who are potential candidates for surgery~~
- ~~2. Clinical or radiological suspicion of neoplasm; or,~~
- ~~3. Clinical or radiological suspicion of infection.~~

**Table D.1**

**Low Back Pain - Potentially Serious Conditions (“Red Flags”) and Recommendations for Initial Diagnostic Work-up**

Possible cause	Key features on history or physical examination	Imaging*	Additional studies*
Cancer	<ul style="list-style-type: none"> <li>• History of cancer with new onset of LBP</li> </ul>	MRI	ESR
	<ul style="list-style-type: none"> <li>• Unexplained weight loss</li> <li>• Failure to improve after 1 month</li> <li>• Age &gt;50 years</li> <li>• Symptoms such as painless neurologic deficit, night pain or pain increased in supine position</li> </ul>	Lumbosacral plain radiography	

## Attachment A

### Revised Guidelines

	<ul style="list-style-type: none"> <li>Multiple risk factors for cancer present</li> </ul>	Plain radiography or MRI	
Spinal column infection	<ul style="list-style-type: none"> <li>Fever</li> <li>Intravenous drug use</li> <li>Recent infection</li> </ul>	MRI	ESR and/or CRP
Cauda equina syndrome	<ul style="list-style-type: none"> <li>Urinary retention</li> <li>Motor deficits at multiple levels</li> <li>Fecal incontinence</li> <li>Saddle anesthesia</li> </ul>	MRI	None
Vertebral compression fracture	<ul style="list-style-type: none"> <li>History of osteoporosis</li> <li>Use of corticosteroids</li> <li>Older age</li> </ul>	Lumbosacral plain radiography	None
Ankylosing spondylitis	<ul style="list-style-type: none"> <li>Morning stiffness</li> <li>Improvement with exercise</li> <li>Alternating buttock pain</li> <li>Awakening due to back pain during the second part of the night</li> <li>Younger age</li> </ul>	Anterior-posterior pelvis plain radiography	ESR and/or CRP, HLA-B27
Nerve compression/ disorders (e.g. herniated disc with radiculopathy)	<ul style="list-style-type: none"> <li>Back pain with leg pain in an L4, L5, or S1 nerve root distribution present &lt; 1 month</li> <li>Positive straight-leg-raise test or crossed straight-leg-raise test</li> </ul>	None	None
	<ul style="list-style-type: none"> <li>Radiculopathic symptoms present &gt;1 month</li> <li>Severe/progressive neurologic deficits (such as foot drop), progressive motor weakness</li> </ul>	MRI**	Consider EMG/NCV
Spinal stenosis	<ul style="list-style-type: none"> <li>Radiating leg pain</li> <li>Older age</li> <li>Pain usually relieved with sitting (Pseudoclaudication a weak predictor)</li> </ul>	None	None
	<ul style="list-style-type: none"> <li>Spinal stenosis symptoms present &gt;1 month</li> </ul>	MRI**	Consider EMG/NCV

\* Level of evidence for diagnostic evaluation is variable

\*\* Only if patient is a potential candidate for surgery or epidural steroid injection

Red Flag: Red flags are findings from the history and physical examination that may be associated with a higher risk of serious disorders. CRP = C-reactive protein; EMG = electromyography; ESR = erythrocyte sedimentation rate; MRI = magnetic resonance imaging; NCV = nerve conduction velocity.

*Extracted and modified from Chou R, Qaseem A, Snow V, et al: Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society. Ann Intern Med. 2007; 147:478-491.*

# Attachment A

## Revised Guidelines

### GUIDELINE NOTE 85, ~~ELECTIVE~~ INDUCTION OF LABOR

Line 1

~~Elective~~ Induction of labor ~~without medical or obstetrical indication~~ is covered only for gestational age beyond 41 and 0/7 weeks, prelabor rupture of membranes, maternal diabetes (pre-existing or gestational), or other medical or obstetrical indications. ~~prior to 39 weeks of completed gestation is not a covered service.~~ ~~Elective~~ Induction of labor is not covered at any gestational age for fetal macrosomia in the absence of maternal diabetes, ~~or~~ for breech presentation, or for elective purposes without a medical or obstetrical indication.

*The following new guidelines will go into effect on April 1, 2013:*

### **GUIDELINE NOTE XXX SMOKING AND SPINAL FUSION**

*Lines 84, 158, 208, 271, 400, 434, 507, 549, 607*

Non-emergent spinal arthrodesis (CPT 22532-22634) is limited to patients who are non-smoking for 6 months prior to the planned procedure, as shown by three negative urine cotinine tests including testing on the day of surgery. Patients should be given access to appropriate smoking cessation therapy.

### **GUIDELINE NOTE XXX ARTIFICIAL DISC REPLACEMENT**

*Line 400, 562*

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

Lumbar artificial disc replacement

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

Cervical artificial disc replacement

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

### **GUIDELINE NOTE XXX NON-PHARMACOLOGIC INTERVENTIONS FOR TREATMENT-RESISTANT DEPRESSION**

*Line 9*

Repetitive transcranial magnetic stimulation (CPT 90867-90868) and electroconvulsive therapy (CPT 90870) are covered only after failure of at least two antidepressants.

## **DIAGNOSTIC GUIDELINE XXX, NEUROIMAGING IN DEMENTIA**

Neuroimaging is covered:

A) To rule out reversible causes of dementia (tumors, normal pressure hydrocephalus and chronic subdural hematoma) via structural neuroimaging only

Neuroimaging is not covered:

A) For screening of asymptomatic patients for dementia

B) To predict progression of the risk of developing dementia in patients with mild cognitive impairment

C) For screening, diagnosis, or monitoring of dementia, with functional neuroimaging (PET, SPECT or fMRI)

*The following new guideline will go into effect with the implementation of the new biennial list projected for October 1, 2014:*

### **GUIDELINE NOTE XXX, FOREIGN BODIES IN THE GI TRACT**

*Line 48, 527*

ICD 10 codes T18.2xxA, T18.3xxA, T18.4xxA, T18.5xxA, T18.8xxA, T18.9xxA are included on Line 48 only when hazardous objects are involved that are likely to cause perforation (e.g. sharp objects >2 inches, neodymium magnets, button batteries) or obstruction.

## **Value-based Benefits Subcommittee Recommendations Summary For Presentation to: Health Evidence Review Commission on 1/10/13**

*For specific coding recommendations and guideline wording, please see the text of the 12/13/12 VbBS minutes.*

### **CODE MOVEMENT**

- The 2013 CPT, HCPCS, and CDT codes were placed as shown in Attachment A. These proposed placements will be placed on the HERC website to be available for viewing by the various health plans. Final approval of these placements will be done at the HERC meeting on January 10, 2013. These codes will appear on the April 1, 2013 Prioritized List as approved by the HERC in January.
- A missing tympanostomy tube removal procedure code was added to the acute mastoiditis line
- Tympanostomy procedure codes that were mistakenly not removed from the hearing loss line were removed
- A pharyngoplasty procedure code was added to the line with congenital neck problems

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

- The use of silver compounds for treatment of dental caries was discussed but no decision regarding coverage was reached
- The prioritization of pseudobulbar affect was discussed but no decision was reached
- A prenatal genetic testing guideline was discussed, and a work group will be convened to write it
- Changes to the guideline for hysterectomy for menstrual bleeding disorder were discussed, and will be readdressed at a future meeting

### **GUIDELINE CHANGES**

- The coding specifications regarding cognitive behavioral therapy for low back pain were changed to indicate the correct CPT code
- Mistakes in the coding specification for bariatric surgery on the type 2 diabetes line were corrected
- The non-prenatal genetic testing guideline was modified to reflect changes needed for the new 2013 CPT genetic testing codes, as shown in Appendix C
- Two dental guidelines were modified and one deleted as shown in Appendix C
- The chronic otitis media with effusion treatment guideline was modified as shown in Appendix C
- A new guideline allowing coverage of puberty suppression in adolescents under new gender dysphoria line was adopted for the ICD-10 (October 2014) Prioritized List as shown in Appendix B

**VALUE-BASED BENEFITS SUBCOMMITTEE**  
**Meridian Park Health Education Center**  
**December 13, 2012**  
**8:30 AM – 2:30 PM**

**Members Present:** Lisa Dodson, MD, Chair; Kevin Olson, MD, Vice-chair; Chris Kirk, MD; James Tyack, DMD; David Pollack MD; Mark Gibson; Irene Crosswell RPh; Laura Ocker, LAc; Susan Williams, MD.

**Members Absent:** none

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

**Also Attending:** Denise Taray, DMAP; Kristi Jacobo, DMAP; Dr. Wally Shaffer, DMAP; David Fischer, AMH; Dr. Bruce Boston, OHSU Pediatric Endocrinology; Dr. Karin Selva, Legacy Pediatric Endocrinology; Jenn Burleton, Transactive; Dr. Ericka King, OHSU Pediatric Otolaryngology; Camille Kerr, Allergan; Gary Allen, DMD, Advantage Dental; Christina Schad, MD, and Julie Brown, Avenir Pharmaceuticals; Steven Duffin, Oral Health Outreach; Beryl Fletcher, ODA; Deborah Loy, Capital Dental; Aubrey Harrison, Basic Rights Oregon.

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

The meeting was called to order at 8:35 am and roll was called. Dr. Williams, an orthopedic surgeon practicing in Roseburg, was introduced as a new member of the subcommittee. Minutes from the 10/11/12 VbBS meeting were reviewed and approved with one change requested by Pollack regarding his remarks on the treatment resistant depression section.

**Action:** HERC staff will post the approved minutes on the website as soon as possible.

Coffman shared the work of a group that is trying to make the coverage guidance process more efficient and more reflective of the actual authority of these guidances. There was a general discussion about what authority the guidances and Prioritized List guidelines have. The HERC has the authority to prioritize conditions, and the Legislature determines the coverage level. Other insurers or other bodies may or may not choose to follow these guidances.

## Straightforward Discussion

### ➤ Topic: Straightforward Issues Table

**Discussion:** Smits introduced a document with straightforward coding changes. There was no discussion.

**Actions:**

- 1) Add 69424 to line 178.
- 2) Remove 69424 and 69433 from line 383
- 3) Add 42950 to line 71

### ➤ Topic: Low Back Pain Coding Specifications

**Discussion:**

Smits introduced a document with changes needed for the low back pain line coding specifications. There was no discussion.

**Actions:**

- 1) Add the following coding recommendation to Line 400 for the April 1, 2013 Prioritized List
  - a. Cognitive behavioral therapy (90785-90840) only pairs on Line 400 with the low back diagnoses (344.60, 722.1, 722.2, 722.7, 724.4)
- 2) Add the following coding recommendation to Line 562 for the April 1, 2013 Prioritized List
  - a. Cognitive behavioral therapy (90785-90840) only pairs on Line 562 with the low back diagnoses (720.2, 721.3, 721.7, 721.8, 721.90, 722.1, 722.2, 722.32, 722.39, 722.5, 722.6, 722.8, 722.9, 724.1, 724.2, 724.5-724.9, 739.2-739.4, 847.1-847.9).
- 3) Change the following coding recommendation for Line 400 for the April 1, 2013 Prioritized List
  - a. Cognitive behavioral therapy ([90785-90840](#)) only pairs on Line 400 with the low back diagnoses (344.60, 722.1, 722.2, 722.7, 724.4)
- 4) Change the following coding recommendation for Line 562 for the April 1, 2013 Prioritized List
  - a. Cognitive behavioral therapy ([90785-90840](#)) only pairs on Line 562 with the low back diagnoses (720.2, 721.3, 721.7, 721.8, 721.90, 722.1, 722.2, 722.32, 722.39, 722.5, 722.6, 722.8, 722.9, 724.1, 724.2, 724.5-724.9, 739.2-739.4, 847.1-847.9).

➤ **Topic: Bariatric Surgery Coding Specification**

**Discussion:** Smits introduced a document with changes needed for the bariatric surgery line coding specifications on the April 1, 2013 list. There was no discussion.

**Actions:**

1) The coding specification for line 33 was changed to read:

CPT codes 43644-43645 and 43846-43848 (Roux-En-Y gastric bypass) and 43770-43774<sup>5</sup> (laparoscopic adjustable gastric banding) are only included on this line as treatment according to the requirements in Guideline Note 8 when paired with:

- 1) a primary diagnosis of 250.x0 or 250.x2 (Type II Diabetes with or without complication);
- 2) a secondary diagnosis of 278.00 (Obesity, Unspecified) or 278.01 (Morbid Obesity); AND,
- 3) a tertiary diagnosis code of V85.35-V85.40<sup>5</sup> (BMI >= 35).

## **New Codes 2013**

➤ **Topic: 2013 CPT codes**

**Discussion:** Smits introduced several documents with recommendations for the placement of the 2013 CPT, CDT and HPCPS codes. These recommendations were accepted as shown in the meeting materials (see Appendix A), with the exceptions below. Other code changes recommended in the various issue documents were also accepted as shown in the meeting materials unless noted below. This discussion section includes the genetic testing and psychiatric CPT codes.

- 1) 52287 (chemodenervation of the bladder). The subcommittee altered the suggested guideline for this procedure to clarify that it was to be used for overactive bladder caused by several types of spinal diseases and that a patient must have failed appropriate pharmacologic management first rather than antimuscarinic medications, as there may be other types of appropriate medication.
- 2) 64615 (Chemodenervation for migraine). This code is recommended to be added to the Excluded File as suggested by staff. There was considerable discussion about the differing recommendations of trusted sources (MED vs NICE). There was some discussion about these sources possibly using different studies or having differing amounts of industry and patient/provider input. Livingston said the MED report found studies with statistically significant differences with botulinum therapy, but that these differences were

not clinically significant. Dodson noted that this treatment might be cost effective if it lowered ER costs/utilization. Croswell as noted that chronic migraine patients are not very functional, and any therapy that would allow them to be more productive should be considered. Gibson recommended not covering due to lack of clinically significant outcomes. Kirk felt that this therapy was not medically appropriate based on the evidence. Payers could make exceptions for high ER utilizing patients if the payer felt that this might decrease their overall costs. Shaffer noted that this exception could not be made for FFS patients if the treatment was placed on the Excluded File. Livingston reviewed GRADE criteria and noted that this therapy would likely not be recommended for coverage using this criteria. The decision was made to not cover.

- 3) 81235 (EGFR (epidermal growth factor receptor) testing). The subcommittee recommended placing on the line which included the diagnosis of non-small cell lung cancer (line 278), as this is the diagnosis for which this code is utilized (not the Diagnostic File). Olson noted that this procedure is a test on tumor tissue, not germ line tissue and therefore is not a genetic test. It therefore should not be included in the non-prenatal genetic testing guideline and that portion of the suggested guideline changes was not accepted.
- 4) 86152/86153 (Cell enumeration using immunologic selection) were recommended for placement on the Excluded File rather than the Diagnostic File. Olson stated that these tests are expensive and their place in cancer care is dubious. He recommended against coverage
- 5) 86711 (JC virus antibody) was placed on the multiple sclerosis and Crohn's disease lines (35 and 268) rather than the Diagnostic File. Livingston reported that this test is only FDA approved for use in these 2 indications. The subcommittee was concerned about over use for other indications without evidence of benefit.
- 6) 90839/90840 (psychotherapy for crisis) were not added to the low back pain lines (400 and 562)
- 7) 90863 (pharmacologic management) was recommended for addition to the Excluded File as this applies only to prescribed psychologists in 2 states (not Oregon). AMH suggested leaving this code open to allow for non-MD and non-NP mental health providers to bill for medication management. Pollack felt that this code was inappropriate for Oregon, as psychologists do not have prescribing privileges here.
- 8) 95782/95783 (pediatric polysomnography) are recommended to be placed on the Diagnostic File rather than the Ancillary File, because the subcommittee felt that these tests are used in the diagnosis of obstructive sleep apnea and other sleep issues. Pollack asked HERC staff to consider moving all polysomnography CPT codes from the Ancillary File to the Diagnostic File
- 9) The "C" HCPCS codes did not have placement determined. These codes are used solely during hospitalization and have never been included on the Prioritized List. There was discussion about the C codes for drug eluting cardiac stents. HERC staff was asked to consider having HTAS review drug eluting vs bare metal cardiac stent technology.

- 10) S8930 (electrical stimulation of auricular acupuncture points) had no final placement decision made. Ocker provided the Regence BCBS coverage position on this technology, which is that it is investigational. Ocker and HERC staff will work with acupuncture experts to determine 1) if this HCPCS code is used solely for a device or if it is intended for use for standard electrical stimulation of ear points; 2) if an acupuncturist who does traditional electrical stimulation of ear points can use the usual acupuncture CPT codes for billing; 3) determine if this procedure should be added to any or all of the current lines which contain acupuncture CPT codes. This topic will be readdressed at the January, 2013 VBBS meeting.
- 11) D7952 was added to line 648 (there was a mistake in line number listed in the meeting materials)

**Actions:**

- 1) See Appendix A for new CPT, CDT and HCPCS code placements
  - a. These proposed placements will be placed on the HERC website to be available for viewing by the various health plans. Final approval of these placements will be done at the HERC meeting on January 10, 2013. These codes will appear on the April 1, 2013 Prioritized List as approved by the HERC in January.
- 2) 77435 was removed from all current lines and are recommended to be added to the Excluded File
- 3) A new guideline was added to line 351 as shown in Appendix B
- 4) 92973, 92975, 92977 were removed from all lines other than lines 51, 76, 108, and 195
- 5) The non-prenatal genetic testing guideline was modified as shown in Appendix C
- 6) Dental guidelines 17 and 53 were modified as shown in Appendix C
- 7) Dental guideline note 91 was deleted

**New Discussion Items**

➤ **Topic: Silver Nitrate Treatments For Dental Caries**

**Discussion:** Livingston introduced a summary document regarding use of silver nitrate for treatment of dental caries. Deborah Loy, Capital Dental, submitted written testimony and gave oral testimony against allowing silver nitrate use. She felt that this treatment was not the right treatment for the vulnerable low income population it was targeted for. She testified that its use had no support from professional organizations and had no U.S. evidence to support its use. She feels that its use results in a very poor cosmetic outcome. She also argued that the various types of silver treatment are not interchangeable, and the usual agent used globally is not FDA approved in the US. Loy also acknowledged that if there were good evidence available to support its use, she and others would reconsider, but at this point there is too little known about harms and about comparative efficacy to current treatments.

Dr. Gary Allen a dentist with Advantage Dental, gave written and oral testimony in favor of the use of silver compounds for treatment of dental caries. He testified that the MED review recommendations did not reflect the findings of the review itself. He feels that silver diamine fluoride has evidence of effectiveness, but that this technology is very old and much of the literature would not be found by a standard search of recent studies. He argued that the cosmetic outcome was not that poor, as it turns an otherwise brown stain into a black stain. Silver compounds are used widely internationally to treat dental caries. However, these compounds are not approved in US for this use, but are under review for approval. Silver nitrate + fluoride varnish is being used by some dental providers in Oregon. Silver diamine fluoride would be preferred when available in the US. Dr. Allen argued that silver treatments would be another tool in the toolbox. The typical course of treatment would be 5 applications over a 3-4 month period with restoration at the end of that course. He argued that halting the bacterial infection is important. He also felt that this therapy may be cost savings if avoiding hospitalization of children for extensive dental work.

Tyack asked clarifying questions about the need for further restorative treatment after treatment with silver nitrate. Livingston noted that no studies looked at the comparative outcomes of repeated applications of silver diamide fluoride with delayed restoration vs immediate restoration (what would be standard of care in the United States). Tyack also expressed concern about the potential for discrimination against poor children with black teeth. Glass ionomer cement was offered as another alternative with superior cosmetic outcomes.

Kirk noted that OHP dental director Mike Shirtcliff has reported significant decrease in ER visits with this treatment in his organization.

Livingston also shared public testimony that had been received by Dr. Steven Duffin.

Questions were asked about how silver treatments are billed. The reply was that these treatments are billed with the CDT code for "desensitizing agent" which is not-specific. If the proposed guideline specifying that it is not a covered treatment is not adopted, then dental plans may cover it. Jacobo noted that the desensitizing code is not currently reimbursed by DMAP and would not be reimbursed under FFS, but that the capitated dental plans could choose to reimburse for it.

Tyack expressed concerns for high costs associated with this approach due to mid-level dental providers in FQHC model using this treatment and then billing at the very expensive FQHC wrap-around rate. Allen responded that this would not likely happen under a DCO global budgeting model. Loy replied that even with DCO's, the FQHC wrap-around payment would still apply. Loy noted that the board of dentistry is currently looking into the type of provider that should be allowed to apply silver compounds.

**Actions:**

The decision was to defer further discussion until the January VBBS meeting. The members will read over the materials in more detail. HERC staff will make a summary of the testimony (written and oral) and other evidence provided for this meeting. HERC staff will also consult the board of dentistry for input on this topic.

**➤ Topic: Pseudobulbar Affect**

**Discussion:** Smits introduced a summary document with recommendations regarding the prioritization of pseudobulbar affect (PBA). Testimony was heard from Christina Schad, MD, on behalf of Avanir Pharmaceuticals. She testified that PBA should be a covered condition, as this condition is under-recognized and undertreated. The prevalence of this condition is 10-20% of patients with underlying neurologic conditions and 40% of ALS patients. About 2 million Americans suffer from PBA. PBA causes distress, affects quality of life, and affects occupational functioning. It affects a patient's ability to interact with health care, participate in rehab, and can cause relationship issues. Dr. Schad testified that this condition is a significant burden on patients, family, and caregivers.

Coffman noted that PBA would be covered as a co-morbid condition on the Prioritized List and that the ICD-9 code should be billed as a secondary code when an underlying condition is present.

Pollack noted that he had a patient that he attempted to try this medication for, and had considerable difficulty obtaining coverage for it. He noted that the patient did not respond well to this treatment. He feels that PBA is a significant condition and should be covered.

Smits noted that a new line could be created for PBA with the next biennial review, and scored with the usual methodology. If more timely movement of this condition is needed, the VBBS could consider where such a line would be located and find a similar line in that area of the List that the diagnosis could be added to.

**Actions:**

No decision was made. Staff will create a mock line with PBA and score it with the usual methodology and bring a proposed new code placement based on this theoretical line to the January VBBS meeting. HERC staff will also contact neurology experts for independent input.

**Coverage Guidances for Review****➤ Topic: Viscosupplementation for Osteoarthritis of the Knee**

**Discussion:** This topic was tabled until the January VBBS meeting.

**Actions:** Will be discussed at the January VBBS meeting.

➤ **Topic: Percutaneous Interventions for Low Back Pain**

**Discussion:** This topic was tabled until the January VBBS meeting.

**Actions:** Will be discussed at the January VBBS meeting.

➤ **Topic: Management of Chronic Otitis Media in Children**

**Discussion:** Livingston introduced a summary document with recommended changes to the otitis media treatment guideline. Dr. Ericka King from OHSU Pediatric ENT testified about concerns she and her colleagues have about the proposed changes to the guideline and about the literature used for the creation of the HERC coverage guidance on this topic. She recommended re-inserting the stricken language “For the child who has had chronic OME and who has a hearing deficiency in the better-hearing ear of 25 dB or greater, myringotomy with tube insertion recommended after a total of 4 to 6 months of effusion with a documented hearing deficit.” She said that children with a 25dB hearing loss are at risk for language delay.

There was discussion that the current location of chronic OME below the funding line was preventing children from getting needed care. The committee directed Dr. King to bring this concern to the legislature as it is a funding issue.

Livingston brought up that the last sentence regarding individualized treatment plans was problematic for DMAP. She recommended putting in wording that ear tubes should be covered for these diagnoses. There was discussion about adding the CPT code for ear tube to these diagnosis lines (Down’s syndrome, craniofacial anomalies, etc.).

Williams suggested adding PE tubes back to the hearing loss lines. Livingston noted that PE tubes were not indicated for hearing loss unless effusion is present, in which case the diagnosis would be on the chronic OME line.

**Actions:**

- 1) The chronic otitis media treatment guideline was modified as shown in Appendix C. it will be brought back to the January VBBS meeting as a straightforward item.

## Previous Discussion Items

### ➤ Topic: Puberty Suppression for Transgendered Youth

**Discussion:** Smits introduced a summary document with information regarding puberty suppression in transgendered youth. Jenn Burleton from TransActive, Dr. Karin Selva from Legacy Pediatric Endocrinology and Dr. Bruce Boston from OHSU Pediatric Endocrinology gave testimony in favor of coverage of this treatment.

The main discussion was about the type of mental health evaluation that would be required prior to this therapy. There are several non-MD mental health providers who are very competent in this area. The proposed guideline wording was changed from “psychiatric evaluation” to “mental health” evaluation.

Tyack and Olson made comments in support of coverage. Tyack felt that there was no alternative treatment and Olson felt that, despite weak evidence, the committee heard strong testimony about the utility of use in this vulnerable population. He also felt that this treatment was unlikely to be abused.

Selva asked that HERC staff ensure that medical visit E&M codes are on the new Gender Dysphoria line for the ICD-10 Prioritized List to allow providers to see these patients for monitoring of this type of treatment. *Note: staff reviewed the new line and it includes E&M codes appropriate for this type of care.*

#### **Actions:**

- 1) A new guideline for the gender dysphoria line on the ICD-10 list was adopted as shown in Appendix B

## Guidelines

### ➤ Topic: Guideline note 44, Menstrual Bleeding Disorders

**Discussion:** Smits introduced a summary document regarding proposed changes to remove a defined hemoglobin level from guideline note 44. Williams expressed concern that without a specific number, there would be no method to objectively determine if anemia was present. Livingston noted that this guideline change would result in increased numbers of hysterectomies for menstrual bleeding disorders. Taray noted that DMAP is already covering many of these cases without the documentation of this hemoglobin level, so the number of new cases with this change would likely be smaller than expected. She noted that there are about 2 cases per month approved by DMAP in the FFS population without a documented hemoglobin of 10. Kirk noted that his plan is using and enforcing this clause. In general, there was a sense that hysterectomy for this indication has significant potential for overuse.

Several alternate wording proposals were put forth. Livingston suggested adding language to require “documented precipitous loss or requiring iron treatment.” Dodson felt that there were already considerable “hoops” to get through in this guideline. She did not feel that the hemoglobin of 10 clause added much to the guideline. She felt that there was no good medical evidence that the value of 10 makes a difference as compared to any other value defining anemia. This number was picked arbitrarily. Taray suggested putting an OR between clauses 1a and 1b; however, the group did not accept this suggestion as it would allow a patient with normal periods but anemia for an unrelated reason to qualify for a hysterectomy.

**Actions:**

- 1) HERC staff will seek input from the OHP medical directors regarding the utility of having a hemoglobin level of 10 required in this guideline. HERC staff will also research other guidelines, such as Blue Cross, to see what type of definition is used for anemia, if any. This topic will be brought back to the March 2013 VBBS meeting (the next OHP medical directors meeting is after the January VBBS meeting)

➤ **Topic: Prenatal genetic testing guideline**

**Discussion:** Livingston introduced a summary document regarding plans to create a prenatal genetic testing guideline. The group decided that it should go through the coverage guidance process and engaging experts to assist.

**Actions:**

- 1) HERC staff to identify experts and bring to a subsequent Evidence-based Guidelines Subcommittee meeting

➤ **Public Comment:**

No additional public comment was received

➤ **Issues for next meeting:**

- Coronary brachytherapy
- External elements exposure issues
- Stereotactic radiation therapy for intracranial AVMs (
- Personal history of cancer V codes
- Auricular acupuncture
- Enzyme replacement therapy for Guacher’s disease and PKU
- Silver compounds for caries treatment
- Pseudobulbar affect prioritization
- Changes needed to the Prioritized List to bring into alignment with coverage guidances on viscosupplementation for osteoarthritis of the knee, percutaneous

interventions for low back pain, and management of chronic otitis media in children

- Guideline on immunizations/prevention tables
- Expensive/marginally effective drug guideline
- Guideline Note 37 on abnormal reflexes radiculopathy

➤ **Next meeting:**

Thursday, January 10, 2013, Meridian Park Hospital, Conference Room 117  
Time: TBD

The meeting adjourned at 2:45 PM.

DRAFT

# Appendix A

## Recommended Placement of New 2013 CPT, CDT and HCPCS Codes

DRAFT

## 2012 CPT Code Review

Code	Code Description	List/File	Proposed April 2013 Placement	Notes
22586	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace	Prioritized	<b>84</b> DEEP ABSCESSSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS; INTESTINAL PERFORATION <b>158</b> CERVICAL VERTEBRAL DISLOCATIONS/FRACTURES, OPEN OR CLOSED; OTHER VERTEBRAL DISLOCATIONS/FRACTURES, OPEN; SPINAL CORD INJURIES WITH OR WITHOUT EVIDENCE OF VERTEBRAL INJURY <b>208</b> CANCER OF BONES <b>271</b> CHRONIC OSTEOMYELITIS <b>400</b> DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT <b>434</b> SPINAL DEFORMITY, CLINICALLY SIGNIFICANT <b>507</b> CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT SPINAL CORD INJURY <b>549</b> BENIGN NEOPLASM BONE AND ARTICULAR CARTILAGE INCLUDING OSTEIOD OSTEOMAS; BENIGN NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE <b>607</b> SPINAL DEFORMITY, NOT CLINICALLY SIGNIFICANT	
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component	Prioritized	<b>208</b> CANCER OF BONES <b>308</b> COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT <b>384</b> RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE <b>467</b> MALUNION AND NONUNION OF FRACTURE	
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component	Prioritized	<b>208</b> CANCER OF BONES <b>308</b> COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT <b>384</b> RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE <b>467</b> MALUNION AND NONUNION OF FRACTURE	
24370	Revision of total elbow arthroplasty, including allograft when performed; humeral or ulnar component	Prioritized	<b>208</b> CANCER OF BONES <b>384</b> RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE	
24371	Revision of total elbow arthroplasty, including allograft when performed; humeral and ulnar component	Prioritized	<b>208</b> CANCER OF BONES <b>384</b> RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE	
31647	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe	Excluded		
31648	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe	Excluded		
31649	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), each additional lobe	Excluded		

## 2012 CPT Code Review

Code	Code Description	List/File	Proposed April 2013 Placement	Notes
31651	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), each additional lobe	Excluded		
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe	Excluded		
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes	Excluded		
32554	Thoracentesis, needle or catheter, aspiration of the pleural space; without imaging guidance	Prioritized	<b>84 DEEP ABSCESSSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS; INTESTINAL PERFORATION 153 PNEUMOTHORAX AND HEMOTHORAX</b>	
32555	with imaging guidance	Prioritized	<b>84 DEEP ABSCESSSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS; INTESTINAL PERFORATION 153 PNEUMOTHORAX AND HEMOTHORAX</b>	
32556	Pleural drainage, percutaneous, with insertion of indwelling catheter; without imaging guidance	Prioritized	<b>84 DEEP ABSCESSSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS; INTESTINAL PERFORATION 153 PNEUMOTHORAX AND HEMOTHORAX</b>	
32557	with imaging guidance	Prioritized	<b>84 DEEP ABSCESSSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS; INTESTINAL PERFORATION 153 PNEUMOTHORAX AND HEMOTHORAX</b>	
32701	Thoracic target(s) delineation for stereotactic body radiation therapy (SRS/SBRT), (photon or particle beam), entire course of treatment	Excluded		
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach	Prioritized	<b>76 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 90 MYOCARDITIS (NONVIRAL), PERICARDITIS (NONVIRAL) AND ENDOCARDITIS 116 CONGENITAL STENOSIS AND INSUFFICIENCY OF AORTIC VALVE 192 MULTIPLE VALVULAR DISEASE 195 CHRONIC ISCHEMIC HEART DISEASE 237 DISEASES AND DISORDERS OF AORTIC VALVE 308 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 354 COCCIDIOIDOMYCOSIS, HISTOPLASMOISIS, BLASTOMYCOTIC INFECTION, OPPORTUNISTIC AND OTHER MYCOSES</b>	
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach	Prioritized	<b>76, 90, 116, 192, 195, 237, 308, 354</b>	
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach	Prioritized	<b>76, 90, 116, 192, 195, 237, 308, 354</b>	
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach	Prioritized	<b>76, 90, 116, 192, 195, 237, 308, 354</b>	

## 2012 CPT Code Review

Code	Code Description	List/File	Proposed April 2013 Placement	Notes
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)	Prioritized	76, 90, 116, 192, 195, 237, 308, 354	
33367	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels) (List separately in addition to code for primary procedure)	Prioritized	76, 90, 116, 192, 195, 237, 308, 354	
33368	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (eg, femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure)	Prioritized	76, 90, 116, 192, 195, 237, 308, 354	
33369	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)	Prioritized	76, 90, 116, 192, 195, 237, 308, 354	
33990	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; arterial access only	Prioritized	90 MYOCARDITIS (NONVIRAL), PERICARDITIS (NONVIRAL) AND ENDOCARDITIS 108 HEART FAILURE 279 CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, TRANSPOSITION OF GREAT VESSELS, HYPOPLASTIC LEFT HEART SYNDROME 367 IDIOPATHIC OR VIRAL MYOCARDITIS AND PERICARDITIS	
33991	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transseptal puncture	Prioritized	90, 108, 279, 367	
33992	Removal of percutaneous ventricular assist device at separate and distinct session from insertion	Prioritized	90, 108, 279, 367	
33993	Repositioning of percutaneous ventricular assist device with imaging guidance at separate and distinct session from insertion	Prioritized	90, 108, 279, 367	

Code	Code Description	List/File	Proposed April 2013 Placement	Notes
36221	Non-selective catheter placement, thoracic aorta, with angiography of the extracranial carotid, vertebral, and/or intracranial vessels, unilateral or bilateral, and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed	Diagnostic		
36222	Selective catheter placement, common carotid or innominate artery, unilateral, any approach, with angiography of the ipsilateral extracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed	Diagnostic		
36223	Selective catheter placement, common carotid or innominate artery, unilateral, any approach, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed	Diagnostic		
36224	Selective catheter placement, internal carotid artery, unilateral, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed	Diagnostic		
36225	Selective catheter placement, subclavian or innominate artery, unilateral, with angiography of the ipsilateral vertebral circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed	Diagnostic		
36226	Selective catheter placement, vertebral artery, unilateral, with angiography of the ipsilateral vertebral circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed	Diagnostic		

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Code	Code Description	List/File	Proposed April 2013 Placement	Notes
36227	Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation	Diagnostic		
36228	Selective catheter placement, each intracranial branch of the internal carotid or vertebral arteries, unilateral, with angiography of the selected vessel circulation and all associated radiological supervision and interpretation (eg, middle cerebral artery, posterior inferior cerebellar artery)	Diagnostic		
37197	Transcatheter retrieval, percutaneous, of intravascular foreign body (eg, fractured venous or arterial catheter), includes radiological supervision and interpretation, and imaging guidance (ultrasound or fluoroscopy), when performed	Prioritized	<b>308</b> COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
37211	Transcatheter therapy, arterial infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, initial treatment day	Prioritized	<b>270</b> ARTERIAL EMBOLISM/THROMBOSIS: ABDOMINAL AORTA, THORACIC AORTA <b>342</b> STROKE <b>378</b> ATHEROSCLEROSIS, PERIPHERAL <b>472</b> ATHEROSCLEROSIS, AORTIC AND RENAL	
37212	Transcatheter therapy, venous infusion for thrombolysis, any method, including radiological supervision and interpretation, initial treatment day	Prioritized	<b>87</b> PHLEBITIS AND THROMBOPHLEBITIS, DEEP <b>303</b> BUDD-CHIARI SYNDROME, AND OTHER VENOUS EMBOLISM AND THROMBOSIS	
37213	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed;	Prioritized	<b>87</b> PHLEBITIS AND THROMBOPHLEBITIS, DEEP <b>270</b> ARTERIAL EMBOLISM/THROMBOSIS: ABDOMINAL AORTA, THORACIC AORTA <b>303</b> BUDD-CHIARI SYNDROME, AND OTHER VENOUS EMBOLISM AND THROMBOSIS <b>342</b> STROKE <b>378</b> ATHEROSCLEROSIS, PERIPHERAL <b>472</b> ATHEROSCLEROSIS, AORTIC AND RENAL	

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Code	Code Description	List/File	Proposed April 2013 Placement	Notes
37214	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed; cessation of thrombolysis including removal of catheter and vessel closure by any method	Prioritized	<b>87 PHLEBITIS AND THROMBOPHLEBITIS, DEEP</b> <b>270 ARTERIAL EMBOLISM/THROMBOSIS: ABDOMINAL AORTA, THORACIC AORTA</b> <b>303 BUDD-CHIARI SYNDROME, AND OTHER VENOUS EMBOLISM AND THROMBOSIS</b> <b>342 STROKE</b> <b>378 ATHEROSCLEROSIS, PERIPHERAL</b> <b>472 ATHEROSCLEROSIS, AORTIC AND RENAL</b>	
38243	Hematopoietic progenitor cell (HPC); HPC boost	Prioritized	<b>79 AGRANULOCYTOSIS</b> <b>103 ACUTE LEUKEMIAS, MYELODYSPLASTIC SYNDROME</b> <b>105 HEREDITARY IMMUNE DEFICIENCIES</b> <b>125 HODGKIN'S DISEASE</b> <b>131 OTHER SPECIFIED APLASTIC ANEMIAS</b> <b>170 NON-HODGKIN'S LYMPHOMAS</b> <b>198 MULTIPLE MYELOMA</b> <b>206 CONSTITUTIONAL APLASTIC ANEMIAS</b> <b>231 TESTICULAR CANCER</b> <b>280 CHRONIC NON-LYMPHOCYTIC LEUKEMIA</b> <b>314 OSTEOPETROSIS</b>	
43206	Esophagoscopy, rigid or flexible; with optical endomicroscopy	Excluded		
43252	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with optical endomicroscopy	Excluded		
44705	Preparation of fecal microbiota for instillation, including assessment of donor specimen	Excluded		
52287	Cystourethroscopy, with injection(s) for chemodenervation of the bladder	Prioritized	<b>351 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION</b>	
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)	Excluded		
78012	Thyroid uptake, single or multiple quantitative measurement(s) (including stimulation, suppression, or discharge, when performed)	Diagnostic		
78013	Thyroid imaging (including vascular flow, when performed);	Diagnostic		

Code	Code Description	List/File	Proposed April 2013 Placement	Notes
78014	Thyroid imaging (including vascular flow, when performed); with single or multiple uptake(s) quantitative measurement(s) (including stimulation, suppression, or discharge, when performed)	Diagnostic		
78071	Parathyroid planar imaging (including subtraction, when performed); with tomographic (SPECT)	Diagnostic		
78072	Parathyroid planar imaging (including subtraction, when performed); with tomographic (SPECT), and concurrently acquired computed tomography (CT) for anatomical localization	Diagnostic		
81201	APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; full gene sequence	Diagnostic		
81202	APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; known familial variants	Diagnostic		
81203	APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; duplication/deletion variants	Diagnostic		
81235	EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)	Prioritized	278 CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS	
81252	GJB2 (gap junction protein, beta 2, 26kDa; connexin 26) (eg, nonsyndromic hearing loss) gene analysis; full gene sequence	Diagnostic		
81253	GJB2 (gap junction protein, beta 2, 26kDa; connexin 26) (eg, nonsyndromic hearing loss) gene analysis; known familial variants	Diagnostic		
81254	GJB6 (gap junction protein, beta 6, 30kDa, connexin 30) (eg, nonsyndromic hearing loss) gene analysis, common variants (eg, 309kb [del(GJB6-D13S1830)] and 232kb [del(GJB6-D13S1854)])	Diagnostic		

Code	Code Description	List/File	Proposed April 2013 Placement	Notes
81321	PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full sequence analysis	Diagnostic		
81322	PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; known familial variant	Diagnostic		
81323	PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant	Diagnostic		
81324	PMP22 (peripheral myelin protein 22) (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; duplication/deletion analysis	Diagnostic		
81325	PMP22 (peripheral myelin protein 22) (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; full sequence analysis	Diagnostic		
81326	PMP22 (peripheral myelin protein 22) (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; known familial variant	Diagnostic		
81479	Unlisted molecular pathology procedure	Suspend for Review		
81500	Oncology (ovarian), biochemical assays of two proteins (CA-125 and HE4), utilizing serum, with menopausal status, algorithm reported as a risk score	Excluded		
81503	Oncology (ovarian), biochemical assays of five proteins (CA-125, apolipoprotein A1, beta-2 microglobulin, transferrin, and pre-albumin), utilizing serum, algorithm reported as a risk score	Excluded		
81506	Endocrinology (type 2 diabetes), biochemical assays of seven analytes (glucose, HbA1c, insulin, hs-CRP, adiponectin, ferritin, interleukin 2-receptor alpha), utilizing serum or plasma, algorithm reporting a risk score	Excluded		

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Code	Code Description	List/File	Proposed April 2013 Placement	Notes
81508	Fetal congenital abnormalities, biochemical assays of two proteins (PAPP-A, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score	Prioritized	1 PREGNANCY	
81509	Fetal congenital abnormalities, biochemical assays of three proteins (PAPP-A, hCG [any form], DIA), utilizing maternal serum, algorithm reported as a risk score	Prioritized	1 PREGNANCY	
81510	Fetal congenital abnormalities, biochemical assays of three analytes (AFP, uE3, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score	Prioritized	1 PREGNANCY	
81511	Fetal congenital abnormalities, biochemical assays of four analytes (AFP, uE3, hCG [any form], DIA) utilizing maternal serum, algorithm reported as a risk score (may include additional results from previous biochemical testing)	Prioritized	1 PREGNANCY	
81512	Fetal congenital abnormalities, biochemical assays of five analytes (AFP, uE3, total hCG, hyperglycosylated hCG, DIA) utilizing maternal serum, algorithm reported as a risk score	Prioritized	1 PREGNANCY	
81599	Unlisted multianalyte assay with algorithmic analysis	Suspend for Review		
82777	Galectin-3	Excluded		
86152	Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood)	Excluded		
86153	Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood); physician interpretation and report, when required	Excluded		
86711	Antibody; JC (John Cunningham) virus	Diagnostic	35 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE 268 MULTIPLE SCLEROSIS AND OTHER DEMYELINATING DISEASES OF CENTRAL NERVOUS SYSTEM	

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Code	Code Description	List/File	Proposed April 2013 Placement	Notes
86828	Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); qualitative assessment of the presence or absence of antibody(ies) to HLA Class I and Class II HLA antigens	Prioritized	Transplant lines (78, 92, 103, 105, 110, 125, 131, 169, 170, 198, 206, 232, 253, 254, 255, 279, 280, 314, 333, 574)	
86829	Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, Flow cytometry); qualitative assessment of the presence or absence of antibody(ies) to HLA Class I or Class II HLA antigens	Prioritized	Transplant lines (78, 92, 103, 105, 110, 125, 131, 169, 170, 198, 206, 232, 253, 254, 255, 279, 280, 314, 333, 574)	
86830	Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, Flow cytometry); antibody identification by qualitative panel using complete HLA phenotypes, HLA Class I	Prioritized	Transplant lines (78, 92, 103, 105, 110, 125, 131, 169, 170, 198, 206, 232, 253, 254, 255, 279, 280, 314, 333, 574)	
86831	Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, Flow cytometry); antibody identification by qualitative panel using complete HLA phenotypes, HLA Class II	Prioritized	Transplant lines (78, 92, 103, 105, 110, 125, 131, 169, 170, 198, 206, 232, 253, 254, 255, 279, 280, 314, 333, 574)	
86832	Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, Flow cytometry); high definition qualitative panel for identification of antibody specificities (eg, individual antigen per bead methodology), HLA Class I	Prioritized	Transplant lines (78, 92, 103, 105, 110, 125, 131, 169, 170, 198, 206, 232, 253, 254, 255, 279, 280, 314, 333, 574)	
86833	Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, Flow cytometry); high definition qualitative panel for identification of antibody specificities (eg, individual antigen per bead methodology), HLA Class II	Prioritized	Transplant lines (78, 92, 103, 105, 110, 125, 131, 169, 170, 198, 206, 232, 253, 254, 255, 279, 280, 314, 333, 574)	
86834	Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, Flow cytometry); semi-quantitative panel (eg, titer), HLA Class I	Prioritized	Transplant lines (78, 92, 103, 105, 110, 125, 131, 169, 170, 198, 206, 232, 253, 254, 255, 279, 280, 314, 333, 574)	
86835	Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, Flow cytometry); semi-quantitative panel (eg, titer), HLA Class II	Prioritized	Transplant lines (78, 92, 103, 105, 110, 125, 131, 169, 170, 198, 206, 232, 253, 254, 255, 279, 280, 314, 333, 574)	

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Code	Code Description	List/File	Proposed April 2013 Placement	Notes
87631	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 3-5 targets	Diagnostic		
87632	6-11 targets	Diagnostic		
87633	12-25 targets	Diagnostic		
87910	Infectious agent genotype analysis by nucleic acid (DNA or RNA); cytomegalovirus	Diagnostic		
87912	Infectious agent genotype analysis by nucleic acid (DNA or RNA); Hepatitis B virus	Diagnostic		
88375	Optical endomicroscopic image(s), interpretation and report, real-time or referred, each endoscopic session	Excluded		
90653	Influenza vaccine, inactivated, subunit, adjuvanted, for intramuscular use	Prioritized	3 PREVENTIVE SERVICES, BIRTH TO 10 YEARS OF AGE 4 PREVENTIVE SERVICES, OVER AGE OF 10	
90672	Influenza virus vaccine, quadrivalent, live, for intranasal use	Prioritized	3 PREVENTIVE SERVICES, BIRTH TO 10 YEARS OF AGE 4 PREVENTIVE SERVICES, OVER AGE OF 10	
90739	Hepatitis B vaccine, adult dosage (2 dose schedule), for intramuscular use	Prioritized	4 PREVENTIVE SERVICES, OVER AGE OF 10	
90785	Interactive complexity (List separately in addition to the code for primary procedure)	Prioritized	MHCD Lines (5,9,27,32,68,70,107,133,180,209,212,222,269,295,305,316,334,390,398,400,412,417,419,425,431,437,445,457,462,469,471,474,481,483,487,488,496,500,508,518,521,544,546,562,569,576,588,608,609,660)	
90791	Psychiatric diagnostic evaluation	Diagnostic		
90792	Psychiatric diagnostic evaluation with medical services	Diagnostic		
90832	Psychotherapy, 30 minutes with patient and/or family member	Prioritized	MHCD Lines (see 90785)	
90833	Psychotherapy, 30 minutes with patient and/or family member when performed with an evaluation and management service	Prioritized	MHCD Lines (see 90785)	
90834	Psychotherapy, 45 minutes with patient and/or family member	Prioritized	MHCD Lines (see 90785)	
90836	Psychotherapy, 45 minutes with patient and/or family member when performed with an evaluation and management service	Prioritized	MHCD Lines (see 90785)	
90837	Psychotherapy, 60 minutes with patient and/or family member	Prioritized	MHCD Lines (see 90785)	

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Code	Code Description	List/File	Proposed April 2013 Placement	Notes
90838	Psychotherapy, 60 minutes with patient and/or family member when performed with an evaluation and management service	Prioritized	MHCD Lines (see 90785)	
90839	Psychotherapy for crisis; first 60 minutes	Prioritized	MHCD Lines (see 90785)	
90840	Psychotherapy for crisis; each additional 30 minutes	Prioritized	MHCD Lines (see 90785)	
90863	Pharmacologic management, including prescription and review of medication, when performed with psychotherapy services	Excluded		
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report	Excluded		
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch	Prioritized	<b>51</b> CORONARY ARTERY ANOMALY <b>76</b> ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION <b>108</b> HEART FAILURE <b>195</b> CHRONIC ISCHEMIC HEART DISEASE	
92921	each additional branch of a major coronary artery	Prioritized	<b>51</b> CORONARY ARTERY ANOMALY <b>76</b> ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION <b>108</b> HEART FAILURE <b>195</b> CHRONIC ISCHEMIC HEART DISEASE	
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch	Prioritized	<b>51</b> CORONARY ARTERY ANOMALY <b>76</b> ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION <b>108</b> HEART FAILURE <b>195</b> CHRONIC ISCHEMIC HEART DISEASE	
92925	each additional branch of a major coronary artery	Prioritized	<b>51</b> CORONARY ARTERY ANOMALY <b>76</b> ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION <b>108</b> HEART FAILURE <b>195</b> CHRONIC ISCHEMIC HEART DISEASE	
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	Prioritized	<b>51</b> CORONARY ARTERY ANOMALY <b>76</b> ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION <b>108</b> HEART FAILURE <b>195</b> CHRONIC ISCHEMIC HEART DISEASE	
92929	each additional branch of a major coronary artery	Prioritized	<b>51</b> CORONARY ARTERY ANOMALY <b>76</b> ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION <b>108</b> HEART FAILURE <b>195</b> CHRONIC ISCHEMIC HEART DISEASE	
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	Prioritized	<b>51</b> CORONARY ARTERY ANOMALY <b>76</b> ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION <b>108</b> HEART FAILURE <b>195</b> CHRONIC ISCHEMIC HEART DISEASE	

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Code	Code Description	List/File	Proposed April 2013 Placement	Notes
92934	each additional branch of a major coronary artery	Prioritized	51 CORONARY ARTERY ANOMALY 76 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 108 HEART FAILURE 195 CHRONIC ISCHEMIC HEART DISEASE	
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel	Prioritized	51 CORONARY ARTERY ANOMALY 76 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 108 HEART FAILURE 195 CHRONIC ISCHEMIC HEART DISEASE	
92938	each additional branch subtended by the bypass graft	Prioritized	51 CORONARY ARTERY ANOMALY 76 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 108 HEART FAILURE 195 CHRONIC ISCHEMIC HEART DISEASE	
92941	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel	Prioritized	76 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION	
92943	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel	Prioritized	51 CORONARY ARTERY ANOMALY 76 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 108 HEART FAILURE 195 CHRONIC ISCHEMIC HEART DISEASE	
92944	each additional coronary artery, coronary artery branch, or bypass graft	Prioritized	51 CORONARY ARTERY ANOMALY 76 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 108 HEART FAILURE 195 CHRONIC ISCHEMIC HEART DISEASE	

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Code	Code Description	List/File	Proposed April 2013 Placement	Notes
93653	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry	Prioritized	<b>304</b> LIFE-THREATENING CARDIAC ARRHYTHMIAS <b>376</b> CARDIAC ARRHYTHMIAS	
93654	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of ventricular tachycardia or focus of ventricular ectopy including intracardiac electrophysiologic 3D mapping, when performed, and left ventricular pacing and recording, when performed	Prioritized	<b>304</b> LIFE-THREATENING CARDIAC ARRHYTHMIAS <b>376</b> CARDIAC ARRHYTHMIAS	
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia	Prioritized	<b>304</b> LIFE-THREATENING CARDIAC ARRHYTHMIAS <b>376</b> CARDIAC ARRHYTHMIAS	
93656	Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with atrial recording and pacing, when possible, right ventricular pacing and recording, His bundle recording with intracardiac catheter ablation of arrhythmogenic focus, with treatment of atrial fibrillation by ablation by pulmonary vein isolation	Prioritized	<b>304</b> LIFE-THREATENING CARDIAC ARRHYTHMIAS <b>376</b> CARDIAC ARRHYTHMIAS	

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Code	Code Description	List/File	Proposed April 2013 Placement	Notes
93657	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation	Prioritized	376 CARDIAC ARRHYTHMIAS	
95017	Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal), sequential and incremental, with venoms, immediate type reaction, including test interpretation and report, specify number of tests	Prioritized	113 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS 234 ANAPHYLACTIC SHOCK; EDEMA OF LARYNX	
95018	Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal), sequential and incremental, with drugs or biologicals, immediate type reaction, including test interpretation and report, specify number of tests	Prioritized	11 ASTHMA 113 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS 234 ANAPHYLACTIC SHOCK; EDEMA OF LARYNX 236 OCCUPATIONAL LUNG DISEASES 338 DISORDERS INVOLVING THE IMMUNE SYSTEM 553 ATOPIC DERMATITIS 554 CONTACT DERMATITIS AND OTHER ECZEMA 575 OTHER NONINFECTIOUS GASTROENTERITIS AND COLITIS 585 ALLERGIC RHINITIS AND CONJUNCTIVITIS, CHRONIC RHINITIS 594 DERMATITIS DUE TO SUBSTANCES TAKEN INTERNALLY	
95076	Ingestion challenge test (sequential and incremental ingestion of test items, eg, food, drug or other substance); initial 120 minutes of testing	Prioritized	11 ASTHMA 113 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS 234 ANAPHYLACTIC SHOCK; EDEMA OF LARYNX 236 OCCUPATIONAL LUNG DISEASES 338 DISORDERS INVOLVING THE IMMUNE SYSTEM 553 ATOPIC DERMATITIS 554 CONTACT DERMATITIS AND OTHER ECZEMA 575 OTHER NONINFECTIOUS GASTROENTERITIS AND COLITIS 585 ALLERGIC RHINITIS AND CONJUNCTIVITIS, CHRONIC RHINITIS 594 DERMATITIS DUE TO SUBSTANCES TAKEN INTERNALLY	
95079	each additional 60 minutes of testing	Prioritized	11 ASTHMA 113 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS 234 ANAPHYLACTIC SHOCK; EDEMA OF LARYNX 236 OCCUPATIONAL LUNG DISEASES 338 DISORDERS INVOLVING THE IMMUNE SYSTEM 553 ATOPIC DERMATITIS 554 CONTACT DERMATITIS AND OTHER ECZEMA 575 OTHER NONINFECTIOUS GASTROENTERITIS AND COLITIS 585 ALLERGIC RHINITIS AND CONJUNCTIVITIS, CHRONIC RHINITIS 594 DERMATITIS DUE TO SUBSTANCES TAKEN INTERNALLY	
95782	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist	Diagnostic		

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Code	Code Description	List/File	Proposed April 2013 Placement	Notes
95783	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist	Diagnostic		
95907	Nerve conduction studies; 1-2 studies	Diagnostic		
95908	Nerve conduction studies; 3-4 studies	Diagnostic		
95909	Nerve conduction studies; 5-6 studies	Diagnostic		
95910	Nerve conduction studies; 7-8 studies	Diagnostic		
95911	Nerve conduction studies; 9-10 studies	Diagnostic		
95912	Nerve conduction studies; 11-12 studies	Diagnostic		
95913	Nerve conduction studies; 13 or more studies	Diagnostic		
95924	Testing of autonomic nervous system function; combined parasympathetic and sympathetic adrenergic function testing with at least 5 minutes of passive tilt	Diagnostic		
95940	Continuous intraoperative neurophysiology monitoring in the operating room, one on one monitoring requiring personal attendance, each 15 minutes	Ancillary		
95941	Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby) or for monitoring of more than one case while in the operating room, per hour	Ancillary		
95943	Simultaneous, independent, quantitative measures of both parasympathetic function and sympathetic function, based on time-frequency analysis of heart rate variability concurrent with time-frequency analysis of continuous respiratory activity, with mean heart rate and blood pressure measures, during rest, paced (deep) breathing, Valsalva maneuvers, and head-up postural change	Diagnostic		

## 2012 CPT Code Review

Code	Code Description	List/File	Proposed April 2013 Placement	Notes
99485	Supervision by a control physician of interfacility transport care of the critically ill or critically injured pediatric patient, 24 months of age or younger, includes two-way communication with transport team before transport, at the referring facility and during the transport, including data interpretation and report; first 30 minutes	Exempt		
99486	each additional 30 minutes	Exempt		
99487	Complex chronic care coordination services; first hour of clinical staff time directed by a physician or other qualified health care professional with no face-to-face visit, per calendar month	Prioritized	*E&M Lines (See below, final page)	
99488	Complex chronic care coordination services; first hour of clinical staff time directed by a physician or other qualified health care professional with one face-to-face visit, per calendar month	Prioritized	*E&M Lines (See below, final page)	
99489	Complex chronic care coordination services; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month	Prioritized	*E&M Lines (See below, final page)	
99495	Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge Medical decision making of at least moderate complexity during the service period Face-to-face visit, within 14 calendar days of discharge	Prioritized	*E&M Lines (See below, final page)	
99496	Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge Medical decision making of high complexity during the service period Face-to-face visit, within 7 calendar days of discharge	Prioritized	*E&M Lines (See below, final page)	

## 2012 CPT Code Review

Code	Code Description	List/File	Proposed April 2013 Placement	Notes
HCPCS Code				
G0452	Molecular pathology procedure; physician interpretation and report	Suspend for Review		
G0453	Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby), per patient, (attention directed exclusively to one patient) each 15 minutes (list in addition to primary procedure)	Ancillary		
G0454	Physician documentation of face-to-face visit for durable medical equipment determination performed by nurse practitioner, physician assistant or clinical nurse specialist	Ancillary		
G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen	Excluded		
G0456	Negative pressure wound therapy, (e. G. Vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions f	Ancillary		
G0457	Negative pressure wound therapy, (e. G. Vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions f	Ancillary		
G0458	Low dose rate (ldr) prostate brachytherapy services, composite rate	Prioritized	356 CANCER OF PROSTATE GLAND	
S0353	Treatment planning and care coordination management for cancer, initial treatment	Ancillary		
S0354	Treatment planning and care coordination management for cancer, established patient with a change of regimen	Ancillary		
S3721	Prostate cancer antigen 3 (pca3) testing	Excluded		
S8930	Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with the patient		No decision made. Will review at the January, 2013 VBBS meeting	

Code	Code Description	List/File	Proposed April 2013 Placement	Notes
<b>CDT Codes</b>				
D0190	Screening of a patient - a screening, including state or federally mandated screenings, to determine an individual's need to be seen by a dentist for diagnosis.	Excluded		
D0191	Assessment of a patient - a limited clinical inspection that is performed to identify possible signs of oral or systemic disease malformation or injury and the potential need for referral for diagnosis and treatment.	Prioritized	58 PREVENTIVE DENTAL SERVICES	Updated Guideline
D0220- D0330	<i>Change to descriptions, replacing "film" or "bitewings" with radiographic image. 14 codes</i>	Diagnostic		
D0340	CEPHALOMETRIC RADIOGRAPHIC IMAGES	Prioritized	647 DENTAL CONDITIONS (EG. MALOCCLUSION)	
D0364	Cone beam CT capture and interpretation with limited field of view less than one whole jaw	Excluded		
D0365	Cone beam CT capture and interpretation with field of view of one full dental arch - mandible	Excluded		
D0366	Cone beam CT capture and interpretation with field of view one full dental arch – maxilla with or without cranium	Excluded		
D0367	Cone beam CT capture and interpretation with field of view of both jaws with or without cranium	Excluded		
D0368	Cone beam CT capture and interpretation for TMJ series including two or more exposures	Excluded		
D0369	Maxillofacial MRI capture and interpretation	Excluded		
D0370	Maxillofacial ultrasound, capture and interpretation	Excluded		
D0371	Sialoendoscopy –capture and interpretation	Excluded		
D0380	Cone beam CT image capture with limited field of view – less than one whole jaw	Excluded		
D0381	Cone beam CT image capture with field of view of one full dental arch – mandible	Excluded		
D0382	Cone beam CT image capture with field of view one full dental arch – maxilla, with and without cranium	Excluded		

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Code	Code Description	List/File	Proposed April 2013 Placement	Notes
D0383	Cone beam CT image capture with field of view of both jaws, with or without cranium.	Excluded		
D0384	Cone beam CT capture images for TMJ series including two or more exposures	Excluded		
D0385	Maxillofacial MRI image capture	Excluded		
D0386	Maxillofacial ultrasound image capture	Excluded		
D0391	Interpretation of diagnostic image by a practitioner not associated with capture of the image, including report	Excluded		
D1206	Topical application of fluoride varnish	Prioritized	58 PREVENTIVE DENTAL SERVICES	
D1208	Topical application of fluoride	Prioritized	58 PREVENTIVE DENTAL SERVICES	
D2710	Crown resin-based composite (indirect)	Prioritized	494 ADVANCED RESTORATIVE DENTAL SERVICES (I.E. BASIC CROWNS)	
D2799	Provisional Crown – Further treatment or completion of a diagnosis necessary prior to final impression. Not to be used as a temporary crown for a routine prosthetic restoration.	Prioritized	676 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT	
D2929	Prefabricated porcelain/ceramic crown- primary tooth	Prioritized	621 ELECTIVE ADVANCED RESTORATIVE (INLAYS,ONLAYS,GOLD FOIL AND HIGH NOBLE METAL RESTORATIONS)	
D2940	Protective restoration Direct placement of a restorative material to protect tooth and/or tissue form. This procedure may be used to relieve pain, promote healing, or prevent further deterioration. Not to be used for endodontic access closure, or as a base or liner under restoration.	Prioritized	283 URGENT DENTAL SERVICES	
D2955	Post removal	Prioritized	676 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT	
D2980	Crown repair, necessitated by restorative material failure	Prioritized	372 BASIC RESTORATIVE DENTAL SERVICES	
D2981	Inlay repair, necessitated by restorative material failure.	Prioritized	621 ELECTIVE ADVANCED RESTORATIVE (INLAYS,ONLAYS,GOLD FOIL AND HIGH NOBLE METAL RESTORATIONS)	
D2982	Onlay repair, necessitated by restorative material failure	Prioritized	621 ELECTIVE ADVANCED RESTORATIVE (INLAYS,ONLAYS,GOLD FOIL AND HIGH NOBLE METAL RESTORATIONS)	
D2983	Veneer repair, necessitated by restorative material failure	Prioritized	675 DENTAL CONDITIONS WHERE TREATMENT IS CHOSEN PRIMARILY FOR AESTHETIC CONSIDERATIONS	
D2990	Resin infiltration of incipient smooth surface lesions – placement of an infiltrating resin restoration for strengthening, stabilizing and/or limiting the progression of the lesion	Prioritized	676 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT	

Code	Code Description	List/File	Proposed April 2013 Placement	Notes
D3352	Apexifaction/recalcification/pulpal regeneration) - interim medication replacement. For visits in which the intra-canal medication is replaced with new medication. Includes any necessary radiographs."	Prioritized	283 URGENT DENTAL SERVICES	
D4210	Gingivectomy or gingivoplasty - four or more contiguous teeth or bounded teeth spaces per quadrant. It is performed to eliminate suprabony pockets or to restore normal architecture when gingival enlargements or asymmetrical or unaesthetic topography is e	Prioritized	232 BASIC PERIODONTICS	Updated Guideline
D4211	Gingivectomy or gingivoplasty -four or more contiguous teeth tooth bounded spaces per quadrant. It is performed to eliminate suprabony pockets or to restore normal architecture when gingival enlargements or asymmetrical or unaesthetic topography is evide	Prioritized	232 BASIC PERIODONTICS	Updated Guideline
D4212	Gingivectomy or gingivoplasty - to allow access for restorative procedures - per tooth	Prioritized	232 BASIC PERIODONTICS	Updated Guideline
D4260	Osseous surgery - (including flap entry & closure - four or more contiguous teeth or tooth bonded spaces per quadrant. The procedure modifies the bony support of teeth by reshaping the alveolar process to achieve a more physiologic form. This must inclu	Prioritized	522 ADVANCED PERIODONTICS	
D4261	Osseous surgery - one to three contiguous teeth or tooth bonded spaces per quadrant. The procedure modifies the bony support of teeth by reshaping the alveolar process to achieve a more physiologic form. This must include the removal of supporting bone	Prioritized	523 ADVANCED PERIODONTICS	
D4266	Guided tissue regeneration -- resorbable barrier, per site This procedure does not include flap entry or closure, or, when indicated, wound debridement, osseous contouring, bone replacement grafts, and placement of biologic materials to aid in osseous reg	DMAP Excluded File	DMAP Excluded File	

Code	Code Description	List/File	Proposed April 2013 Placement	Notes
D4267	Guided tissue regeneration -- non-resorbable barrier, per site (includes membrane removal) This procedure does not include flap entry or closure, or, when indicated, wound debridement, osseous contouring, bone replacement grafts, and placement of biologic	DMAP Excluded File		
D4277	Free soft tissue graft procedure (including donor site surgery) - first tooth or edentulous tooth site in graft	Prioritized	522 ADVANCED PERIODONTICS (E.G. SURGICAL PROCEDURES AND SPLINTING)	
D4278	Free soft tissue graft procedure (including donor site surgery) -each additional contiguous tooth position in same graft site	Prioritized	522 ADVANCED PERIODONTICS (E.G. SURGICAL PROCEDURES AND SPLINTING)	
D4381	Localized delivery of antimicrobial agents via controlled release vehicle into diseased crevicular tissue, per tooth. FDA approved subgingival delivery devices containing antimicrobial medication(s) are inserted into periodontal pockets to suppress the p	Prioritized	522 ADVANCED PERIODONTICS	
D6051	Interim abutment - includes placement and removal. A healing cap is not an interim abutment	Prioritized	648 IMPLANTS (I.E. IMPLANT PLACEMENT AND ASSOCIATED CROWN OR PROSTHESIS)	
D6056	Prefabricated abutment - includes modification and placement. Modification of a prefabricated abutment may be necessary	Prioritized	648 IMPLANTS	
D6057	Custom fabricated abutment - includes placement – Created by a laboratory process specific for an individual application	Prioritized	648 IMPLANTS	
D6101	Debridement of a periimplant defect and surface cleaning of exposed implant surfaces, including flap entry and closure	Prioritized	648 IMPLANTS	
D6102	Debridement and osseous contouring of a periimplant defect; includes surface cleaning of exposed implant surfaces and flap entry and closure	Prioritized	648 IMPLANTS	
D6103	Bone graft for repair of periimplant defect – not including flap entry and closure or when indicated, placement of a barrier membrane or biologic materials to aid in osseous regeneration	Prioritized	648 IMPLANTS	

## 2012 CPT Code Review

Code	Code Description	List/File	Proposed April 2013 Placement	Notes
D6104	Bone graft at time of implant placement – placement of a barrier membrane, or biologic materials at aid in osseous regeneration are reported separately	Prioritized	648 IMPLANTS	
D6253	Provisional Pontic – Further treatment or completion of a diagnosis necessary prior to final impression. Not be used as a temporary pontic for routine prosthetic fixed partial dentures.	Prioritized	621 ELECTIVE ADVANCED RESTORATIVE (INLAYS, ONLAYS, GOLD FOIL AND HIGH NOBLE METAL RESTORATIONS)	
D6793	Provisional Retainer Crown – Further treatment of completion or a diagnosis necessary prior to final impression. Not be used as a temporary retainer crown for routine prosthetic fixed partial dentures.	Prioritized	621 ELECTIVE ADVANCED RESTORATIVE (INLAYS, ONLAYS, GOLD FOIL AND HIGH NOBLE METAL RESTORATIONS)	
D6975	Coping	Prioritized	631 COMPLEX PROSTHODONTICS	
D6980	Fixed partial denture repair, repair necessitated by restorative material failure	Prioritized	372 BASIC RESTORATIVE DENTAL WORK	
D7921	Collection and application of autologous blood concentrate product	Excluded		
D7951	Sinus augmentation with bone or bone substitutes via a lateral open approach - The augmentation of the sinus cavity to increase alveolar height for reconstruction of edentulous portions of the maxilla. This procedure is performed via a lateral open approach. This includes obtaining the bone or bone substitutes. Placement of a barrier membrane if used should be reported separately.	Prioritized	648 DENTAL CONDITIONS (EG. MISSING TEETH)	
D7952	Sinus augmentation via a vertical approach - The augmentation of the sinus to increase alveolar height by vertical access through the ridge crest by raising the floor of the sinus and grafting as necessary. This includes obtaining the bone or bone substitutes.	Prioritized	648 DENTAL CONDITIONS (EG. MISSING TEETH)	
D9972	External bleaching per arch - performed in office	Prioritized	675 COSMETIC DENTAL SERVICES	
D9975	External bleaching - external bleaching system for applications - per arch includes materials and fabrication of custom trays	Prioritized	675 COSMETIC DENTAL SERVICES	

## Evaluation & Management (E&M) Lines

1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31,32,33,34,35,36,37,38,39,40,41,42,43,44,45,46,47,48,49,50,51,52,53,54,55,56,57,58,59,61,62,63,64,65,66,67,68,69,71,72,73,74,75,76,77,78,79,80,81,82,83,84,85,87,88,89,90,91,93,94,95,96,97,98,99,100,101,102,104,106,107,108,109,111,112,113,114,115,116,117,118,119,120,121,122,123,124,126,127,128,129,130,132,133,134,135,136,137,138,139,140,141,142,143,144,145,146,147,148,149,150,151,152,153,154,155,156,157,158,159,160,161,162,163,164,165,166,167,168,171,173,174,175,176,178,179,180,181,183,184,185,186,187,188,189,190,191,192,193,194,195,196,197,199,200,201,202,203,204,205,207,208,209,210,211,212,213,214,215,216,217,218,219,220,221,222,223,224,225,226,227,228,229,230,233,234,235,236,237,238,239,240,241,242,243,244,245,246,248,249,250,251,252,256,257,258,259,260,261,262,263,264,265,266,267,268,269,270,271,272,273,274,275,276,277,278,279,281,282,283,284,285,286,287,288,289,290,291,292,293,294,295,296,297,299,300,301,302,303,304,305,306,307,308,309,310,311,312,313,315,316,317,318,319,320,321,323,324,325,326,327,328,329,330,331,332,334,335,336,337,338,339,340,341,342,343,344,345,347,348,349,351,352,353,354,355,356,357,360,361,362,363,364,365,366,367,368,369,370,371,375,376,377,378,379,380,381,382,383,384,385,386,387,388,389,390,391,394,395,396,397,398,400,402,403,404,405,406,407,408,409,410,412,413,415,416,417,418,419,420,421,422,423,424,425,426,427,428,429,430,431,432,433,434,435,437,438,439,440,441,442,443,444,445,446,447,448,449,450,451,452,453,454,455,457,458,459,460,461,462,463,465,466,467,469,470,471,472,473,474,475,476,478,479,481,482,483,484,485,486,487,488,489,490,492,493,495,496,497,498,499,500,501,502,503,504,505,506,507,508,509,510,511,512,514,515,516,517,518,519,521,523,526,527,528,529,530,532,534,535,536,537,538,539,541,542,543,544,545,546,547,549,550,551,552,553,554,555,556,559,560,561,562,563,564,565,566,567,568,569,570,571,572,573,574,575,576,577,578,579,580,581,582,583,585,589,591,592,594,595,596,597,598,599,600,601,602,603,604,605,606,607,608,609,610,611,613,614,615,616,617,618,619,620,622,623,624,625,627,628,630,634,635,636,637,638,639,641,642,643,644,645,646,649,650,651,652,653,655,656,658,659,660,661,662,663,664,665,666,667,668,669,670,671,673,674,675,676,678,680,681,682,683,684,685,686,687,688,689,690,691,692

## **Appendix B**

### **New Guidelines**

#### **New Guidelines for the April 1, 2013 Prioritized List**

##### **GUIDELINE NOTE XXX, CHEMODENERVATION OF THE BLADDER**

*Line 351*

Chemodenervation of the bladder (CPT 55287) is included on this line only for treatment of overactive bladder caused by spinal cord injury, multiple sclerosis, and other spinal cord diseases in patients in whom appropriate pharmacologic therapy have proven to be ineffective or poorly tolerated.

#### **New Guidelines for the October 1, 2014 ICD-10 Prioritized List**

##### **GUIDELINE XXX, GENDER DYSPHORIA**

*Line 521*

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

## Appendix C

### Revised Guidelines

#### DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE

Coverage of genetic testing in a non-prenatal setting shall be determined by the algorithm shown in Figure C.1 unless otherwise specified below.

A) Related to genetic testing for patients with breast/ovarian and colon/endometrial cancer suspected to be hereditary, or patients at increased risk to due to family history.

1) Services are provided according to the Comprehensive Cancer Network Guidelines.

a) Lynch syndrome (hereditary colorectal and endometrial cancer) services (CPT 81292-81300, 81317-81319) and familial adenomatous polyposis (FAP) services (CPT 81201-81203) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Colorectal Cancer Screening. V.2.2011~~42~~ (4/22/10 4/27/12). [www.nccn.org](http://www.nccn.org)

b) BRCA1/BRCA2 testing services (CPT 81211-81217) for women without a personal history of breast and/or ovarian cancer should be provided to high risk women as defined in **GUIDELINE NOTE 3, PROPHYLACTIC TREATMENT FOR PREVENTION OF BREAST CANCER IN HIGH RISK WOMEN** or as otherwise defined by the US Preventive Services Task Force

c) BRCA1/BRCA2 testing services (CPT 81211-81217) for women with a personal history of breast and/or ovarian cancer and for men with breast cancer should be provided according to the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovarian. V.1.2011 (4/7/11).

[www.nccn.org](http://www.nccn.org)

d) PTEN (Cowden syndrome) services (CPT 81321-81323) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Colorectal Cancer Screening. V.1.2012 (5/2/12).  
[www.nccn.org](http://www.nccn.org)

2) Genetic counseling should precede genetic testing for hereditary cancer. Very rarely, it may be appropriate for a genetic test to be performed prior to genetic counseling for a patient with cancer. If this is done, genetic counseling should be provided as soon as practical.

a) Pre and post-test genetic counseling by the following providers should be covered.

i) Medical Geneticist (M.D.) - Board Certified or Active Candidate Status from the American Board of Medical Genetics

ii) Clinical Geneticist (Ph.D.) - Board Certified or Active Candidate Status from the American Board of Medical Genetics.

## Appendix C

- iii) Genetic Counselor - Board Certified or Active Candidate Status from the American Board of Genetic Counseling, or Board Certified by the American Board of Medical Genetics.
- iv) Advance Practice Nurse in Genetics - Credential from the Genetic Nursing Credentialing Commission.

3) If the mutation in the family is known, only the test for that mutation is covered. For example, if a mutation for BRCA 1 has been identified in a family, a single site mutation analysis for that mutation is covered (CPT 81215), while a full sequence BRCA 1 and 2 (CPT 81211) analyses is not. There is one exception, for individuals of Ashkenazi Jewish ancestry with a known mutation in the family, the panel for Ashkenazi Jewish BRCA mutations is covered (CPT 81212).

4) Costs for rush genetic testing for hereditary breast/ovarian and colon/endometrial cancer is not covered.

B) Related to diagnostic evaluation of individuals with intellectual disability (defined as a full scale or verbal IQ < 70 in an individual > age 5), developmental delay (defined as a cognitive index <70 on a standardized test appropriate for children < 5 years of age), Autism Spectrum Disorder, or multiple congenital anomalies:

1) CPT 81228, Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (eg, Bacterial Artificial Chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis): Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder.

2) CPT 81229, Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder; ONLY IF consanguinity AND recessive disease is suspected, OR UPD (uniparental disomy) is suspected, OR other suspected mechanism that is not detected by the oligo microarrays (CPT 81228).

3) Array-based evaluation of multiple molecular probes (CPT 88384-88386) will be covered for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder for 2012.

4) CPT 81243, 81244, Fragile X genetic testing is covered for individuals with intellectual disability/developmental delay. Although the yield of Fragile X is 3.5-10%, this is included because of additional reproductive implications.

## Appendix C

5) A visit with the appropriate specialist (often genetics, developmental pediatrics, or child neurology), including physical exam, medical history, and family history is covered. Physical exam, medical history, and family history by the appropriate specialist, prior to any genetic testing is often the most cost-effective strategy and is encouraged.

### C) Related to other tests with specific CPT codes:

#### 1). The following tests are not covered:

- a. CPT 81225, CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, \*2, \*3, \*5, \*6)
- b. 81226, CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism), gene analysis, common variants (eg, \*2, \*3, \*4, \*5, \*6, \*9, \*10, \*17, \*19, \*29, \*35, \*41, \*1XN, \*2XN, \*4XN).
- c. CPT 81227, CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, \*2, \*3, \*5, \*6)
- d. CPT 81291, MTHFR (5,10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis, common variants (eg, 677T, 1298C)
- e. 81330, SMPD1 (sphingomyelin phosphodiesterase 1, acid lysosomal) (eg, Niemann-Pick disease, Type A) gene analysis, common variants (eg, R496L, L302P, fsP330)
- f. 81350, UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (eg, irinotecan metabolism), gene analysis, common variants (eg, \*28, \*36, \*37)
- g. CPT 81355, VKORC1 (vitamin K epoxide reductase complex, subunit 1) (eg, warfarin metabolism), gene analysis, common variants (eg, -1639/3673)

#### 2) The following tests are covered only if they meet the criteria for the Non-Prenatal Genetic Testing Algorithm AND the specified situations:

- a. CPT 81205, BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (eg, Maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X): Cover only when the newborn screening test is abnormal and serum amino acids are normal
- b. CPT 81223, CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; full gene sequence: covered for patients who are symptomatic or who have positive newborn screening for CF AND genetic testing for common mutations is negative AND if the patients ethnicity has <90% coverage by common mutation panels.
- c. CPT 81224, CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; intron 8 poly-T analysis (eg, male infertility): Covered only after genetic counseling.
- d. CPT 81240, F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant: Not covered for routine testing in the following circumstances: (1) adults with idiopathic venous thromboembolism. (2) Asymptomatic adult family members of

## Appendix C

patients with idiopathic venous thromboembolism and F5 mutation, for the purpose of considering primary prophylactic anticoagulation. Test may have clinical utility in other circumstances, e.g. family history of coagulopathy, deciding short range anticoagulation therapy, problems with anticoagulation therapy management, multiple pregnancy losses.

- e. CPT 81241, F5 (coagulation Factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant: Not covered for routine testing in the following circumstances: (1) adults with idiopathic venous thromboembolism. (2) Asymptomatic adult family members of patients with idiopathic venous thromboembolism and F5 mutation, for the purpose of considering primary prophylactic anticoagulation. Test may have clinical utility in other circumstances, e.g. family history of coagulopathy, deciding short range anticoagulation therapy, problems with anticoagulation therapy management, multiple pregnancy losses.
- f. CPT 81256, HFE (hemochromatosis) (eg, hereditary hemochromatosis) gene analysis, common variants (eg, C282Y, H63D): Covered for diagnostic testing of patients with elevated transferrin saturation or ferritin levels. Covered for predictive testing ONLY when a first degree family member has treatable iron overload from HFE.
- g. 81332 SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1) (eg, alpha-1-antitrypsin deficiency), gene analysis, common variants (eg, \*S and \*Z): The alpha-1-antitrypsin protein level should be the first line test of a suspected diagnosis of AAT deficiency in symptomatic individuals with unexplained liver disease or obstructive lung disease that is not asthma or in a middle age individual with unexplained dyspnea. Generic testing or the alpha-1 phenotype test is appropriate if the protein test is abnormal or borderline. The genetic test is appropriate for siblings of people with AAT deficiency regardless of the AAT protein test results.

3) Do not cover a more expensive genetic test (generally one with a wider scope or more detailed testing) if a cheaper (smaller scope) test is available and has, in this clinical context, a substantially similar sensitivity. For example, do not cover CFTR gene sequencing as the first test in a person of Northern European Caucasian ancestry because the gene panels are less expensive and provide substantially similar sensitivity in that context.

### **GUIDELINE NOTE 17, PREVENTIVE DENTAL CARE**

*Line 58*

Dental cleaning and fluoride treatments are limited to once per 12 months for adults and twice per 12 months for children up to age 19 (D1110, D1120, D1203, D1204, D1206). More frequent dental cleanings and/or fluoride treatments may be required for certain higher risk populations. [Additionally, assessment \(D0191\) may be performed once per 12 months for adults and twice per 12 months for children up to age 19.](#)

## Appendix C

### GUIDELINE NOTE 53, BASIC PERIODONTICS

*Line 232*

Only for the treatment of severe drug-induced hyperplasia (D4210, D4211, [D4212](#)). Payable only when there are pockets of 5 mm or greater (D4341).

### ~~GUIDELINE NOTE 91, ONE SURFACE POSTERIOR COMPOSITE RESTORATIONS~~

~~*Line 372*~~

~~HCPSC code D2391 is only included on this line for one surface posterior composite restorations on occlusal surfaces and class V surfaces in the esthetic zone (buccal surfaces of teeth 3,4,5,12,13,14,19,20,21,28,29,30,A,B,I,J,K,L,S,T).~~

### GUIDELINE NOTE 51, CHRONIC OTITIS MEDIA WITH EFFUSION

*Line 502*

Antibiotic and other medication therapy ([including antihistamines, decongestants, and nasal steroids](#)) are not indicated for children with chronic otitis media with effusion (OME) ([without another appropriate diagnosis](#)).

[There should be a 3 to 6 month watchful waiting period after diagnosis of otitis media with effusion, and if documented hearing loss is greater than or equal to 25dB in the better hearing ear, tympanostomy surgery may be indicated given short but not long term improvement in hearing. Formal audiometry is indicated for](#) cChildren with chronic OME present for 3 months or longer. ~~or~~ [Children](#) with language delay, learning problems, or significant hearing loss ~~at any time~~ should have hearing testing [upon diagnosis](#). Children with chronic OME who are not at risk [for language or developmental delay](#) should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

For the child who has had chronic OME and who has a hearing deficiency in the better-hearing ear of 25 dB or greater, myringotomy with tube insertion [is](#) recommended after a total of 4 to 6 months of effusion with a documented hearing deficit.

Adenoidectomy [is not indicated at the time of first pressure equalization tube insertion](#). ~~It may be indicated in~~ ~~is an appropriate surgical treatment for chronic OME~~ in children over 3 years ~~with~~ [who are having](#) their second set of tubes. ~~First time tubes are not an indication for an adenoidectomy.~~

[Tube insertion should be covered for patients with craniofacial anomalies, Down's syndrome, cleft palate, and patients with speech and language delay along with co-morbid hearing loss.](#)

## Coronary Brachytherapy

### **Issue:**

During the 2013 CPT code review of cardiac stenting, HERC staff identified that the CPT code for coronary brachytherapy is on multiple inappropriate lines.

Description: Intracoronary brachytherapy with gamma or beta radioactive ribbons for the management of in-stent restenosis of native coronary vessels following successful PTCA. Multiple contraindications exist, including acute MI, left ventricular ejection fraction <40%, and type of lesion.

Current list placement: CPT code 92974 (Transcatheter placement of radiation delivery device for subsequent coronary intravascular brachytherapy) is currently on multiple lines (approximately 40). It is only used for coronary artery stent issues. At the 2013 CPT code review, cardiac stenting was limited to 4 lines with coronary artery disease diagnoses. The coronary brachytherapy code is therefore on multiple lines that are inappropriate.

### Recommendation:

- 1) Remove 92974 from all current lines except
  - i. **51 CORONARY ARTERY ANOMALY**
  - ii. **76 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION**
  - iii. **108 HEART FAILURE**
  - iv. **195 CHRONIC ISCHEMIC HEART DISEASE**

## External Elements Exposure Issue Summary

Question: Should changes in coverage be made for a variety of “exposure” to element conditions?

Question Source: Jim Beggs, Medical Director, CCC

Issue:

Dr. Beggs raised concerns that motion sickness is covered for OHP, and simultaneously realized that the 994 series probably needed a re-look. He raised concerns as to whether OHP should cover G-force and weightlessness complications or exhaustion. He also raised the concern that many of these codes appear to be “secondary descriptors rather than primary illnesses and coverage should perhaps derive from their specific effect rather than how it happens.”

### **994 Effects of other external causes**

Excludes: certain adverse effects not elsewhere classified (995.0-995.8)

994.0 Effects of lightning ➡ COVERED

Shock from lightning  
Struck by lightning NOS

Excludes:  
burns (940.0-949.5)

994.1 Drowning and nonfatal submersion ➡ COVERED

Bathing cramp  
Immersion

994.2 Effects of hunger ➡ NOT Covered

Deprivation of food

**Starvation**

994.3 Effects of thirst ➡ NOT Covered

Deprivation of water

994.4 **Exhaustion** due to exposure ➡ COVERED

994.5 **Exhaustion** due to excessive exertion ➡ COVERED

Exhaustion due to overexertion

994.6 **Motion sickness** ➡ COVERED

**Air sickness**

**Seasickness**

**Travel sickness**

994.7 Asphyxiation and strangulation ➡ COVERED

Suffocation (by):

bedclothes  
cave-in  
constriction  
mechanical  
plastic bag  
pressure

## External Elements Exposure Issue Summary

strangulation

Excludes:

asphyxia from:

carbon monoxide (986)

inhalation of food or foreign body (932-934.9)

other gases, fumes, and vapors (987.0-987.9)

994.8 Electrocution and nonfatal effects of electric current ➡ COVERED

Shock from electric current

Shock from electroshock gun (taser)

Excludes:

electric burns (940.0-949.5)

994.9 Other effects of external causes ➡ COVERED

Effects of:

abnormal gravitational [**G**] forces or states

**weightlessness**

### HERC Staff additional background:

994.2 and 994.3 are in the funded region of the List, on Line 132.

Code	Description	Line Placement
994.2	Effects of hunger	132 PHYSICAL AND SEXUAL ABUSE INCLUDING RAPE
994.3	Effects of thirst	132 PHYSICAL AND SEXUAL ABUSE INCLUDING RAPE

### HERC Staff Recommendations

*If recommendation column is blank, no change is recommended.*

Line 187 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (EG. LIGHTNING STRIKE, HEATSTROKE)		
Code	Description	Recommendation
692.77	Sunburn of third degree	
991.0	Frostbite of face	
991.1	Frostbite of hand	
991.2	Frostbite of foot	

## External Elements Exposure Issue Summary

<b>Line 187 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (EG. LIGHTNING STRIKE, HEATSTROKE)</b>		
<b>Code</b>	<b>Description</b>	<b>Recommendation</b>
991.3	Frostbite of other and unspecified sites	
991.4	Immersion foot	
991.5	Chilblains	
991.8	Other specified effects of reduced temperature	
991.9	Unspecified effect of reduced temperature	
992.0	Heat stroke and sunstroke	
992.1	Heat syncope	
992.2	Heat cramps	
992.3	Heat exhaustion, anhydrotic	
992.4	Heat exhaustion due to salt depletion	
992.5	Heat exhaustion, unspecified	
992.6	Heat fatigue, transient	
992.7	Heat edema	
992.8	Other specified heat effects	
992.9	Unspecified effects of heat and light	688 DERMATOLOGICAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
993.2	Other and unspecified effects of high altitude	
994.0	Effects of lightning	
994.1	Drowning and nonfatal submersion	
994.4	Exhaustion due to exposure	
994.5	Exhaustion due to excessive exertion	691 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
994.6	Motion sickness	539 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM
994.7	Asphyxiation and strangulation	
994.8	Electrocution and nonfatal	

## External Elements Exposure Issue Summary

Line 187 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (EG. LIGHTNING STRIKE, HEATSTROKE)		
Code	Description	Recommendation
	effects of electric current	
994.9	Other effects of external causes (abnormal gravitational forces or states weightlessness)	
995.89	Other specified adverse effects, not elsewhere classified (hypothermia due to anesthesia)	

And with ICD-10

Code	Description	Prior Placement	Recommended Placement
992.9	Unspecified effects of heat and light	187	688
994.5	Exhaustion due to excessive exertion	187	691
994.6	Motion sickness	187	539
T67.9xxA	Effect of heat and light, unspecified, initial encounter	187	187
T67.9xxD	Effect of heat and light, unspecified, subsequent encounter	DMAP Ancillary Codes File	688
T73.3xxA	Exhaustion due to excessive exertion, initial encounter	DMAP Ancillary Codes File,187	691
T75.3xxA	Motion sickness, initial encounter	DMAP Ancillary Codes File,187	539

# Stereotactic Radiosurgery for Intracranial Arteriovenous Malformations

Question: Should stereotactic radiosurgery be covered for treatment of intracranial arteriovenous malformations (AVMs)?

Question source: OHP Medical Director

Issue: cerebral AVMs (ICD-9 747.81) are on Line 201 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN. There are various treatments on this line, including embolization and intracranial surgery. Intracranial stereotactic radiosurgery (CPT 77263-77295, 77300, 77332-77336, 77370-77372, 77402-77416, 77432) is on various lines for treatment of benign and malignant tumors of the CNS. However, it is currently not covered for treatment of AVMs.

From Dr. Chris Kirk:

We have a member with “anomaly of cerebrovascular system” – ICD-9 code 747.81. It is a deep parietal AVM. He cannot have surgery due to its deep location. It is not amenable to embolization because of its lack of a specific arterial vessel that can be embolized. The team at OHSU would like to treat him with Stereotactic Radiosurgery (CPT codes: 77263, 77280, 77295, 77300, 77334, 77336, 77370, 77414, 77417, 77432, 77371, 77372) They make the claim that this is “...a commonly accepted treatment method for this patient’s situation...” and that it is supported in the literature (they offered no citations).

## Evidence

- 1) **Friedlander 2007**, review of AVMs
  - a. Radiosurgery is often recommended if an arteriovenous malformation is less than 3 cm in diameter and is located in an eloquent area where surgery is likely to cause a neurologic deficit.
  - b. Although data from randomized trials to guide the choice of intervention are lacking, treatment (surgical resection, radiosurgery, embolization, or a combination of these) is generally considered appropriate for arteriovenous malformations that are grade I to III.<sup>24,33</sup> The choice of therapy will depend on the specific features of the lesion, with consideration of the age of the patient, presence or absence of bleeding and associated aneurysms, diameter and location of associated aneurysms, and pattern of venous drainage.
- 2) **Fleetwood 2002**, review of AVMs
  - a. All three treatment modalities—microsurgery, endovascular embolisation, and radiosurgery—have an established role in treatment of patients with arteriovenous malformations

## Stereotactic Radiosurgery for Intracranial Arteriovenous Malformations

### 3) Other policies

#### a. Aetna 2012

- i. Cranial stereotactic radiosurgery with a gamma knife, Cyberknife, or linear accelerator (LINAC) is considered medically necessary when used for treatment of members with symptomatic, small (less than 3 cm) arterio-venous (AV) malformations, aneurysms, and benign tumors (acoustic neuromas (vestibular schwannomas), meningiomas, hemangiomas, pituitary adenomas, craniopharyngiomas, and neoplasms of the pineal gland) if the lesion is unresectable due to its deep intracranial location or if the member is unable to tolerate conventional operative intervention

#### b. Cigna 2012

- i. Covers stereotactic radiosurgery for arteriovenous malformation of the brain or spine

Summary: intracranial stereotactic radiosurgery appears to be a standard, accepted treatment for certain patients with AVMs

#### Recommendation:

- 1) Add intracranial stereotactic radiosurgery to line 201 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
  - a. 77263-77295, 77300, 77332-77336, 77370-77372, 77402-77416, 77432

## Personal History of Cancer V Codes

Question: should additional personal history of cancer diagnosis codes be on funded lines?

Question source: DMAP and HERC staff

Issue: Most V10 series codes (personal history of cancer) are located on funded lines. For many cancers, there is an altered screening schedule (more frequent colonoscopy in colon cancer, for example) or screening modality (e.g. breast MRI instead of mammogram in breast cancer) if a patient has a history of that cancer. Other cancer survivors may need periodic PET scans, X-rays, blood work, specialist visits, or other types of surveillance and follow up.

Most V10 codes are located on funded lines. However, 2 are located on unfunded lines and several are located on the Excluded List. These should be considered for movement to funded lines. There are several “unspecified” codes that are Excluded and should remain so.

Recommendation:

- 1) Adopt the changes outlined in the following table

## Personal History of Cancer V Codes

<b>Code</b>	<b>Code Description</b>	<b>Current Location</b>	<b>Proposed Location</b>	<b>Notes/Comments</b>
V10.09	Personal history of malignant neoplasm of other gastrointestinal tract	Excluded	<b>165</b> CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS <b>277</b> CANCER OF RETROPERITONEUM, PERITONEUM, OMENTUM AND MESENTERY <b>341</b> CANCER OF PANCREAS <b>459</b> CANCER OF GALLBLADDER AND OTHER BILIARY	Indicated for use in ICD-9: cancer of pancreas, small intestine, gallbladder, retroperitoneum, and similar
V10.29	Personal history of malignant neoplasm of other respiratory and intrathoracic organs	Excluded	<b>207</b> CANCER OF SOFT TISSUE <b>276</b> CANCER OF ENDOCRINE SYSTEM, EXCLUDING THYROID; CARCINOID SYNDROME <b>278</b> CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS	Indicated for use in ICD-9: cancer of pleura, thymus, heart, mediastinum
V10.44	Personal history of malignant neoplasm of other female genital organs	Excluded	<b>311</b> CANCER OF VAGINA, VULVA AND OTHER FEMALE GENITAL ORGANS	Indicated for use in ICD-9: cancer of vagina, vulva
V10.69	Personal history of other leukemia	Excluded	<b>181</b> ACUTE NON-LYMPHOCYTIC LEUKEMIAS <b>310</b> CHRONIC LEUKEMIAS; POLYCYTHEMIA RUBRA VERA	Indicated for use in ICD-9: other specified leukemia (207 family), unspecified leukemia (208 family)
V10.79	Personal history of other lymphatic and hematopoietic neoplasms	Excluded	<b>221</b> NON-HODGKIN'S LYMPHOMAS <b>249</b> ACUTE LYMPHOCYTIC LEUKEMIAS (ADULT) AND MULTIPLE MYELOMA <b>310</b> CHRONIC LEUKEMIAS; POLYCYTHEMIA RUBRA VERA	Indicated for use in ICD-9: other malignant neoplasms of lymphoid and histiocytic tissue (202 family), multiple myeloma and immunoproliferative neoplasms (203 family)
V10.88	Personal history of malignant neoplasm of other endocrine glands and related structures	<b>622</b> SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS	<b>207</b> CANCER OF SOFT TISSUE	Indicated for use in ICD-9: cancer of connective tissue and soft tissue (171 family)
V10.91	Personal history of malignant neuroendocrine tumor	<b>622</b>	<b>209</b> CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA <b>276</b> CANCER OF ENDOCRINE SYSTEM, EXCLUDING THYROID; CARCINOID SYNDROME <b>622</b> SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS	Indicated for use in ICD-9: carcinoid tumor NOS, neuroendocrine tumor NOS, Merkel cell carcinoma

## Personal History of Cancer V Codes

## Auricular Electro-Acupuncture

Issue: The new HCPCS code for auricular acupuncture was discussed at the December VBBS meeting. At that time, HERC staff indicated that there was not enough information available to make a placement determination for this code. Staff has consulted experts and reviewed additional materials.

Definition: Auricular electrostimulation involves the stimulation of acupuncture points on the ear. Devices, including the P-Stim and E-pulse, have been developed to provide ambulatory electrical stimulation over a period of several days. Auricular electrostimulation is being evaluated for a variety of conditions, including pain, depression, and anxiety. The P-Stim device is a single-use miniature electrical stimulator for auricular acupuncture points that is worn behind the ear with a self-adhesive electrode patch. A selection stylus that measures electrical resistance is used to identify 3 auricular acupuncture points.

Current List status:

New code: S8930 Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with the patient

Current lines with acupuncture CPT codes for traditional acupuncture:

- 1 PREGNANCY
- 5 ABUSE OR DEPENDENCE OF PSYCHOACTIVE SUBSTANCE
- 6 TOBACCO DEPENDENCE
- 15 HIV DISEASE (INCLUDING ACQUIRED IMMUNODEFICIENCY SYNDROME) AND RELATED OPPORTUNISTIC INFECTIONS
- 68 SUBSTANCE-INDUCED DELUSIONAL AND MOOD DISORDERS; INTOXICATION
- 70 SUBSTANCE-INDUCED DELIRIUM
- 212 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE
- 400 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT
- 435 MIGRAINE HEADACHES
- 562 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT
- 563 TENSION HEADACHES

Expert input:

**Peter Martin**, LAc, Associate Medical Director with CHP Group

Mr. Martin reported that the HCPCS code is likely used for payment for the device used for this type of acupuncture.

## Auricular Electro-Acupuncture

### **Roger Batchelor, DAOM L.Ac., NCNM**

Devices for full-body and ear acupuncture are typically the same, and usually simple. These devices are essential for acupuncture. It is comfortable for patients and efficient for practitioners. Research on conventional devices is extensive, such as the work of Becker and most notably Dr. Han, Ji-Sheng. Han led government research on acupuncture in China for 30 years, and found that electro acupressure or acupuncture (specifically alternating between 2 and 100 Hz) boosted all 5 known neurotransmitters in the cerebrospinal fluid. He published a wealth of research articles in English, searchable on PubMed, and presented at top-level scientific conferences internationally. For this, he was awarded China's top science prize a few years ago. Most LAc's are unaware of Dr. Han's work, but it provides rich scientific basis for ElectroAcupuncture (EA). Many acupuncturists use a simple 10 Hz if an alternating current is not available on their machines --many of my MD acupuncture colleagues use this as a convention. It was the waveform successfully applied on two acupoints on a patient's head during a 3 hour surgery at OHSU in 2004 that precluded the use of any chemical anesthesia. One EA device, called 'micro current,' markets something that claims great effects --although the patient does not feel anything. Some of my colleagues swear by these devices, attending special workshops by the manufacturer. As is the case with most medical devices, however, there is no independent research on them.

In the past, this was billed as Electro acupuncture, for slightly more than conventional. These devices do not require additional training nor capital investment, since the devices cost less than \$500, and great ones run for about \$300 or less. I've never understood why a separate code or cost was justified with these devices. This billing practice probably encouraged the use of EA by practitioners, which is harmless, but is not a good model for influencing practice for the sake of a few dollars.

The list makes sense. It is an essential practice for acute situations where hours of stimulation are needed, such as surgical or dental anesthesia/analgesia, or obstetric labor and delivery. It is interesting that every research article I surveyed that compared EA to conventional acupuncture for treating depression had superior results for EA: that was about a dozen articles in 2005. It makes a strong case for EA with this condition. EA is well known for pain of all types. I would not limit it to the pain conditions below. It would not be my first choice for pregnancy, but is essential for labor and delivery. Working at Hooper Detox, we found EA to help difficult detoxification, such as opiates.

## Auricular Electro-Acupuncture

### Other policies:

#### 1) Wellmark BCBS 2012

- a. Electrical stimulation of auricular acupuncture points is considered **investigational**

#### 2) Regence BCBS 2012

- a. Electrical stimulation of auricular acupuncture points is considered **investigational** for all indications, including but not limited to chronic and acute pain.

### Recommendation:

- 1) Possible placements for S8930 (Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with the patient) are:
  - a. The excluded list
    - i. Investigational, acupuncturists may use traditional acupuncture CPT codes
  - b. Current acupuncture lines, as experts feel that this is useful and cost is not high
    - i. 1 PREGNANCY
    - ii. 5 ABUSE OR DEPENDENCE OF PSYCHOACTIVE SUBSTANCE
    - iii. 6 TOBACCO DEPENDENCE
    - iv. 15 HIV DISEASE (INCLUDING ACQUIRED IMMUNODEFICIENCY SYNDROME) AND RELATED OPPORTUNISTIC INFECTIONS
    - v. 68 SUBSTANCE-INDUCED DELUSIONAL AND MOOD DISORDERS; INTOXICATION
    - vi. 70 SUBSTANCE-INDUCED DELIRIUM
    - vii. 212 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE
    - viii. 400 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT
    - ix. 435 MIGRAINE HEADACHES
    - x. 562 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT
    - xi. 563 TENSION HEADACHES
  - c. Current acupuncture lines, with a guideline specifying that this code is not to be used for proprietary devices (see wording below)

### **GUIDELINE NOTE XXX AURICULAR ACUPUNCTURE**

*Lines 1, 5, 6, 15, 68, 70, 212, 400, 435, 562, 563*

## Auricular Electro-Acupuncture

HCPCS code S8930 is included on these lines for traditional electro-acupuncture. Use of proprietary electrical stimulation devices, such as P-Stim and E-pulse, is not included on these lines.

## **Enzyme Replacement Therapy - Gaucher's Disease**

### Question:

What should the HERC determine about placement on the Prioritized List for enzyme replacement therapy for Gaucher's Disease?

### Question Source:

ICD-10 pediatric metabolic consultants

Dr. Neil Buist, and Dr. Dave Koeller, OHSU

Genzyme pharmaceuticals

### Issue:

At the August 2012 VBBS/HERC meetings enzyme replacement therapies (with the exception of infantile Pompe's disease) were included on Line 684, including treatment of Gaucher's disease. At that time, there was no high quality data (Cochrane reviews or randomized controlled trials) identified to support coverage. Those studies that were identified appear to focus on primary endpoints of hemoglobin concentrations and not on patient-oriented outcomes. Since that time, the ICD-10 pediatric metabolic consultants Drs. Buist and Koeller have approached staff with additional evidence and the makers of Cerezyme have also submitted evidence with the request that since this is so rare RCT evidence is not available and case series and registries should be considered.

### Clinical Background:

Gaucher disease is characterized by a deficiency of  $\beta$ -glucocerebrosidase activity, resulting in accumulation of glucocerebroside in tissue macrophages which become engorged and are typically found in the liver, spleen, and bone marrow and occasionally in lung, kidney, and intestine. Secondary hematologic sequelae include severe anemia and thrombocytopenia in addition to the characteristic progressive hepatosplenomegaly, skeletal complications, including osteonecrosis and osteopenia with secondary pathological fractures.

### Current Prioritized List Status

ICD 9 272.7 Lipoidosis

Line	Condition	Treatment
67	METABOLIC DISORDERS INCLUDING HYPERLIPIDEMIA	MEDICAL THERAPY
78	NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS	MEDICAL AND SURGICAL TREATMENT (EG. G-TUBES, J-TUBES, RESPIRATORS, TRACHEOSTOMY, UROLOGICAL PROCEDURES)
110	END STAGE RENAL DISEASE	RENAL TRANSPLANT
318	NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS	MEDICAL AND SURGICAL TREATMENT (EG. DURABLE MEDICAL EQUIPMENT AND ORTHOPEDIC PROCEDURE)
375	NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS	MEDICAL THERAPY
407	DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	MEDICAL THERAPY (SHORT TERM REHABILITATION WITH DEFINED GOALS)
684	ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	EVALUATION

ICD-10 E75.22 Gaucher disease

GUIDELINE NOTE 67, ENZYME REPLACEMENT THERAPY

Lines 264,684

Enzyme replacement therapy for infantile Pompe's disease is included on Line 264. All other enzyme replacement therapies are included on Line 684.

Evidence summary

*Previous searches:*

*Cochrane – nothing*

*NICE – nothing*

*BMJ clinical evidence – nothing*

*There have been no randomized controlled trials comparing treatment to placebo or standard care. There has been one RCT done on this subject, but only examined comparative effectiveness of one enzyme replacement to another (Cerezyme to Ceredase) without a placebo control.*

#### Submitted studies reviewed

*Barton, 1991* – original FDA qualifying study

1. N = 12 patients, 4 adults and 8 children
2. Type of study – case series
3. Injections q1-2weeks for 9-12 months
4. Results:
  - a. Hemoglobin concentration increased in 12/12, and platelet count in 7/12
  - b. Splenic volume decreased in 12/12 and hepatic volume in 5/12
  - c. Improvement in biochemical markers
  - d. “all children gained weight during the study and all children grew taller.”
  - e. Subjective improvements in quality of life

*Charrow, 2007*

1. Registry study
2. Population defined as those with bone crisis the year before therapy
3. Bone crises are based on physician reports
4. Results: Following ERT treatment, the percentage of positive bone pain responses per patient declined to 30%, 29%, and 30% in the first, second and third years on ERT, respectively. These represent 38%, 40%, and 39% declines in the percentage of bone pain responses per patient compared to before treatment (p,0.0001 for each year post-ERT).
5. After starting ERT, the percentage of patients with bone crisis reports decreased significantly to 5%, 1%, and 3% of patients in the first, second and third years of therapy, respectively

*Ficicioglu, 2008*

1. Clinical review of miglustat (substrate reduction therapy)
2. No methodology identified
3. 6-36 month results show improvements in bone pain, improvements in hemoglobin and platelet concentrations. Efficacy of miglustat may be comparable to enzyme replacement therapy
4. Adverse effects are significant, such as diarrhea and bloating, tremor, and peripheral neuropathy
5. Approved in the US for those in whom ERT is not an option

*Masek, 1999*

1. Prospective cohort study of Ceredase
2. Evaluated Quality of Life using standard questionnaire, up to 2 years
3. N= 25 adults
4. Results:

- a. At 6 months, energy level and fatigue was improved (compared to baseline), and improvement in 7/8 scores by 18 months.

*Pastores, 2011*

1. Clinical review of Gaucher's disease
2. No methodology identified
3. Other types of symptomatic therapy include:
  - a. Miglustat - resulted
    - i. Significant decrease in liver and spleen volume after six to 18 months, with clinical improvement noted over 24 months.
    - ii. Bone involvement and platelet and hemoglobin values remained stable or were modestly improved [Cox et al 2000, Elstein et al 2004a, Pastores et al 2005].
    - iii. An increase in bone density at the lumbar spine and femoral neck was reported to occur as early as six months after the initiation of miglustat monotherapy [Pastores et al 2007].
    - iv. Adverse effects: The most common adverse reactions noted in the clinical trials were weight loss (60% of individuals), and bloating, flatulence, and diarrhea (80%), which resolved or diminished with longer use of the product.
  - b. Partial or total splenectomy
  - c. Transfusion of blood products
  - d. Analgesics for bone pain
  - e. Joint replacement surgery
  - f. Supplemental calcium, vitamin d, and bisphosphanates

*Sims, 2008*

1. 48 month, open-label, longitudinal cohort study
2. Comparison was baseline, no control group
3. Improvements in bone pain, bone mineral density, and bone crisis at 3 months

*Weinrub, 2002*

1. Registry study
2. N=1028 patients
3. Results:
  - a. Hemoglobin levels improved (most in the first 6 months of treatment)
  - b. Hepatomegaly decreased by 30-40%
  - c. Splenomegaly decreased by 40-50% (but still remained at least 5x normal size)
  - d. In patients with pretreatment bone pain or bone crises, 52% (67/128) were pain free after 2 years and 94% (48/51) reported no additional crises.
4. Considerations: this is registry data so follow up may be limited in those with differing results. No comparison between those receiving therapy and not receiving therapy.

*Wenstrup, 2007*

1. Comparative cohort study between non-ERT and ERT treated patients
2. Non ERT (N=160) and ERT treatment (N=342 patients)
3. All registry patients with lumbar spine DEXA scores available
4. Considerations: The no ERT group tended to be less severe overall as evidenced by higher baseline hemoglobin and platelet counts, lower spleen and liver volumes, and lower presence of bone pain and occurrence of bone crisis. At baseline both significantly worse than standard population and possibly significantly different from each other
5. Results: Dose response relationship was present with ERT and improvement in bone density
6. Although they obtained baseline bone pain and bone crisis data, this was not followed up (or reported on)
7. May take up to 8 years to see effects

*Zimran, 2010*

1. Open label case series, Velaglucerase alfa
2. 12 patients, 9/12 completed 39 months.
3. Evaluated at 9 months and 48 months
4. Results improvements at 9 and 48 months:
  - a. Hemoglobin increased (19.2% and 21.7%)
  - b. Platelet counts increased (67% and 158%)
  - c. Normalized liver volume (-18.2%, -42.8%)
  - d. Normalized spleen volume (-49.5%, -79.3%)

Commerical Plans

*Aetna, 2012*

Alglucerase (Ceredase), Imiglucerase (Cerezyme), Miglustat (Zavesca), Taliglucerase alfa (Eleyso), and Velaglucerase Alfa (VPRIV)

Aetna considers alglucerase (Ceredase), imiglucerase (Cerezyme), miglustat (Zavesca), taliglucerase alfa (Eleyso), and velaglucerase alfa (VPRIV) medically necessary for adult members with Type 1 Gaucher disease who have any of the following signs and symptoms:

- Moderate to severe anemia (hemoglobin less than or equal to 11.5 g/dL (adult women) or 12.5 g/dL (adult men) or less than or equal to 1.0 g/dL or more below the lower limit of normal for age and sex); or
- Significant hepatomegaly (liver size 1.25 or more times normal (1,750 cc in adults)) or splenomegaly (spleen size 5 or more times normal (875 cc in adults)); or
- Skeletal disease beyond mild osteopenia and Erlenmeyer flask deformity; or
- Symptomatic disease, including abdominal or bone pain, fatigue, exertional limitation, weakness, or cachexia; or
- Thrombocytopenia (platelet count less than or equal to 120,000/mm<sup>3</sup>).

Aetna considers alglucerase, imiglucerase, miglustat, taliglucerase alfa, and velaglucerase alfa medically necessary for children and adolescents less than 18 years of age who are diagnosed with Type 1 Gaucher disease.

Aetna considers alglucerase, imiglucerase, miglustat, taliglucerase alfa, and velaglucerase alfa experimental and investigational for all other indications because of insufficient evidence in the peer-reviewed literature.

This policy is based, in part, on the recommendations of the International Collaborative Gaucher Group U.S. Regional Coordinators and the National Institutes of Health Technology Assessment Conference on Gaucher Disease.

#### *Cigna, 2012*

Cigna covers the following long-term enzyme replacement therapies as medically necessary for Type 1 Gaucher disease:

- imiglucerase (Cerezyme®)
- taliglucerase alfa (Elelyso™)
- velaglucerase alfa (VPRIV™)

Cigna covers miglustat (Zavesca®) as medically necessary for the treatment of mild to moderate Type 1 Gaucher disease in adults for whom enzyme replacement therapy is not a therapeutic option.

When coverage is available and medically necessary, the dosage, frequency, site of administration, and duration of enzyme replacement therapy should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to enzyme replacement therapy.

#### *Health Partners, 2011*

Enzyme replacement therapy for Gaucher's disease is considered medically necessary for pediatric and adult patients with a confirmed diagnosis of Type I Gaucher disease resulting in one or more of the following conditions: moderate to severe anemia, thrombocytopenia with bleeding tendency, bone disease, significant hepatomegaly or splenomegaly.

The labeled dosage is 60 units/kg administered every other week as a 60-minute intravenous infusion. However, after therapeutic goals are achieved, the lowest effective dose should be used.

Annual reauthorizations will require (1) a statement of progress against therapy goals which should include assessments of hemoglobin, platelet count, and liver and/or spleen volumes by MRI (when MRI is clinically indicated); and (2) for all regimens using more than 30 units/kg every other week, a statement of medical necessity indicating that the lowest effective dose to maintain therapeutic goals is being used.

### Cost information

Based on a recommended dosing of 60U/kg every 2 weeks, the monthly cost for a 100kg person would be \$50,088. This translates to an annual cost of \$601,056.

### Summary

There are no high quality studies to support the use of enzyme replacement therapy for Gaucher Type 1. There are case series and cohort studies without controls that demonstrate improvements in hemoglobin, platelets, spleen size, liver size, bone density, bone crises, and bone pain. There is a single comparative study that found improvement in bone mineral density at 8 years. There is no data available about patients who discontinue therapy or who choose not to be on therapy compared to those remaining on therapy. This comparative data would be possible to obtain from the registry. There no evidence to show that ongoing treatment with ERT prevents long-term clinical complications (e.g. infection, hospitalization, and mortality).

### HERC Staff Recommendation

1. **Option 1:** Make no change. Await comparative data to demonstrate efficacy on patient-oriented outcomes.
2. **Option 2:** If the decision is made to prioritize this therapy higher, Guideline Note 67 would need to be modified as follows:

#### GUIDELINE NOTE 67, ENZYME REPLACEMENT THERAPY

*Lines [67](#), [264](#),[684](#)*

Enzyme replacement therapy for [Type 1 Gaucher disease is included on Line 67 and for](#) infantile Pompe's disease is included on Line 264. All other enzyme replacement therapies are included on Line 684.

Consider adding this additional wording to the guideline:

Enzyme replacement therapy is only included on Line 67 for Type 1 Gaucher's disease in adults when at least [two or three](#) of the following criteria are met:

- Moderate to severe anemia (hemoglobin less than or equal to 11.5 g/dL (adult women) or 12.5 g/dL (adult men) or less than or equal to 1.0 g/dL or more below the lower limit of normal for age and sex); or
- Significant hepatomegaly (liver size 1.25 or more times normal (1,750 cc in adults)) or splenomegaly (spleen size 5 or more times normal (875 cc in adults)); or
- Skeletal disease beyond mild osteopenia and Erlenmeyer flask deformity; or

- Symptomatic disease, including abdominal or bone pain, fatigue, exertional limitation, weakness, or cachexia; or
- Thrombocytopenia (platelet count less than or equal to 120,000/mm<sup>3</sup>) with bleeding history

For children and adolescents with Type 1 Gaucher's disease, the above criteria do not need to be met, they simply must be symptomatic.

For all recipients of enzyme replacement therapy there needs to be documentation of responsiveness to the enzyme replacement therapy and the lowest effective dose should be used in order for continued coverage.

# Silver Compounds For Dental Caries

Question: Should coverage for silver compounds (silver nitrate plus topical fluoride or silver diamine fluoride) to prevent and treat dental caries be added to the Prioritized List?

Question source: Senator Bates

Issue: At the December 13, 2012 VBBS meeting, the evidence on the use of silver compounds (specifically silver diamine fluoride) was reviewed, and public testimony was heard about the pros and cons of use of silver nitrate plus fluoride varnish for the arresting of dental caries.

## Summary of the evidence

Silver diamine fluoride appears to be effective at preventing and arresting caries based on evidence only performed resource-poor settings (and none in the United States). There are no studies on silver nitrate + fluoride which is what would be used in the U.S. There are no studies evaluating the utility of arresting of caries compared to standard of care which is immediate restoration compared to delayed restoration.

## Summary of the argument in favor of silver compounds

- It stops the infection in the tooth
- Silver is coming back into favor
- Allows for those who do not want restoration (or immediate restoration) to have a means to arrest caries progression
- Inexpensive chemical
- Anecdotal evidence from Advantage that it is decreasing their ED visits

## Summary of the argument against silver compounds

- There is no data in the US supporting this as a treatment
- There are no known studies in process actually evaluating the efficacy of arresting caries compared to immediate restorative treatment
- There is permanent tooth discoloration that occurs
- Restoration is still required
- There is a potential large cost associated with the recommended 5 visits over 3-4 months, and then there would still be the cost of restoration
- No professional associations recommend it

## Oregon Board of Dentistry input

From Patrick Braatz, Executive Director, Oregon Board of Dentistry

“No official position it is something that Dentists may use.

The Board has recently developed an administrative rule to allow Dental Hygienists and dental assistants to also apply if a dentist has authorized, but that rule has not yet passed.”

## Silver Compounds For Dental Caries

AAPD Clinical Guideline, updated 2011.

Guideline on Caries-risk Assessment and Management for Infants, Children, and Adolescents.

-- one of the advocates stated that AAPD recommended it.

The clinical guideline had the following language:

“ Other approaches to the assessment and treatment of dental caries will emerge with time and, with evidence of effectiveness, may be included in future guidelines on caries risk assessment and management protocols. For example, there are emerging trends to use calcium and phosphate remineralizing solution to reverse dental caries.<sup>53</sup> Other fluoride compounds, such as **silver diamine fluoride<sup>54</sup>** and **stannous fluoride<sup>55</sup>**, may be more effective than sodium fluoride for topical applications.”

Conclusion: Silver diamine fluoride may be included in future guidelines as evidence of effectiveness emerges

American Dental Association: Center for Evidence-based Dentistry

- No official position
1. Critical summary January 2011 of the following review: *Rosenblatt A, Stamford TC, Niederman R. Silver diamine fluoride: a caries "silver-fluoride bullet". Journal of Dental Research. 2009;88(2):116-25*
  2. Strengths and Weaknesses of the Systematic Review:  
The reviewers used accepted methods to identify and select studies on SDF based on a priori inclusion criteria and the two studies reached similar conclusions. The reported preventive fractions and numbers needed to treat in the systematic review did not compare the SDF to fluoride varnish, and instead compared outcomes for SDF and fluoride varnish to the control groups.
  3. Strengths and Weaknesses of the Evidence:  
Both studies in the review were prospective studies with relatively large numbers of subjects in each study group, which was the main strength. While one of the studies compared SDF to no treatment, the other compared SDF to fluoride varnish. In addition, Chu and colleagues (2002) did not estimate trial sample sizes using a priori power calculations. Safety outcome measures associated with SDF were not clearly defined. There are potential problems with concluding that SDF is safe based on results from a study that may not be adequately powered to detect differences in adverse outcomes that are rare. Lastly, one study assessed the effectiveness of SDF on primary maxillary anterior teeth while the other focused on primary canines, primary molars, and permanent first molars.
  4. Implications for Dental Practice:

## Silver Compounds For Dental Caries

Results from two studies suggest that SDF is a promising chemotherapeutic agent that arrests and prevents caries in children. However, SDF has not been approved by the FDA for clinical use in the United States. Additional studies are needed to assess safety. There are also concerns associated with staining caused by SDF, which can be addressed by restoring the SDF-treated teeth with glass ionomer. SDF may have the potential to be used in clinical settings as a chemotherapeutic agent to effectively control and reduce dental caries in high-risk populations.

### Summary

There is evidence in resource-poor countries that silver diamine fluoride is effective at preventing and arresting caries. However, there is no evidence of the effectiveness of silver nitrate + fluoride varnish which is what would be used in the US (because the FDA has not approved silver diamine fluoride) and there are no US studies of either type of treatment. There are concerns about costs of repeated visits when restoration is still required and there is no data supporting that delayed restoration compared to immediate restoration is beneficial. Cosmetic concerns about permanent black staining in the teeth exist. Although the international studies are promising, no US major dental organizations currently recommend the use of silver compounds. This appears to be an experimental treatment at this time, and more research demonstrating efficacy and safety is required prior to allowing OHP patients to have this procedure done.

### Recommendations:

- 1) Do not add silver treatments to the Prioritized List
- 2) Add a guideline to indicate that neither this treatment (Silver diamine fluoride) nor a proxy (silver nitrate plus fluoride) are included on the Prioritized List

### **Guideline Note XX Silver compounds for dental caries**

*Lines 58, 372, 373, 494, 621*

Silver compounds for dental caries prevention and treatment are not included on these or any lines on the Prioritized List for coverage consideration.

## CG – Viscosupplementation for the Knee

Question: How should the HERC approved Coverage Guidance – Viscosupplementation for the knee—be incorporated into the Prioritized List?

Question source: Health Evidence Review Commission

Issue: HERC approved the Coverage Guidance: Viscosupplementation for the knee in October, 2012. This coverage guidance needs to be evaluated for application within the Prioritized List.

### HERC Coverage Guidance

Viscosupplementation should not be covered for the treatment of pain associated with Osteoarthritis (OA) of the knee.

Current Prioritized List status:

CPT 20610 (Arthrocentesis, aspiration, and/or injection; major joint or bursa (e.g. shoulder, hip, knee joint) is used to for viscosupplementation of the knee. This CPT code is found on lines 52, 84, 151, 161, 308, 384, 406, 443, 455, 489, 529, 531, 549, 619, 623, and 634. Osteoarthritis of the knee (715.16, .26, .36, .96) is found on lines 384 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE and 489 OSTEOARTHRITIS AND ALLIED DISORDERS. Internal derangement of the knee (ICD-9 716) is located on lines 455 INTERNAL DERANGEMENT OF KNEE AND LIGAMENOUS DISRUPTIONS OF THE KNEE, POTENTIALLY RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT and 638 SPRAINS AND STRAINS OF ADJACENT MUSCLES AND JOINTS, MINOR.

### Recommendations:

1. Add the following Guideline to lines 384, 455, and 489.

#### **GUILDELINE XXX, VISCOSUPPLEMENTATION OF THE KNEE**

*Lines 384, 455, 489*

Viscosupplementation of the knee (CPT 20610) is not covered for treatment of osteoarthritis of the knee.

## CG – Percutaneous Interventions for Low Back Pain

Question: How should the HERC approved Coverage Guidance – Percutaneous interventions for low back pain—be incorporated into the Prioritized List?

Question source: Health Evidence Review Commission

Issue: HERC approved the Coverage Guidance: Percutaneous interventions for low back pain in October, 2012. This coverage guidance needs to be evaluated for application within the Prioritized List.

### HERC Coverage Guidance

For radicular low back pain, Epidural steroid injections should be covered for patients with persistent radiculopathy due to herniated lumbar disc; 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. If an epidural steroid injection does not offer benefit, repeated injections should not be covered.

Epidural steroid injections should NOT be covered for spinal stenosis.

For radicular low back pain, the following treatments should NOT be covered:

- coblation nucleoplasty
- radiofrequency denervation

For nonradicular low back pain, the following treatments should NOT be covered:

- facet joint corticosteroid injection
- prolotherapy
- intradiscal corticosteroid injection
- 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

## CG – Percutaneous Interventions for Low Back Pain

Current Prioritized List status:

CPT code	Code description	Current List/Line(s)	Recommended Changes
20552-20553	Injection, single or multiple trigger point(s)	529,531,619,623	
20600	Arthrocentesis, aspiration and /or injection; small joint or bursa (eg, fingers, toes)	52,84,161,308,443,489,529,531,619,623,634	Remove 720.1 (Spinal enthesopathy) from line 52
20605	intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa)	52,84,161,308,326,443,489,531,561,619,623,634	Remove 720.1 from line 52
20610	major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa)	52,84,151,161,308,384,406,443,455,489,529,531,549,619,623,634	Remove 720.1 from line 52
22521-22522	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection; lumbar	Excluded	
22526 - 22527	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level	Excluded	
27096	Injection procedure for sacroiliac joint, anesthetic steroid, with image guidance (fluoroscopy or CT) including arthrography when performed	Diagnostic	Excluded
62292	Injection procedure, arterial, for occlusion of arteriovenous malformation, spinal	Excluded	
62310	Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, epidural or subarachnoid; cervical or thoracic	Ancillary	
62311	<b>lumbar</b> , sacral (caudal)	Ancillary	Add to line 400
64412	Injection, anesthetic agent; spinal accessory nerve	Ancillary	
64479	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); cervical or thoracic, single level	Excluded	
64480	each additional level	Excluded	
64483	Injection(s), anesthetic agent	164 HERPES	Remove from line 164

## CG – Percutaneous Interventions for Low Back Pain

	and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); <b>lumbar</b> or sacral, single level	ZOSTER; HERPES SIMPLEX AND WITH NEUROLOGICAL AND OPHTHALMOLOGICAL COMPLICATIONS	Add to line 400
64484	each additional level	164	Remove from line 164 Add to line 400
64490-64495	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint)	Excluded	
64633-64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT)	Excluded	
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	Ancillary	

Diagnosis codes (ICD-9) included in the HERC guidance are found on lines:  
 52 RHEUMATOID ARTHRITIS AND OTHER INFLAMMATORY POLYARTHROPATHIES  
 400 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT  
 434 SPINAL DEFORMITY, CLINICALLY SIGNIFICANT  
 562 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT  
 607 SPINAL DEFORMITY, NOT CLINICALLY SIGNIFICANT  
 638 SPRAINS AND STRAINS OF ADJACENT MUSCLES AND JOINTS, MINOR

### Recommendations:

- 1) Move 720.1 (Spinal enthesopathy) [M46.0 in ICD-10] from line 52 RHEUMATOID ARTHRITIS AND OTHER INFLAMMATORY POLYARTHROPATHIES to lines 516 PERIPHERAL ENTHESOPATHIES--MEDICAL THERAPY and 531 PERIPHERAL ENTHESOPATHIES--SURGICAL THERAPY
  - a. Consistent with other enthesopathies
  - b. Will no longer pair with treatment codes for radicular low back pain
- 2) Add lumbar epidural steroid injections (CPT 62311, 64483, 64484) to line 400 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT with the guideline below
  - a. Rationale: Line 400 contains radicular back pain diagnoses and disk displacement diagnoses

### **GUIDELINE NOTE XXX, EPIDURAL STEROID INJECTIONS, OTHER PERCUTANEOUS INTERVENTIONS FOR LOW BACK PAIN**

*Lines 52, 400, 434, 562, 607, 638*

Epidural steroid injections (CPT 62311, 64483, 64484) are covered for patients with persistent radiculopathy due to a herniated lumbar disc; it is recommended that shared decision-making regarding epidural steroid

## **CG – Percutaneous Interventions for Low Back Pain**

injection include a specific discussion about inconsistent evidence showing moderate short-term benefits, and lack of long-term benefits. If an epidural steroid injection does not offer benefit, repeated injections should not be covered. Epidural steroid injections are not covered for spinal stenosis or for patients with low back pain without radiculopathy.

The following interventions are not covered for low back pain, with or without radiculopathy: facet joint corticosteroid injection, prolotherapy, intradiscal corticosteroid injection, local injections, botulinum toxin injection, intradiscal electrothermal therapy, therapeutic medial branch block, radiofrequency denervation, sacroiliac joint steroid injection, coblation nucleoplasty, percutaneous intradiscal radiofrequency thermocoagulation, and radiofrequency denervation.

## CG – Management of Chronic Otitis Media with Effusion in Children

Question: How should the HERC approved Coverage Guidance – Management of chronic otitis media with effusion in children—be incorporated into the Prioritized List?

Question source: Health Evidence Review Commission

Issue: HERC approved the Coverage Guidance: Management of chronic otitis media with effusion in children in October, 2012. This coverage guidance needs to be evaluated for application within the Prioritized List.

At the December 2012 VBBS meeting testimony was heard and a discussion to make modifications to the proposed guideline followed. The proposal had recommended striking language including the definition of 25dB hearing loss, and the decision was made to leave this language as part of the guideline. Additionally, the “individualized” treatment language was not operationalizeable by DMAP and so the proposal was to add tympanostomy tubes to those specified underlying condition lines (e.g. Down syndrome, cleft palate, and craniofacial anomalies). It was decided not to add these codes to the speech and language delay lines because these are dysfunction lines.

### HERC Coverage Guidance

Antibiotic and other medication therapy (including antihistamines, decongestants, and nasal steroids) should not be covered for children with children with otitis media with effusion (OME) (without another appropriate diagnosis).

There should be a 3 to 6 month watchful waiting period after diagnosis of otitis media with effusion, and if documented persistent hearing loss is greater than or equal to 25dB in the better hearing ear, referral for tympanostomy surgery may be covered, given short, but not long-term, improvement in hearing.

Formal audiometry should be covered for children with chronic OME present for 3 months or longer. Children with language delay, learning problems, or significant hearing loss should have hearing testing covered initially upon diagnosis. Children with chronic OME who are not at risk for language or developmental delay should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

Adenoidectomy should not be covered at the time of the first pressure equalization tube insertion.

Patients with craniofacial anomalies, Down’s syndrome, cleft palate, and patients with speech and language delay along with hearing loss should have coverage based on an individualized treatment plan.

## **CG – Management of Chronic Otitis Media with Effusion in Children**

Current Prioritized List status: chronic otitis media is included on line 502 CHRONIC OTITIS MEDIA Treatment: PE TUBES/ADENOIDECTOMY/TYMPANOPLASTY, MEDICAL THERAPY. Currently, guideline note 51 applies to this line.

**Line:** 502  
**Condition:** CHRONIC OTITIS MEDIA (See Guideline Notes 51,64,65,76)  
**Treatment:** PE TUBES/ADENOIDECTOMY/TYMPANOPLASTY, MEDICAL THERAPY  
**ICD-9:** 380.50-380.53,381.10-381.89,382.1-382.3,382.9,383.1,383.20-383.31,383.9,384.20-384.9  
**CPT:** 42830-42836,69210-69222,69310,69400-69511,69601-69650,69700,69801,69905,69910,69979,92562-92565,92571-92577,92590,92591,98966-98969,99051,99060,99070,99078,99201-99360,99366,99374,99375,99379-99412,99429-99444,99468-99480,99605-99607  
**HCPCS:** G0396,G0397,G0406-G0408,G0425-G0427,S0270-S0274

### **GUIDELINE NOTE 51, CHRONIC OTITIS MEDIA WITH EFFUSION**

#### *Line 502*

Antibiotic and other medication therapy are not indicated for children with chronic otitis media with effusion (OME). Children with chronic OME present for 3 months or longer or with language delay, learning problems, or significant hearing loss at any time should have hearing testing. Children with chronic OME who are not at risk should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

For the child who has had chronic OME and who has a hearing deficiency in the better-hearing ear of 25 dB or greater, myringotomy with tube insertion recommended after a total of 4 to 6 months of effusion with a documented hearing deficit.

Adenoidectomy is an appropriate surgical treatment for chronic OME in children over 3 years with their second set of tubes. First time tubes are not an indication for an adenoidectomy.

## CG – Management of Chronic Otitis Media with Effusion in Children

Code	Line	Condition	Treatment	Staff REcommendation
749.00	49	CONGENITAL AIRWAY OBSTRUCTION WITH OR WITHOUT CLEFT PALATE	MEDICAL AND SURGICAL TREATMENT, ORTHODONTICS	Do not add tympanostomy codes to this line because about airway obstruction.
749.00	325	CLEFT PALATE AND/OR CLEFT LIP	EXCISION AND REPAIR VESTIBULE OF MOUTH, ORTHODONTICS	Add tympanostomy codes
756.0	273	DEFORMITIES OF HEAD	CRANIOTOMY/CRANIECTOMY	Do not add codes to this line

Down syndrome is located on the dysfunction lines, as well as speech and language delay is located on dysfunction line 375. These are not ideal locations for adding tympanostomy codes.

### HERC Staff Recommendations:

1. Make the following changes to Guideline Note 51

#### **GUIDELINE NOTE 51, CHRONIC OTITIS MEDIA WITH EFFUSION**

Lines [325](#), [502](#)

Antibiotic and other medication therapy ([including antihistamines, decongestants, and nasal steroids](#)) are not indicated for children with chronic otitis media with effusion (OME) ([without another appropriate diagnosis](#)).

[There should be a 3 to 6 month watchful waiting period after diagnosis of otitis media with effusion, and if documented hearing loss is greater than or equal to 25dB in the better hearing ear, tympanostomy surgery may be indicated, given short but not long term improvement in hearing. Formal audiometry is indicated for](#) cChildren with chronic OME present for 3 months or longer. ~~or~~ [Children](#) with language delay, learning problems, or significant hearing loss ~~at any time~~ should have hearing testing [upon diagnosis](#). Children with chronic OME who are not at risk [for language delay \(such as those with hearing loss <25dB in the better hearing ear\) or developmental delay](#) (should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

Adenoidectomy [is not indicated at the time of first pressure equalization tube insertion.](#) ~~It may be indicated in~~ ~~is an appropriate surgical treatment for~~

## CG – Management of Chronic Otitis Media with Effusion in Children

~~chronic OME~~ in children over 3 years ~~with~~ who are having their second set of tubes. ~~First time tubes are not an indication for an adenoidectomy.~~

Patients with craniofacial anomalies, Down's syndrome, and cleft palate, or documented speech and language delay along with hearing loss and chronic otitis media with effusion are intended to have coverage through the co-morbidity rule.

2. Add the following cpt codes to Line 325 CLEFT PALATE AND/OR CLEFT LIP
  - 69433 Tympanostomy (requiring insertion of ventilating tube, local or topical anesthesia)
  - 69436 Tympanostomy (requiring insertion of ventilating tube, general anesthesia)
  - 69424 Ventilating tube removal requiring general anesthesia

## Comorbidity Rule

### ORS 410-141-0480

#### Oregon Health Plan Benefit Package of Covered Services

(1) Division members are eligible to receive, subject to Section (11) of this rule, those treatments for the condition/treatment pairs funded on the Oregon Health Services Commission's (HSC) Prioritized List of Health Services adopted under OAR 410-141-0520 when such treatments are medically or dentally appropriate, except that services must also meet the prudent layperson standard defined in OAR 410-141-0140. Refer to 410-141-0520 for funded line coverage information.

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(8) In addition to the coverage available under section (1) of this rule, a Division member may be eligible to receive, subject to section (11), services for treatments that are below the funded line or not otherwise excluded from coverage:

(a) Services can be provided if it can be shown that:

(A) The OHP client has a funded condition for which documented clinical evidence shows that the funded treatments are not working or are contraindicated; and

(B) Concurrently has a medically related unfunded condition that is causing or exacerbating the funded condition; and

(C) Treating the unfunded medically related condition would significantly improve the outcome of treating the funded condition;

(D) Ancillary services that are excluded and other services that are excluded are not subject to consideration under this rule;

(E) Any unfunded or funded co-morbid conditions or disabilities must be represented by an ICD-9-CM diagnosis code or when the condition is a mental disorder, represented by DSM-IV diagnosis coding to the highest level of axis specificity; and

(F) In order for the treatment to be covered, there must be a medical determination and finding by the Division for fee-for-service OHP clients or a finding by the Prepaid Health Plan (PHP) for Division members that the terms of section (a)(A)–(C) of this rule have been met based upon the applicable:

(i) Treating physician opinion;

(ii) Medical research;

(iii) Community standards; and

(iv) Current peer review.

(b) Before denying treatment for an unfunded condition for any Division member, especially a Division member with a disability or with a co-morbid condition, providers must determine whether the Division member has a funded condition/treatment pair that would entitle the Division member to treatment under the program and both the funded and unfunded conditions must be represented by an ICD- 9-CM diagnosis code; or, when the condition is a mental disorder, represented by DSM-IV diagnosis coding to the highest level of axis specificity.

## Immunization Guideline

Question: Should the current Prevention Tables have immunization recommendations removed and placed into a separate table to be maintained by the Oregon Immunization Program?

Question source: HERC staff, Oregon Immunization Program staff

Issue: The current Prevention Tables are out of date, and are not scheduled to be replaced until the ICD-10 List in 2014. The immunization recommendations in these tables are out of date, and not regularly updated. The Oregon Immunization Program has proposed having an updated table to be hosted by OIP and regularly updated by their staff. This table will be available through a link in a new Prioritized List guideline.

Traditionally, HSC/HERC has followed ACIP immunization recommendations, which are created by public health experts and the CDC. The OIP program follows ACIP guidelines.

If the following guideline referring to the OIP table is adopted, then changes will need to be made to the Prevention Tables as shown below.

Recommendations:

- 1) Adopt the guideline regarding immunizations as shown below
  - a. The link is to a table to be regularly updated by the Oregon Immunization Program (see second document)
- 2) Accept the changes to the Prevention Tables as shown below

### **GUIDELINE NOTE XXX IMMUNIZATIONS**

*Lines 3,4*

Immunizations are covered as recommended in the following table. The immunization table is updated and maintained on this website

<http://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Documents/DMAPvactable.pdf>

# Immunization Guideline

## Birth to 10 Years

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### Interventions Considered and Recommended for the Periodic Health Examination

### Leading Causes of Death Conditions originating in perinatal period Congenital anomalies Sudden infant death syndrome (SIDS) Unintentional injuries (non-motor vehicle) Motor vehicle injuries

---

### Interventions for the General Population

---

#### SCREENING

Height and weight  
Blood pressure  
Vision screen (3-4 yr)  
Hemoglobinopathy screen (birth)<sup>1</sup>  
Phenylalanine level (birth)<sup>2</sup>  
T4 and/or TSH (birth)<sup>3</sup>  
Effects of STDs  
FAS, FAE, drug affected infants<sup>4</sup>  
Hearing, developmental, behavioral and/or psychosocial screens<sup>5</sup>  
Learning and attention disorders<sup>6</sup>  
Signs of child abuse, neglect, family violence

Limit fat and cholesterol; maintain caloric balance; emphasize grains, fruits, vegetables (age >2 yr)  
Regular physical activity\*

#### Substance User

Effects of passive smoking\*  
Anti-tobacco message\*

#### Dental Health

Regular visits to dental care provider\*  
Floss, brush with fluoride toothpaste daily\*  
Advice about baby bottle tooth decay\*

#### COUNSELING

##### Injury Prevention

Child safety car seats (age <5 yr)  
Lap-shoulder belts (age >5 yr)  
Bicycle helmet; avoid bicycling near traffic  
Smoke detector, flame retardant sleepwear  
Hot water heater temperature <120-130F  
Window/stair guards, pool fence, walkers  
Safe storage of drugs, toxic substances, firearms and matches  
Syrup of ipecac, poison control phone number  
CPR training for parents/caretakers  
Infant sleeping position

##### Mental Health/Chemical Dependency

Parent education regarding:

- Child development
- Attachment/bonding
- Behavior management
- Effects of excess TV watching
- Special needs of child and family due to:
  - Familial stress or disruption
  - Health problems
  - Temperamental incongruence with parent
  - Environmental stressors such as community violence or disaster, immigration, minority status, homelessness

• Referral for MHCD and other family support services as indicated

##### Diet and Exercise

Breast-feeding, iron-enriched formula and foods (infants and toddlers)

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<sup>1</sup>Whether screening should be universal or targeted to high-risk groups will depend on the proportion of high-risk individuals in the screening area, and other considerations. <sup>2</sup>If done during first 24 hr of life, repeat by age 2 wk. <sup>3</sup>Optimally between day 2 and 6, but in all cases before newborn nursery discharge. <sup>4</sup>Parents with alcohol and/or drug use. Children with history of intrauterine addiction. Physical and behavioral indicators: hypertension, gastritis, esophagitis, hematological disorders, poor nutritional status, cardiac arrhythmias, neurological disorders, intrauterine growth retardation, mood swings, difficulty concentrating, inappropriateness, irritability or agitation, depression, bizarre behavior, abuse and neglect, behavior problems. <sup>5</sup>Screening must be conducted with a standardized, valid, and reliable tool. Recommended developmental, behavioral and/or psychosocial screening tools include and are not limited to: a) Ages and Stages Questionnaire (ASQ); b) Parent Evaluation of Developmental Status, (PEDS) plus/minus PEDS:Developmental Milestones (PEDS:DM); c) ASQ:Social Emotional (ASQ:SE); and d) Modified Checklist for Autism in Toddlers (M-CHAT). <sup>6</sup>Consider screening with full DSM-IV criteria for attention deficit disorder, inattentive or hyperactive types, in children with significant overall academic or behavioral difficulty including academic failure and/or learning difficulty, especially in reading, math or handwriting.

\*The ability of clinical counseling to influence this behavior is unproven.

# Immunization Guideline

## Birth to 10 Years (Cont'd)

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### Interventions for the General Population (Cont'd)

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#### IMMUNIZATIONS

Diphtheria-tetanus-acellular-pertussis (DTaP)  
Inactivated poliovirus (OPV)  
Measles-mumps-rubella (MMR)  
H. influenzae type b (Hib) conjugate  
Hepatitis B  
Varicella  
Pneumococcal

Hepatitis A  
Influenza  
Rotavirus  
Human papillomavirus (HPV)

#### CHEMOPROPHYLAXIS

Ocular prophylaxis (birth)

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~~HPV2 and HPV4 for females aged 9 to 26. HPV4 for males aged 9 through 26.~~

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### Interventions for the High-Risk Population

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Hemoglobin/hematocrit (HR1)  
HIV testing (HR2)  
PPD (HR3)  
~~Hepatitis A vaccine (HR4);~~  
~~Pneumococcal polysaccharide vaccine (HR5)~~  
~~Meningococcal vaccine (HR6)~~  
Blood lead level (HR7)

Daily fluoride supplement (HR8)  
Avoid excess/midday sun, use protective clothing\* (HR9)  
Screen for child abuse, neurological, mental health conditions  
Increased well-child visits (HR10)

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### High-Risk Groups

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**HR1** = Infants age 6-12 mo who are: living in poverty, black, Native American or Alaska Native, immigrants from developing countries, preterm and low-birthweight infants, infants whose principal dietary intake is unfortified cow's milk.

**HR2** = Infants born to high-risk mothers whose HIV status is unknown. Women at high risk include: past or present injection drug use; persons who exchange sex for money or drugs, and their sex partners; injection drug-using, bisexual, or HIV-positive sex partners currently or in past; persons seeking treatment for STDs; blood transfusion during 1978-1985.

**HR3** = Persons infected with HIV, close contacts of persons with known or suspected TB, persons with medical risk factors associated with TB, immigrants from countries with high TB prevalence, medically underserved low-income populations (including homeless), residents of long-term care facilities.

~~**HR4** = Persons >2 yr living in areas where the disease is endemic and where periodic outbreaks occur (e.g., certain Alaska Native, Pacific Island, Native American, and religious communities). Consider for institutionalized children aged >2 yr. Clinicians should also consider local epidemiology.~~

~~**HR5** — Children aged 2 years or older with certain underlying medical conditions, including a cochlear implant.~~

~~**HR6** — Children aged 2 through 10 years with persistent complement component deficiency, anatomic or functional asplenia, and certain other conditions placing them at high risk.~~

## Immunization Guideline

**HR74** = Children about age 12 mo who: 1) live in communities in which the prevalence of lead levels requiring individual intervention, including residential lead hazard control or chelation, is high or undefined; 2) live in or frequently visit a home built before 1950 with dilapidated paint or with recent or ongoing renovation or remodeling; 3) have close contact with a person who has an elevated lead level; 4) live near lead industry or heavy traffic; 5) live with someone whose job or hobby involves lead exposure; 6) use lead-based pottery; or 7) take traditional ethnic remedies that contain lead.

**HR85** = Children living in areas with inadequate water fluoridation (<0.6 ppm).

**HR96** = Persons with a family history of skin cancer, a large number of moles, atypical moles, poor tanning ability, or light skin, hair, and eye color.

**HR107** = Having a: chronically mentally ill parent; substance abusing parent; mother who began parenting as a teen. Living at or below poverty. Having: parents involved in criminal behavior; experienced an out-of-home placement(s), multiple moves, failed adoption(s). Being homeless. Having suffered physical, emotional or sexual abuse, or severe neglect. Having: a chronic health problem in the family; an absence of a family support system. Being substance affected at birth.

# Immunization Guideline

## Ages 11-24 Years

Interventions Considered  
and Recommended for the  
Periodic Health Examination

Leading Causes of Death  
Motor vehicle/other unintentional injuries  
Homicide  
Suicide  
Malignant neoplasms  
Heart diseases

## Interventions for the General Population

### SCREENING

Height and weight  
Blood pressure<sup>1</sup>  
High-density lipoprotein cholesterol (HDL-C) and  
total blood cholesterol (age 20-24 if high-risk)<sup>2</sup>  
Papanicolaou (Pap) test<sup>3</sup>  
Chlamydia screen<sup>4</sup> (females <25 yr)  
Rubella serology or vaccination hx<sup>5</sup>  
(females >12 yr)  
Learning and attention disorders<sup>6</sup>  
Signs of child abuse, neglect, family violence  
Alcohol, inhalant, illicit drug use<sup>7</sup>  
Eating disorders<sup>8</sup>  
Anxiety and mood disorders<sup>9</sup>  
Suicide risk factors<sup>10</sup>

### COUNSELING

#### Injury Prevention

Lap/shoulder belts  
Bicycle/motorcycle/ATV helmet\*  
Smoke detector\*  
Safe storage/removal of firearms\*  
Smoking near bedding or upholstery

#### Substance Use

Avoid tobacco use  
Avoid underage drinking and illicit drug use\*  
Avoid alcohol/drug use while driving, swimming,  
boating, etc.\*

#### Sexual Behavior

STD prevention: abstinence\*; avoid high-risk  
behavior\*; condoms/female barrier with spermicide\*  
Unintended pregnancy: contraception

#### Diet and Exercise

Limit fat and cholesterol; maintain caloric  
balance; emphasize grains, fruits, vegetables  
Adequate calcium intake (females)  
Regular physical activity\*

#### Dental Health

Regular visits to dental care provider\*  
Floss, brush with fluoride toothpaste daily\*

#### Mental Health/Chemical Dependency

Parent education regarding:

- Adolescent development
- Behavior management
- Effects of excess TV watching
- Special needs of child and family due to:
  - Familial stress or disruption
  - Health problems
  - Temperamental incongruence with parent
  - Environmental stressors such as
    - community violence or disaster,
    - immigration, minority status,
    - ..homelessness
- Referral for MHCD and other family support services as indicated

<sup>1</sup>Periodic BP for persons aged  $\geq 18$  yr. <sup>2</sup>High-risk defined as having diabetes, family history of premature coronary disease or familial hyperlipidemia, or multiple cardiac risk factors. <sup>3</sup>Screening to start at age 21; screening should occur at least every 3 years. <sup>4</sup>If sexually active. <sup>5</sup>Serologic testing, documented vaccination history, and routine vaccination against rubella (preferably with MMR) are equally acceptable alternatives. <sup>6</sup>Consider screening with full DSM-IV criteria for attention deficit disorder, inattentive or hyperactive types, in children with significant overall academic or behavioral difficulty including academic failure and/or learning difficulty, especially in reading, math or handwriting. <sup>7</sup>Persons using alcohol and/or drugs. Physical and behavioral indicators: liver disease, pancreatitis, hypertension, gastritis, esophagitis, hematological disorders, poor nutritional status, cardiac arrhythmias, alcoholic myopathy, ketoacidosis, neurological disorders: smell of alcohol on breath, mood swings, memory lapses or losses, difficulty concentrating, blackouts, inappropriateness, irritability or agitation, depression, slurry speech, staggering gait, bizarre behavior, suicidal indicators, sexual dysfunction, interpersonal conflicts, domestic violence, child abuse and neglect, automobile accidents or citation arrests, scholastic or behavior problems, secretiveness or vagueness about personal or medical history. <sup>8</sup>Persons with a weight >10% below ideal body weight, parotid gland hypertrophy or erosion of tooth enamel. Females with a chemical dependency. <sup>9</sup>In women who are at increased risk, diagnostic evaluation should include an assessment of history of sexual and physical violence, interpersonal difficulties, prescription drug utilization, medical and reproductive history. <sup>10</sup>Recent divorce, separation, unemployment, depression, alcohol or other drug abuse, serious medical illness, living alone, homelessness, or recent bereavement.

\*The ability of clinical counseling to influence this behavior is unproven.

# Immunization Guideline

## Ages 11-24 Years (Cont'd)

### Interventions for the General Population (Cont'd)

#### IMMUNIZATIONS

TDaP (11-16-yr)  
Hepatitis B<sup>1</sup>  
MMR (11-12-yr)<sup>2</sup>  
Varicella (11-12-yr)<sup>3</sup>  
Rubella<sup>4</sup> (females >12-yr)  
Influenza<sup>5</sup>

Polio<sup>6</sup>  
Human papillomavirus (HPV)<sup>7</sup>  
Meningococcal (11-12-yr)<sup>8</sup>

#### CHEMOPROPHYLAXIS

Multivitamin with folic acid (females planning/capable of pregnancy)

If not previously immunized: current visit, 1 and 6 mo later. <sup>2</sup>If no previous second dose of MMR. <sup>3</sup>If susceptible to chickenpox. <sup>4</sup>Serologic testing, documented vaccination history, and routine vaccination against rubella (preferably with MMR) are equally acceptable alternatives. <sup>5</sup>Yearly (6 mo through 18 yrs). <sup>6</sup>If not previously immunized. <sup>7</sup>HPV<sup>2</sup> and HPV<sup>4</sup> for females aged 9 to 26. HPV<sup>4</sup> for males aged 9 through 26. <sup>8</sup>Children 13 through 18 if not previously vaccinated.

### Interventions for the High-Risk Population

Screen for

Syphilis RPR/VDRL (HR1);  
Gonorrhea (female) (HR2)  
HIV (HR3)  
Chlamydia (female) (HR4);  
Tuberculosis - PPD (HR3,5)

Advise to reduce infection risk (HR3,6)

Immunize with

~~MMR (HR12)~~  
~~Hepatitis A vaccine (HR7)~~  
~~Meningococcal vaccine (HR7)~~  
~~Pneumococcal polysaccharide vaccine (HR8)~~  
~~Influenza vaccine (HR9)~~  
~~Varicella vaccine (HR10)~~

~~MMR (HR12)~~

~~Hepatitis A vaccine (HR7)~~

Avoid excess/midday sun, use protective clothing\* (HR~~12~~7)

Folic acid 4.0 mg (HR~~13~~8)

Daily fluoride supplement (HR~~14~~9)

Screen for child abuse, neurological, mental health conditions

Increased well-child/adolescent visits (HR~~15~~10)

Refer for genetic counseling and evaluation for BRCA testing by appropriately trained health care provider (HR~~16~~11).

### High-Risk Groups

**HR1** = Persons who exchange sex for money or drugs, and their sex partners; persons with other STDs (including HIV); and sexual contacts of persons with active syphilis. Clinicians should also consider local epidemiology.

**HR2** = Females who have: two or more sex partners in the last year; a sex partner with multiple sexual contacts; exchanged sex for money or drugs; or a history of repeated episodes of gonorrhea. Clinicians should also consider local epidemiology.

## Immunization Guideline

### Ages 11-24 Years (Cont'd)

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**HR3** = Males who had sex with males after 1975; past or present injection drug use; persons who exchange sex for money or drugs, and their sex partners; injection drug-using, bisexual or HIV-positive sex partner currently or in the past; blood transfusion during 1978-85; persons seeking treatment for STDs. Clinicians should also consider local epidemiology.

**HR4** = Sexually active females with multiple risk factors including: history of prior STD; new or multiple sex partners; age < 25; nonuse or inconsistent use of barrier contraceptives; cervical ectopy. Clinicians should consider local epidemiology of the disease in identifying other high-risk groups.

**HR5** = HIV positive, close contacts of persons with known or suspected TB, persons with medical risk factors associated with TB, immigrants from countries with high TB prevalence, medically underserved low-income populations (including homeless), alcoholics, injection drug users, and residents of long-term facilities.

**HR6** = Persons who continue to inject drugs.

~~**HR7** = Children aged 11 through 12 years with persistent complement component deficiency, anatomic or functional asplenia, and certain other conditions placing them at high risk.~~

~~**HR8** = Immunocompetent persons with certain medical conditions, including chronic cardiopulmonary disorders, diabetes mellitus, and anatomic asplenia. Immunocompetent persons who live in high-risk environments/social settings (e.g., certain Native American and Alaska Native populations).~~

~~**HR9** = Annual vaccination of: residents of chronic care facilities; persons with chronic cardiopulmonary disorders, metabolic diseases (including diabetes mellitus); hemoglobinopathies, immunosuppression, or renal dysfunction.~~

~~**HR10** = Healthy persons aged >13 yr without a history of chickenpox or previous immunization. Consider serologic testing for presumed susceptible persons aged >13 yr.~~

~~**HR11** = Persons born after 1956 who lack evidence of immunity to measles or mumps (e.g., documented receipt of live vaccine on or after the first birthday, laboratory evidence of immunity, or a history of physician-diagnosed measles or mumps).~~

**HR127** = Persons with a family or personal history of skin cancer, a large number of moles, atypical moles, poor tanning ability, or light skin, hair, and eye color.

**HR138** = Women with prior pregnancy affected by neural tube defect planning a pregnancy.

## Immunization Guideline

### Ages 11-24 Years (Cont'd)

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**HR149** = Persons aged <17 yr living in areas with inadequate water fluoridation (<0.6 ppm).

**HR150** = Having a: chronically mentally ill parent; substance abusing parent; mother who began parenting as a teen. Living at or below poverty. Having: parents involved in criminal behavior; experienced an out-of-home placement(s), multiple moves, failed adoption(s). Being homeless. Having suffered physical, emotional or sexual abuse, or severe neglect. Having: a chronic health problem in the family; an absence of a family support system. Being substance affected at birth.

**HR161** = A family history of breast or ovarian cancer that includes a relative with a known deleterious mutation in BRCA1 or BRCA2 genes; two first-degree relatives with breast cancer, one of whom received the diagnosis at age 50 years or younger; a combination of three or more first- or second-degree relatives with breast cancer regardless of age at diagnosis; a combination of both breast and ovarian cancer among first- and second-degree relatives; a first-degree relative with bilateral breast cancer; a combination of two or more first- or second-degree relatives with ovarian cancer regardless of age at diagnosis; a first- or second-degree relative with both breast and ovarian cancer at any age; and a history of breast cancer in a male relative. For women of Ashkenazi Jewish heritage, an increased risk family history risk includes any first-degree relative (or two second-degree relatives on the same side of the family) with breast or ovarian cancer.

# Immunization Guideline

## Ages 25-64 Years

Interventions Considered  
and Recommended for the  
Periodic Health Examination

Leading Causes of Death  
Malignant neoplasms  
Heart diseases  
Motor vehicle/other unintentional injuries  
Human immunodeficiency virus infection  
Suicide and homicide

### Interventions for the General Population

#### SCREENING

Blood pressure  
Height and weight  
High-density lipoprotein cholesterol (HDL-C) and total blood cholesterol (men age 35-64, women age 45-64, all age 25-64 if high-risk<sup>1</sup>)  
Papanicolaou (Pap) test<sup>2</sup>  
Fecal occult blood test (FOBT) and/or flexible sigmoidoscopy, or colonoscopy (>50 yr)<sup>3</sup>  
Mammogram<sup>4</sup> (women 40-74 yrs)  
Rubella serology or vaccination hx<sup>5</sup> (women of childbearing age)  
Bone density measurement (women age 60-64 if high-risk)<sup>6</sup>  
Fasting plasma glucose for patients with hypertension or hyperlipidemia  
Learning and attention disorders<sup>7</sup>  
Signs of child abuse, neglect, family violence  
Alcohol, inhalant, illicit drug use<sup>8</sup>  
Eating disorders<sup>9</sup>  
Anxiety and mood disorders<sup>10</sup>  
Suicide risk factors<sup>11</sup>  
Somatoform disorders<sup>12</sup>  
Environmental stressors<sup>13</sup>

#### COUNSELING

**Substance Use**  
Tobacco cessation  
Avoid alcohol/drug use while driving, swimming, boating, etc.\*

#### Diet and Exercise

Limit fat and cholesterol; maintain caloric balance; emphasize grains, fruits, vegetables  
Adequate calcium intake (women)  
Regular physical activity\*

#### Injury Prevention

Lap/shoulder belts  
Bicycle/motorcycle/ATV helmet\*  
Smoke detector\*  
Safe storage/removal of firearms\*  
Smoking near bedding or upholstery

#### Sexual Behavior

STD prevention: abstinence\*; avoid high-risk behavior\*; condoms/female barrier with spermicide\*  
Unintended pregnancy: contraception

#### Dental Health

Regular visits to dental care provider\*  
Floss, brush with fluoride toothpaste daily\*

#### IMMUNIZATIONS

Tdap boosters<sup>14</sup>  
Human papillomavirus (HPV)<sup>15</sup>  
Rubella<sup>5</sup> (women of childbearing age)  
Zoster (60 or older)

#### CHEMOPROPHYLAXIS

Multivitamin with folic acid (females planning or capable of pregnancy)  
Discuss aspirin prophylaxis for those at high-risk for coronary heart disease

<sup>1</sup>High-risk defined as having diabetes, family history of premature coronary disease or familial hyperlipidemia, or multiple cardiac risk factors. <sup>2</sup>Women who are or have been sexually active and who have a cervix: q < 3 yr. <sup>3</sup>FOBT: annually; flexible sigmoidoscopy: every 5 years; colonoscopy: every 10 years. <sup>4</sup>The screening decision for women 40-49 should be a mutual decision between a woman and her clinician. If a decision to proceed with mammography is made, it should be done every 2 years. <sup>5</sup>Between the ages of 50-74, screening mammography should be performed every 2 years. <sup>6</sup>Serologic testing, documented vaccination history, and routine vaccination (preferably with MMR) are equally acceptable. <sup>7</sup>High-risk defined as weight <70kg, not on estrogen replacement. <sup>8</sup>Consider screening with full DSM-IV criteria for attention deficit disorder, inattentive or hyperactive types, in children with significant overall academic or behavioral difficulty including academic failure and/or learning difficulty, especially in reading, math or handwriting. <sup>9</sup>Persons using alcohol and/or drugs. Physical and behavioral indicators: liver disease, pancreatitis, hypertension, gastritis, esophagitis, hematological disorders, poor nutritional status, cardiac arrhythmias, alcoholic myopathy, ketoacidosis, neurological disorders: smell of alcohol on breath, mood swings, memory lapses or losses, difficulty concentrating, blackouts, inappropriateness, irritability or agitation, depression, slurry speech, staggering gait, bizarre behavior, suicidal indicators, sexual dysfunction, interpersonal conflicts, domestic violence, child abuse and neglect, automobile accidents or citation arrests, scholastic or behavior problems, secretiveness or vagueness about personal or medical history. <sup>10</sup>Persons with a weight >10% below ideal body weight, parotid gland hypertrophy or erosion of tooth enamel. Females with a chemical dependency. <sup>11</sup>In women who are at increased risk, diagnostic evaluation should include an assessment of history of sexual and physical violence, interpersonal difficulties, prescription drug utilization, medical and reproductive history. <sup>12</sup>Recent divorce, separation, unemployment, depression, alcohol or other drug abuse, serious medical illness, living alone, homelessness, or recent bereavement. <sup>13</sup>Multiple unexplained somatic complaints. <sup>14</sup>Community violence or disaster, immigration, homelessness, family medical problems. <sup>15</sup>One-time Tdap dose to

# Immunization Guideline

~~substitute for Td booster; then boost with Td every 10 years. <sup>45</sup>HPV2 and HPV4 for women aged 19 through 26. Discussion with provider regarding HPV4 for males aged 19 through 26.~~

\*The ability of clinical counseling to influence this behavior is unproven.

# Immunization Guideline

## Ages 25-64 Years (Cont'd)

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### Interventions for the High-Risk Population

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RPR/VDRL (HR1); screen for gonorrhea (female) (HR2), HIV (HR3), chlamydia (female) (HR4);

PPD (HR75)

advice to reduce Infection risk (HR86)

~~Hepatitis B vaccine (HR5); Hepatitis A vaccine (HR6); pneumococcal polysaccharide vaccine (HR9); influenza vaccine (HR10); MMR (HR11); varicella~~

~~—vaccine, (HR12); meningococcal vaccine (HR16)~~

Avoid excess/midday sun, use protective clothing\* (HR137)

Folic acid 4.0 mg (HR148)

Refer for genetic counseling and evaluation for BRCA testing by appropriately trained health care provider (HR159)

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### High Risk Groups

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**HR1** = Persons who exchange sex for money or drugs, and their sex partners; persons with other STDs (including HIV); and sexual contacts of persons with active syphilis. Clinicians should also consider local epidemiology.

**HR2** = Women who exchange sex for money or drugs, or who have had repeated episodes of gonorrhea. Clinicians should also consider local epidemiology.

**HR3** = Males who had sex with males after 1975; past or present injection drug use; persons who exchange sex for money or drugs, and their sex partners; injection drug-using, bisexual or HIV-positive sex partner currently or in the past; blood transfusion during 1978-1985; persons seeking treatment for STDs. Clinicians should also consider local epidemiology.

**HR4** = Sexually active women with multiple risk factors including: history of STD; new or multiple sex partners; nonuse or inconsistent use of barrier contraceptives; cervical ectopy. Clinicians should consider local epidemiology.

~~**HR5** = Blood-product recipients (including hemodialysis patients), men who have sex with men, injection drug users and their sex partners, persons with multiple recent sex partners, persons with other STDs (including HIV).~~

~~**HR6** = Persons living in areas where the disease is endemic and where periodic outbreaks occur (e.g., certain Alaska Native, Pacific Island, Native American, and religious communities); men who have sex with men; injection or street drug users. Consider for institutionalized persons. Clinicians should also consider local epidemiology.~~

## Immunization Guideline

### Ages 25-64 Years (Cont'd)

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**HR75** = HIV positive, close contacts of persons with known or suspected TB, persons with medical risk factors associated with TB, immigrants from countries with high TB prevalence, medically underserved low-income populations (including homeless), alcoholics, injection drug users, and residents of long-term facilities.

**HR86** = Persons who continue to inject drugs.

~~**HR9** = Immunocompetent institutionalized persons >50-yr and immunocompetent with certain medical conditions, including chronic cardiac or pulmonary disease, diabetes mellitus, and anatomic asplenia. Immunocompetent persons who live in high-risk environments or social settings (e.g., certain Native American and Alaska Native populations).~~

~~**HR10** = Annual vaccination of residents of chronic care facilities; persons with chronic cardiopulmonary disorders, metabolic diseases (including diabetes mellitus), hemoglobinopathies, immunosuppression or renal dysfunction.~~

~~**HR11** = Persons born after 1956 who lack evidence of immunity to measles or mumps (e.g., documented receipt of live vaccine on or after the first birthday, laboratory evidence of immunity, or a history of physician-diagnosed measles or mumps).~~

~~**HR12** = Healthy adults without a history of chickenpox or previous immunization. Consider serologic testing for presumed susceptible adults.~~

**HR137** = Persons with a family or personal history of skin cancer, a large number of moles, atypical moles, poor tanning ability, or light skin, hair, and eye color.

**HR148** = Women with previous pregnancy affected by neural tube defect who are planning pregnancy.

**HR159** = A family history of breast or ovarian cancer that includes a relative with a known deleterious mutation in BRCA1 or BRCA2 genes; two first-degree relatives with breast cancer, one of whom received the diagnosis at age 50 years or younger; a combination of 3 or more first- or second-degree relatives with breast cancer regardless of age at diagnosis; a combination of both breast and ovarian cancer among first- and second-degree relatives; a first-degree relative with bilateral breast cancer; a combination of two or more first- or second-degree relatives with ovarian cancer regardless of age at diagnosis; a first- or second-degree relative with both breast and ovarian cancer at any age; and a history of breast cancer in a male relative. For women of Ashkenazi Jewish heritage, an increased risk family history risk includes any first-degree relative (or two second-degree relatives on the same side of the family) with breast or ovarian cancer.

~~**HR16** = Adults with anatomic or functional asplenia or persistent complement component deficiencies; first-year college students living in dormitories, military recruits~~

# Immunization Guideline

## Age 65 and Older

Interventions Considered  
and Recommended for the  
Periodic Health Examination

Leading Causes of Death  
Heart diseases  
Malignant neoplasms (lung, colorectal,  
breast)  
Cerebrovascular disease  
Chronic obstructive pulmonary disease  
Pneumonia and influenza

### Interventions for the General Population

#### SCREENING

Blood pressure  
Height and weight  
Fecal occult blood test (FOBT) and/or flexible  
sigmoidoscopy or colonoscopy t.<sup>1</sup>  
Mammogram (women ages 65-74)<sup>2</sup>  
Bone density measurement (women)  
Fasting plasma glucose for patients with hypertension or  
hyperlipidemia  
Vision screening  
Assess for hearing impairment  
Signs of elder abuse, neglect, family violence  
Alcohol, inhalant, illicit drug use<sup>3</sup>  
Anxiety and mood disorders<sup>4</sup>  
Somatoform disorders<sup>5</sup>  
Environmental stressors<sup>6</sup>  
Abdominal aortic aneurysm (AAA) (men aged 65 to 75 who  
have ever smoked)<sup>7</sup>

#### COUNSELING

##### Substance Use

Tobacco cessation  
Avoid alcohol/drug use while driving, swimming,  
boating, etc.\*

##### Diet and Exercise

Limit fat and cholesterol; maintain caloric  
balance; emphasize grains, fruits, vegetables  
Adequate calcium intake (women)  
Regular physical activity\*

Assess eating environment

#### Injury Prevention

Lap/shoulder belts  
Motorcycle and bicycle helmets\*  
Fall prevention\*  
Safe storage/removal of firearms\*  
Smoke detector\*  
Set hot water heater to <120-130°F  
CPR training for household members  
Smoking near bedding or upholstery

#### Dental Health

Regular visits to dental care provider\*  
Floss, brush with fluoride toothpaste daily\*  
Sexual Behavior  
STD prevention: avoid high-risk sexual behavior\*;  
use condoms

#### IMMUNIZATIONS

Pneumococcal vaccine  
Influenza\*  
Tetanus-diphtheria (Td)-boosters  
Zoster vaccine

#### CHEMOPROPHYLAXIS

Discuss aspirin prophylaxis for those at high-risk  
for coronary heart disease

<sup>1</sup>FOBT: annually; flexible sigmoidoscopy: every 5 years; colonoscopy: every 10 years through age 75. <sup>2</sup>Screening mammography should be performed every 2 years. <sup>3</sup>Persons using alcohol and/or drugs. Physical and behavioral indicators: liver disease, pancreatitis, hypertension, gastritis, esophagitis, hematological disorders, poor nutritional status, cardiac arrhythmias, alcoholic myopathy, ketoacidosis, neurological disorders: smell of alcohol on breath, mood swings, memory lapses or losses, difficulty concentrating, blackouts, inappropriateness, irritability or agitation, depression, slurry speech, staggering gait, bizarre behavior, suicidal indicators, sexual dysfunction, interpersonal conflicts, domestic violence, child abuse and neglect, automobile accidents or citation arrests, scholastic or behavior problems, secretiveness or vagueness about personal or medical history. <sup>4</sup>In women who are at increased risk, diagnostic evaluation should include an assessment of history of sexual and physical violence, interpersonal difficulties, prescription drug utilization, medical and reproductive history. <sup>5</sup>Multiple unexplained somatic complaints. <sup>6</sup>Community violence or disaster, immigration, homelessness, family medical problems. <sup>7</sup>One-time ultrasound. \*Annually.

\*The ability of clinical counseling to influence this behavior is unproven

# Immunization Guideline

## Age 65 and Older (Cont'd)

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### Interventions for the High-Risk Population

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PPD (HR1); amantadine/rimantadine (HR4)	HIV screen (HR3); <del>hepatitis B vaccine (HR8)</del> RPR/VDRL (HR9)
Fall prevention intervention (HR5) Consider cholesterol screening (HR6) Avoid excess/midday sun, use protective clothing* (HR7); hepatitis A vaccine (HR2)	Advice to reduce Infection risk (HR10) <del>Varicella vaccine (HR11)</del> Refer to meal and social support resources Refer for genetic counseling and evaluation for BRCA testing by appropriately trained health care provider (HR12)

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### High Risk Groups

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**HR1** = HIV positive, close contacts of persons with known or suspected TB, persons with medical risk factors associated with TB, immigrants from countries with high TB prevalence, medically underserved low-income populations (including homeless), alcoholics, injection drug users, and residents of long-term facilities.

~~**HR2** = Persons living in areas where the disease is endemic and where periodic outbreaks occur (e.g., certain Alaska Native, Pacific Island, Native American, and religious communities); men who have sex with men; injection or street drug users. Consider for institutionalized. Clinicians should also consider local epidemiology.~~

**HR3** = Men who had sex with males after 1975; past or present injection drug use; persons who exchange sex for money or drugs, and their sex partners; injection drug-using, bisexual or HIV-positive sex partner currently or in the past; blood transfusion during 1978-1985; persons seeking treatment for STDs. Clinicians should also consider local epidemiology.

**HR4** = Consider for persons who have not received influenza vaccine or are vaccinated late; when the vaccine may be ineffective due to major antigenic changes in the virus; to supplement protection provided by vaccine in persons who are expected to have a poor antibody response; and for high-risk persons in whom the vaccine is contraindicated.

**HR5** = Persons aged 75 years and older; or aged 70-74 with one or more additional risk factors including: use of certain psychoactive and cardiac medications (e.g., benzodiazepines, antihypertensives); use of >4 prescription medications; impaired cognition, strength, balance, or gait. Intensive individualized home-based multifactorial fall prevention intervention is recommended in settings where adequate resources are available to deliver such services.

**HR6** = Although evidence is insufficient to recommend routine screening in elderly persons, clinicians should consider cholesterol screening on a case-by-case basis for persons ages 65-75 with additional risk factors (e.g., smoking, diabetes, or hypertension).

**HR7** = Persons with a family or personal history of skin cancer, a large number of moles, atypical moles, poor tanning ability, or light skin, hair, and eye color.

~~**HR8** = Blood product recipients (including hemodialysis patients), men who have sex with men, injection drug users and their sex partners, persons with multiple recent sex partners, persons with other STDs~~

## Immunization Guideline

~~(including HIV).~~

**HR9** = Persons who exchange sex for money or drugs, and their sex partners; persons with other STDs (including HIV); and sexual contacts of persons with active syphilis. Clinicians should also consider local epidemiology.

**HR10** = Persons who continue to inject drugs.

~~**HR11** = Healthy adults without a history of chickenpox or previous immunization. Consider serologic testing for presumed susceptible adults.~~

**HR12** = A family history of breast or ovarian cancer that includes a relative with a known deleterious mutation in BRCA1 or BRCA2 genes; two first-degree relatives with breast cancer, one of whom received the diagnosis at age 50 years or younger; a combination of three or more first- or second degree relatives with breast cancer regardless of age at diagnosis; a combination of both breast and ovarian cancer among first- and second- degree relatives; a first-degree relative with bilateral breast cancer; a combination of two or more first- or second-degree relatives with ovarian cancer regardless of age at diagnosis; a first- or second-degree relative with both breast and ovarian cancer at any age; and a history of breast cancer in a male relative. For women of Ashkenazi Jewish heritage, an increased family history risk includes any first-degree relative (or two second degree relatives on the same side of the family) with breast or ovarian cancer.

# Immunization Guideline

## Pregnant Women\*\*

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### Interventions Considered and Recommended for the Periodic Health Examination

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#### Interventions for the General Population

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##### First visit

Blood pressure  
Hemoglobin/hematocrit  
Hepatitis B surface antigen (HBsAg)  
RPR/VDRL  
Chlamydia screen (<25 yr)  
Rubella serology or vaccination history  
D(Rh) typing, antibody screen  
Offer CVS (<13 wk)<sup>1</sup> or amniocentesis (15-18 wk)<sup>1</sup>  
(age>35 yr)  
Offer hemoglobinopathy screening  
Assess for problem or risk drinking  
HIV screening

##### Follow-up visits

Blood pressure  
Urine culture (12-16 wk)

Screening for gestational diabetes<sup>2</sup>  
Offer amniocentesis (15-18 wk)<sup>1</sup> (age>35 yr)  
Offer multiple marker testing<sup>1</sup> (15-18 wk)  
Offer serum  $\alpha$ -fetoprotein<sup>1</sup> (16-18 wk)

##### COUNSELING

Tobacco cessation; effects of passive smoking  
Alcohol/other drug use  
Nutrition, including adequate calcium intake Encourage breastfeeding  
Lap/shoulder belts  
Infant safety car seats  
STD prevention: avoid high-risk sexual behavior\*; use condoms\*

##### CHEMOPROPHYLAXIS

Multivitamin with folic acid<sup>3</sup>

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<sup>1</sup>Women with access to counseling and follow-up services, reliable standardized laboratories, skilled high-resolution ultrasound, and, for those receiving serum marker testing, amniocentesis capabilities. <sup>2</sup>Universal screening is recommended for areas (states, counties, or cities) with an increased prevalence of HIV infection among pregnant women. In low-prevalence areas, the choice between universal and targeted screening may depend on other considerations (see Ch. 28). <sup>3</sup>Beginning at least 1 mo before conception and continuing through the first trimester..

\*The ability of clinical counseling to influence this behavior is unproven.

\*\*See tables for ages 11-24 and 25-64 for other preventive services recommended for women of these age groups.

# Immunization Guideline

## Pregnant Women (Cont'd)

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### Interventions for the High-Risk Population

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POPULATION	POTENTIAL INTERVENTIONS
High-risk sexual behavior	(See detailed high-risk definitions) Screen for chlamydia (1st visit) (HR1), gonorrhea (1st visit) (HR2), HIV (1st visit) ( <del>HR3</del> ); HBsAg (3rd trimester) (HR4); RPR/VDRL (3rd trimester) (HR5)
Injection drug use	HBsAg (3rd trimester) (HR4); advice to reduce infection risk (HR6)
Unsensitized D-negative women	D(Rh) antibody testing (24-28 wk) (HR7)
Risk factors for Down syndrome	Offer CVS <sub>1</sub> (1st trimester), amniocentesis <sub>1</sub> (15-18 wk) (HR8)
Previous pregnancy with neural tube defect	Offer amniocentesis <sub>1</sub> (15-18 wk), folic acid 4.0 mg <sub>3</sub> (HR9)
High risk for child abuse	Targeted case management

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### High Risk Groups

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**HR1** = Women with history of STD or new or multiple sex partners. Clinicians should also consider local epidemiology. Chlamydia screen should be repeated in 3rd trimester if at continued risk.

**HR2** = Women under age 25 with two or more sex partners in the last year, or whose sex partner has multiple sexual contacts; women who exchange sex for money or drugs; and women with a history of repeated episodes of gonorrhea. Clinicians should also consider local epidemiology. Gonorrhea screen should be repeated in the 3rd trimester if at continued risk.

**HR4** = Women who are initially HBsAg negative who are at high risk due to injection drug use, suspected exposure to hepatitis B during pregnancy, multiple sex partners

**HR5** = Women who exchange sex for money or drugs, women with other STDs (including HIV), and sexual contacts of persons with active syphilis. Clinicians should also consider local epidemiology

**HR6** = Women who continue to inject drugs

**HR7** = Unsensitized D-negative women

**HR8** = Prior pregnancy affected by Down syndrome, advanced maternal age (>35 yr), known carriage of chromosome rearrangement

**HR9** = Women with previous pregnancy affected by neural tube defect

## Therapies With Marginal Benefit and/or High Cost Issue Summary

Question: Shall a guideline be adopted dealing with therapies with marginal benefit and high cost?

Question Source: HERC Staff, P&T Committee

Issue Summary: A number of recent issues have come up in which there are decisions around therapies that have marginal benefit and very high cost. HERC staff has been working with the Pharmacy and Therapeutics (P&T) Committee on how the Prioritized List interfaces with the work of the P&T committee.

Historically, when there is a condition with treatments that have significantly different cost-effectiveness or marginal benefit, HERC has chosen to prioritize treatments both above and below the funded region of the List or not put the treatment of questionable benefit on the List at all. P&T is performing assessments on benefit as well as cost for a number of medications and interventions. HERC could potentially refer to assessments completed by the P&T as it relates to the Prioritized List. In this way, the principles for prioritization can take into account evidence and cost-effectiveness research that the P&T committee performs.

The Prioritized List currently has a guideline that provides broad-based principles for cancer treatment at the end of life with marginal benefit and may serve as a model for developing a guideline of other treatments of little or no benefit and/or high cost.

### **GUIDELINE NOTE 12, TREATMENT OF CANCER WITH LITTLE OR NO BENEFIT PROVIDED NEAR THE END OF LIFE**

*Lines 102, 103, 123-125, 144, 159, 165, 166, 170, 181, 197, 198, 207, 208, 218, 220, 221, 228, 229, 231, 243, 249, 252, 275-278, 280, 287, 292, 310-312, 320, 339-341, 356, 459, 586, 622*

This guideline only applies to patients with advanced cancer who have less than 24 months median survival with treatment.

All patients receiving end of life care, either with the intent to prolong survival or with the intent to palliate symptoms, should have/be engaged with palliative care providers (for example, have a palliative care consult or be enrolled in a palliative care program).

Treatment with intent to prolong survival is not a covered service for patients with any of the following:

- Median survival of less than 6 months with or without treatment, as supported by the best available published evidence
- Median survival with treatment of 6-12 months when the treatment is expected to improve median survival by less than 50%, as supported by the best available published evidence
- Median survival with treatment of more than 12 months when the treatment is expected to improve median survival by less than 30%, as supported by the best available published evidence
- Poor prognosis with treatment, due to limited physical reserve or the ability to withstand treatment regimen, as indicated by low performance status.

Unpublished evidence may be taken into consideration in the case of rare cancers which are universally fatal within six months without treatment.

The Health Evidence Review Commission is reluctant to place a strict \$/QALY (quality adjusted life-year) or \$/LYS (life-year saved) requirement on end-of-life treatments, as such measurements are only approximations and cannot take into account all of the merits of an individual case. However, cost must be taken into consideration when considering treatment options near the end of life. For example, in no instance can it be justified to spend \$100,000 in public resources to increase an individual's expected survival by three months when hundreds of thousands of Oregonians are without any form of health insurance.

## Therapies With Marginal Benefit and/or High Cost Issue Summary

Treatment with the goal to palliate is addressed in Statement of Intent 1, Palliative Care.

### HERC Staff Recommendation:

- 1) Discuss adopting a new ancillary guideline note for the Prioritized List

#### ANCILLARY GUIDELINE XXX, THERAPIES WITH MARGINAL BENEFIT AND/OR HIGH COST

It is the intent of the Commission that therapies that exhibit the following characteristics generally not be included in the funded region of the Prioritized List:

- i. Marginal or clinically unimportant benefit,
- ii. Very high cost in which the cost does not justify the benefit, and
- iii. Significantly greater cost compared to alternate therapies when both have similar efficacy

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

As codes for prescription drugs and certain other ancillary services are not included on the Prioritized List, it is more difficult to indicate the importance of these services through the prioritization process. The Commission recognizes the evidence-based reviews being conducted by the Pharmacy and Therapeutics Committee and hereby prioritizes those services found in Table XX located at [www...](#) (e.g. *as of October 1, 2013*) to be prioritized on the line listed below that corresponds with the condition being treated:

<b>ICD-9-CM Codes</b>	<b>Condition classification</b>	<b>Line</b>
001-139, 771, V01-V09, V12.0, V18.8	Infectious & parasitic diseases	683
140-209, V10, V16, V58.0-V58.1, V67.1-V67.2	Malignant neoplasms	622
210-239	Benign neoplasms	656
240-279, 775, V12.1-V12.2, V18.0-V18.1	Endocrine, nutritional and metabolic diseases & immunity disorders	684
280-289, V12.3, V18.2-V18.3, V58.2	Diseases of the blood and blood-forming organs	685
290-319, V11, V17.0, V18.4, V67.3	Mental, behavioral and neurodevelopmental disorders	681
320-359, 740-742,	Diseases of the nervous system	687

## Therapies With Marginal Benefit and/or High Cost Issue Summary

779, V12.4, V17.2, V58.72		
360-389, 743-744, V19.0-V19.3, V57.4, V58.71	Diseases of the sensory organs	686
390-459, 745-747, 773-774, 776, V12.5, V17.1, V17.3-V17.4, V58.73	Diseases of the circulatory system	685
460-519, 748, 769-770, V12.6, V17.5-V17.6, V57.0, V58.74	Diseases of the respiratory system	689
520-579, 749-751, 777, V12.7, V18.5, V58.75	Diseases of the digestive system	692
580-629, 752-753, V13.0, V13.2, V18.6-V18.7, V25-V26, V56, V58.76	Diseases of the genitourinary system	690
630-679, V13.1, V22-V24, V27-V28	Complications of pregnancy, childbirth and the puerperium	690
680-709, 757, 778, V13.3, V19.4, V58.77	Diseases of the skin and subcutaneous tissue	688
710-739, 754-756, V13.4-V13.5, V17.7-V17.8, V54, V57.1-V57.2, V57.8, V58.78, V67.4	Diseases of the musculoskeletal system and connective tissue	691
758-766, 768, 780-799, V13.6-V13.9, V14-V15, V18.9, V19.6-V19.8, V20-V21, V29-V39, V40-V53, V55, V57.3, V57.9, V58.3-V58.6, V58.8-V58.9, V59-V66, V67.0, V67.5-V67.9, V68-V91	Symptoms, signs and ill-defined conditions	692*
767-768, 772, 800-	Injury and poisoning	663

## Therapies With Marginal Benefit and/or High Cost Issue Summary

999		
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\* Rename Line 692, "Gastrointestinal Conditions and Other Miscellaneous Conditions with No or Minimally Effective Treatments or No Treatment Necessary." Consider adding a new line to January 2016 list that separates out miscellaneous conditions from Line 692.

## Reflexes Issue Summary

Question: Should Guideline Note 37 be further clarified with intent about the definition of “abnormal reflexes?”

Question Source: John Sattenspiel, LIPA, OHP Managed Care Medical Directors

Issue: Guideline Note 37 defines neurologic impairment, and abnormal reflexes can be one of the criteria. Dr. Sattenspiel raises the concern that abnormal reflexes are quite subjective and possibly over-interpreted.

From Dr. Sattenspiel

This statement is from Disorders of the Nervous System – Reeves & Swenson and in my mind it is a reasonable description of reflex examination and grading:

### ***Examination of myotatic ("deep tendon") reflexes***

*The muscle stretch (myotatic) reflex is a simple reflex, with the receptor neuron having direct connections to the muscle spindle apparatus in the muscle and with the alpha motor neurons in the central nervous system that send axons back to that muscle (Fig. 8-1). Normal muscle stretch reflexes result in contraction only of the muscle whose tendon is stretched and the agonist muscles (i.e., muscles that have the same action). There is also inhibition of antagonist muscles.*

*Reflexes are graded at the bedside in a semi-quantitative manner. The response levels of deep tendon reflexes are grade 0-4+, with 2+ being normal. The designation "0" signifies no response at all, even after reinforcement. Reinforcement requires a maximal isometric contraction of muscles of a remote part of the body, such as clenching the jaw, pushing the hands or feet together (depending on whether an upper or lower limb reflex is being tested), or locking the fingers of the two hands and pulling (termed the Jendrassik maneuver). This kind of maneuver probably amplifies reflexes by two mechanisms: by distracting the patient from voluntarily suppressing the reflex and by decreasing the amount of descending inhibition.*

*The designation 1+ means a sluggish, depressed or suppressed reflex, while the term trace means that a barely detectable response is elicited. Reflexes that are noticeably more brisk than usual are designated 3+, while 4+ means that the reflex is hyperactive and that there is clonus present. Clonus is a repetitive, usually rhythmic, and variably sustained reflex response elicited by manually stretching the tendon. This clonus may be sustained as long as the tendon is manually stretched or may stop after up to a few beats despite continued stretch of the tendon. In this case it is useful to note how many beats are present.*

## Reflexes Issue Summary

*One sign of reflex hyperactivity is contraction of muscles that have different actions while eliciting a muscle stretch reflex (for example, contraction of thigh adductors when testing the patellar reflex or contraction of finger flexor muscles when testing the brachioradialis reflex). This has been termed "pathological spread of reflexes."*

*Practice observing normal reflexes in patients and initially among students is an excellent way to determine the range of normalcy. **Almost any grade of reflex (outside of sustained clonus) can be normal.** Asymmetry of reflexes is a key for determining normalcy when extremes of response do not make the designation obvious. The patient's symptoms may facilitate the determination of which side is normal, i.e., the more active or the less active side. If this is a problem, the remainder of the neurologic examination and findings usually clarify the issue.*

*Decreased reflexes should lead to suspicion that the reflex arc has been affected. This could be the sensory nerve fiber but may also be the spinal cord gray matter or the motor fiber. This motor fiber (the anterior horn cell and its motor axon coursing through the ventral root and peripheral nerve) is termed the "lower motor neuron" (LMN). LMN lesions result in decreased reflexes. The descending motor tracts from the cerebral cortex and brain stem are termed the "upper motor neurons" (UMN). Lesions of the UMNs result in increased reflexes at the spinal cord by decreasing tonic inhibition of the spinal segment.*

*Lesions of the cerebellum and basal ganglia in humans are not associated with consistent changes in the muscle stretch reflex. Classically, destruction of the major portion of the cerebellar hemispheres in humans is associated with pendular deep-tendon reflexes. The reflexes are poorly checked so that when testing the patellar reflex, for example, the leg may swing to-and-fro (like a pendulum). In normal individuals, the antagonist muscles (in this example, the hamstrings) would be expected to dampen the reflex response almost immediately. However, this is not a common sign of cerebellar disease and many other signs of cerebellar involvement are more reliable and diagnostic (see [Chapt. 10](#)). Basal ganglia disease (e.g., parkinsonism) usually is not associated with any predictable reflex change; most often the reflexes are normal.*

Note particularly the second highlighted section. I would advocate for a statement that reflex status could be removed; or at least clarified to require absence of reflexes or markedly diminished reflexes to be considered as objective evidence that meets the guideline for coverage. What we often see is reflexes graded on an 5 point scale, reported as 4/5, and presented as sufficient to meet criteria as objective findings of impairment.

### Current Prioritized List Status

#### **GUIDELINE NOTE 37, DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT**

Line: 400

Neurologic impairment or radiculopathy is defined as objective evidence of one or more of the following:

2

## Reflexes Issue Summary

- A) Abnormal reflexes
- B) Segmental muscle weakness
- C) Segmental sensory loss
- D) EMG or NCV evidence of nerve root impingement
- E) Cauda equina syndrome,
- F) Neurogenic bowel or bladder
- G) Long tract abnormalities

Otherwise, disorders of spine not meeting these criteria (e.g. pain alone) fall on Line 562 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT

### HERC Staff Recommendation

1. Option 1 - Modify Guideline Note 37 as follows:

#### **GUIDELINE NOTE 37, DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT**

Line: 400

Neurologic impairment or radiculopathy is defined as objective evidence of one or more of the following:

- A) Abnormal reflexes ([i.e. asymmetric, with markedly diminished or absent reflexes](#))
- B) Segmental muscle weakness
- C) Segmental sensory loss
- D) EMG or NCV evidence of nerve root impingement
- E) Cauda equina syndrome,
- F) Neurogenic bowel or bladder
- G) Long tract abnormalities

Otherwise, disorders of spine not meeting these criteria (e.g. pain alone) fall on Line 562 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT

2. Option 2 - make no change

# **Evidence-based Report Development Rule**

Secretary of State  
**NOTICE OF PROPOSED RULEMAKING HEARING\***  
A Statement of Need and Fiscal Impact accompanies this form.

Oregon Health Authority, Oregon Health Policy and Research 409  
Agency and Division Administrative Rules Chapter Number

Zarie Haverkate 1225 Ferry St SE, 1<sup>st</sup> Floor, Salem, OR 97301 503-373-1574  
Rules Coordinator Address Telephone

**RULE CAPTION**

**Health Evidence Review Commission Process for Evidence-based Reports**

Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

January 16, 2013 1:30 p.m. General Services Bldg., Mt. Mazama Room, 1225 Ferry St SE, Salem, OR Zarie Haverkate  
Hearing Date Time Location Hearings Officer

*Auxiliary aids for persons with disabilities are available upon advance request.*

**RULEMAKING ACTION**

Secure approval of new rule numbers (Adopted or Renumbered rules) with the Administrative Rules Unit prior to filing.

ADOPT: OAR 409-060-0100, 409-060-010<sup>0110</sup>, 409-060-0120, 409-060-0130, 409-060-0140, and 409-060-0150.

Stat. Auth. : ORS 414.695 & 413.042

Stats. Implemented: ORS 414.695 & 414.698

**RULE SUMMARY**

The Office for Oregon Research and Development needs to adopt rules to document the process the Health Evidence Review Commission (HERC) will follow in developing medical technology assessments and other evidence based reports based on comparative effectiveness research so that the public and interested stakeholders understand what to expect from the Commission and know how to best provide input into the process.

Friday, January 18, 2013 @ 5 p.m.

Last Day for Public Comment (Last day to submit written comments to the Rules Coordinator)

*Zarie Haverkate* Zarie Haverkate 12/14/12  
Signature Printed name Date

\*Hearing Notices published in the Oregon Bulletin must be submitted by 5:00 pm on the 15th day of the preceding month unless this deadline falls on a weekend or legal holiday, upon which the deadline is 5:00 pm the preceding workday. ARC 920-2005

Secretary of State  
**STATEMENT OF NEED AND FISCAL IMPACT**

A Notice of Proposed Rulemaking Hearing or a Notice of Proposed Rulemaking accompanies this form.

**Oregon Health Authority, Oregon Health Policy and Research**

**409**

Agency and Division

Administrative Rules Chapter Number

**Health Evidence Review Commission Process for Evidence-based Reports**

Rule Caption (Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.)

In the Matter of: **The adoption of OAR 409-060-0100, 409-060-0100, 409-060-0120, 409-060-0130, 409-060-0140, and 409-060-0150.**

Statutory Authority: **ORS 414.695 & 413.042**

Stats. Implemented: **ORS 414.695 & 414.698**

Need for the Rule(s): **The Authority needs to adopt these rules to clearly document the process the Health Evidence Rule Commission will follow in developing medical technology assessments and related reviews based on comparative effectiveness research so that the public and interested stakeholders understand what to expect from the Commission and know how to best provide input into the process.**

Documents Relied Upon, and where they are available: **ORS 414.695 & 414.698 available at:**

<http://www.leg.state.or.us/ors/414.html>.

Fiscal and Economic Impact: **Adopting these rules will have no fiscal impact on the Authority other state agencies, local government, clients, the public, or businesses, including small businesses.**

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)): **None.**
2. Cost of compliance effect on small business (ORS 183.336): **There is no cost of compliance.**
  - a. Estimate the number of small businesses and types of business and industries with small businesses subject to the rule:  
**None**
  - b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services: **N/A**
  - c. Equipment, supplies, labor and increased administration required for compliance: **N/A**

How were small businesses involved in the development of this rule? **No impact to small businesses.**

Administrative Rule Advisory Committee consulted?: **Yes**

If not, why?:

  
Signature

Zarie Haverkate

Printed name

12/14/12

Date

Administrative Rules Unit, Archives Division, Secretary of State, 800 Summer Street NE, Salem, Oregon 97310. ARC 925-2007

**CHAPTER 409  
OREGON HEALTH AUTHORITY,  
OFFICE FOR OREGON HEALTH POLICY AND RESEARCH**

**DIVISION 60  
HEALTH EVIDENCE REVIEW COMMISSION**

**Comparative Effectiveness and Evidence-based Reports**

**409-060-0100 Scope**

- (1) These rules (OAR 409-060-0100 to 409-060-0150) define criteria and processes that the Health Evidence Review Commission shall use to develop evidence-based reports, including medical technology assessments, evidence-based guidelines and coverage guidances.
- (2) The Commission may consider evidence relating to prescription drugs that is relevant to an evidence-based report but may not conduct a drug class evidence review or evidence-based report solely of a prescription drug.

Stat. Auth.: ORS 414.695 & 413.042

Stats. Implemented: ORS 414.695 & 414.698

**409-060-0110  
Definitions**

The following definitions apply to OAR 409-060-0100 to 409-060-0150:

- (1) “Ad hoc expert” means an individual identified by the Commission as having particular expertise in a technology or its application.
- (2) “Commission” means the Health Evidence Review Commission.
- (3) “Coverage guidance” means a report approved by the Commission on a health service or technology which makes coverage recommendations for insurers and health care purchasers in furthering the use of evidence-based healthcare.
- (4) “Evidence-based guideline” means an evidence-based report on a health service or technology, for use by health care providers in encouraging the use of the safest and most effective care possible.
- (5) “Evidence-based report” means a medical technology assessment, evidence-based guideline or coverage guidance which includes conclusions and recommendations based on the information in the source documents, and which incorporates the clinical context necessary for the information to be properly interpreted by policymakers.
- (6) “EbGS” means the Evidence-based Guidelines Subcommittee.

- (7) “HTAS” means the Health Technology Assessment Subcommittee
- (8) “Medical technology” or “technology” means medical equipment and devices, medical or surgical procedures and other techniques used or prescribed by health care providers in delivering health care to individuals, and the organizational or supportive systems within which health care is delivered.
- (9) “Medical technology assessment” means an evidence-based report on the use, clinical effectiveness and risks, and cost of a technology in comparison with its alternatives.
- (10) “OHPR” means the Office for Oregon Health Policy and Research.
- (11) “Subcommittee” means a subcommittee established by the Commission.
- (12) “Trusted source” means a source designated by the Commission for use in developing an evidence-based report.

Stat. Auth.: ORS 414.695 & 413.042

Stats. Implemented: 414.695 & 414.698

#### **409-060-0120**

#### **Health Evidence Review Commission Process for Evidence-based Reports**

- (1) The Commission shall develop evidence-based reports or may direct a Subcommittee to prepare these reports. The Commission shall identify reports from trusted sources to serve as the basis for these reports. Meetings shall be public and conducted in a manner consistent with the Commission’s policies and procedures.
- (2) Topics for review shall be publicly identified at least 30 days prior to the initial Subcommittee meeting at which a draft evidence-based report is reviewed. In this notice, the Subcommittee shall make publicly available the primary evidence source documents to be used in creating the initial draft report, except when source documents are proprietary. In lieu of proprietary source documents, the Subcommittee shall make publicly available a citation of the evidence source. In the case of a primary evidence source, a full listing of citations from the proprietary source with a summary of evidence findings. If additional sources are added to the initial draft report after this notice, the Subcommittee shall publicly identify them no later than 14 days prior to the Subcommittee meeting where they will be discussed.
- (3) When developing an evidence-based report, the Commission or its designated Subcommittee shall consult with two or more ad hoc experts on the subject matter of the evidence-based report. Subcommittee shall publicly solicit ad hoc experts at least 30 days prior to the meeting at which it reviews the initial draft evidence-based report. One of the ad hoc experts must be a provider who manages patients who would potentially receive the treatment, service or device in question. Candidates wishing to serve as ad hoc

experts shall disclose conflicts of interest according to HERC bylaws. The OHPR Administrator shall appoint ad hoc experts..

- (4) After the Subcommittee reviews the initial draft report, the subcommittee may revise the initial draft report. The Subcommittee shall then solicit public comment on this version of the draft report over a 30-day period. Draft reports posted for comment shall include citations for all sources used in developing the report and a summary of evidence findings. The Subcommittee shall publicly disclose written comments received during the 30-day period, draft responses and additional revisions (if any) to the draft report at least seven days before the Subcommittee meeting at which the Subcommittee reviews public comments. After discussing the available evidence and considering public comment, including additional verbal testimony, the Subcommittee shall make conclusions as to the overall importance of beneficial effects versus potential harms and approve its final draft evidence-based report reflecting these conclusions.
- (5) Before an evidence-based report is reviewed at a Commission meeting, a final draft report approved by the Subcommittee, along with all written public comments received during the public comment period and the Subcommittee's responses to these public comments shall be made publicly available for a period of at least 14 days. At the meeting, the Commission shall consider the Subcommittee's approved draft report and accept further public comment.
- (6) After evaluating the report and public comments the Commission may take one of three actions:
  - (a) Accept the report as written.
  - (b) Make edits to the report and accept as modified.
  - (c) Return the report to the Subcommittee with recommendations for further work.
- (7) The Commission or its Subcommittees may revise evidence-based reports when additional information relevant to the report becomes available or if the findings of one or more of the source reports change. The Commission or its Subcommittees may initiate a review at the request of interested parties who provide information or interpretations not considered in developing an existing evidence-based report. At a minimum, the HERC or one of its Subcommittees shall review the need to update each report within two years after its adoption or most recent revision.

Stat. Auth.: ORS 414.695 & 413.042

Stats. Implemented: 414.695 & 414.698

**409-060-0130****Medical Technology Assessments**

- (1) Medical technology assessments undertaken by the Commission shall be developed by HTAS and may include any technologies listed in the definition in ORS 414.695 and 414.698(1). Medical technology assessments shall be performed in cases where technology assessments from trusted sources do not exist or require the consideration of additional evidence. Medical Technology Assessments shall include a new search of the current peer-reviewed research on the topic. Assessments shall be developed according to the process described in OAR 409-060-0120 except as described in this section.

Stat. Auth.: ORS 414.695 & 413.042

Stats. Implemented: 414.695 & 414.698

**409-060-0140****Evidence-based Guidelines**

The EbGS shall develop evidence based guidelines based on one or more existing guideline from trusted sources, which may involve the consideration of additional research. Evidence-based guidelines shall be developed according to the process described in OAR 409-060-0120 except as described in this section.

Stat. Auth.: ORS 414.695 & 413.042

Stats. Implemented: 414.695 & 414.698

**409-060-0150****Coverage Guidances**

- (1) A Subcommittee shall develop coverage guidances which shall be based on reports developed by trusted sources, and may cite supplemental evidence which is more recent or beyond the scope of the report. Coverage Guidances shall be developed according to the process described in OAR 409-060-0120 except as described in this section.
- (2) OAR 409-060-0120(3) does not apply to this section. Instead, if the Subcommittee responsible for development of the report lacks sufficient expertise in the relevant field, or a request is received from an interested outside party the Subcommittee shall solicit an ad hoc expert to provide additional information as requested. Requests from interested parties to appoint ad hoc experts must be submitted fourteen days prior to the subcommittee's first review of the initial draft coverage guidance. The subcommittee may appoint ad hoc experts based on requests that arrive after this point. Candidates wishing to serve as ad hoc experts shall disclose conflicts of interest according to HERC bylaws. The OHPR administrator shall appoint ad hoc experts. Ad hoc experts shall answer technical questions and provide clinical context during the review of the evidence.

Stat. Auth.: ORS 414.695 & 413.042

Stats. Implemented: 414.695 & 414.698

# Coverage Guidance Process

## Potential changes to the coverage guidance process

Question: How should the coverage guidance process and reports be modified?

Question source: HERC, subcommittees, and HERC staff

Issue: The subcommittees and HERC have all identified challenges with the current coverage guidance process and areas which there have been discussions about modification. HERC Staff, the Center, and the Committee Chairs have met and attempted to revise the coverage guidance process to capture these concerns.

- 1) What should be the theoretical framework underlying the decisions made in coverage guidances?
- 2) When there is insufficient evidence, what decision should be made?
- 3) Should the use of coverage language be modified and what should the coverage guidances say with regard to different types of plans (e.g., OHP vs commercial)?
- 4) How should the process be better streamlined so that HERC is not revisiting coverage guidances multiple times?
- 5) Should the coverage guidances be modified to address some implementation concerns, especially regarding national or Oregon standards?
- 6) How should the use of outside expert input into the process be modified?
- 7) Providers are often unaware of what is going on, resulting in feedback that occurs after the coverage guidances have been approved. Should there be a different outreach plan?
- 8) What should be the initial approach to developing a recommendation for a topic?
- 9) Should there be additional explanation of the committee deliberations for the final coverage recommendations including in the Coverage Guidance document?

### Concerns and HERC Staff Recommendations

- 1) **Concern:** What should be the theoretical framework underlying the decisions made in coverage guidances?

#### **HERC Staff Recommendations:**

- A. Use a GRADE-based format
- B. Add GRADE-lite summary table to the Coverage Guidances
- C. Use strong and weak recommendations
- D. Add description of GRADE framework to Coverage Guidances

- 2) **Concern:** When there is insufficient evidence, what decision should be made?

**HERC Staff Recommendation:**

- A. Use algorithm as guide
- B. Use GRADE-lite methodology to allow other considerations than quality of evidence including: values and preferences, costs, and balance between desirable and undesirable effects
- C. Consider if “no recommendation” is ever an option, or if a weak recommendation (for or against) would always be indicated. Similarly, should language such as “it is recommended coverage not be restricted” be used when there is the reasonable possibility of real and permanent harm

- 3) Concern:** Should the use of coverage language be modified and what should the coverage guidances say with regard to different types of plans?

**HERC Staff Recommendation:**

- A. VBBS makes coverage recommendations for OHP, but language will to be helpful for other plans. There is some concern about strong language for coverage for non-OHP plans.
  - a. Option 1 – Keep wording the same should/should not cover, weak or strong
  - b. Option 2 - Change wording to say is/is not recommended for coverage, weak or strong
    - i. Benefits – still has coverage language but away from “should cover” language
  - c. Option 3 – change wording to say is/is not recommended, weak or strong
    - i. Benefit – more adherent to GRADE language
    - ii. Drawbacks – likely would increase confusion about whether this is a guideline or a coverage guidance
  - d. Option 4 – change wording to say there is strong/weak rationale for/against coverage.
  - e. Consider if there is a role for the term moderate, in addition to strong and weak, to allow for greater granularity
- B. Adapt GRADE-lite framework
- C. Other plans can use strong/weak language to make their own coverage decisions

- 4) Concern:** How should the process be better streamlined so that HERC is not revisiting coverage guidances multiple times?

**HERC Staff Recommendation:**

- a. CG go directly from subcommittee to VBBS for coverage decision for OHP and then to HERC for final approval. If implementation concerns are raised at VBBS then could be sent back to originating subcommittee for consideration prior to going to HERC.

- 5) **Concern:** Should the coverage guidances be modified to address some implementation concerns, especially regarding national or Oregon standards?

**HERC Staff Recommendation:**

- A. Add policy landscape section
- i. Search National Quality Measures Clearinghouse for pertinent metrics
  - ii. Add Oregon's Quality Strategy for CCOs (includes 100 performance strategies) if applicable
  - iii. Consider
    - i. Staff to look at national professional society activities (not exhaustive, just if readily available)
    - ii. Ask experts and/or specialty society about statewide or national efforts

- 6) **Concern:** How should the use of outside expert input into the process be modified?

**HERC Staff Recommendation:**

The Rules Advisory Committee met and the following draft language on the use of experts is present in the draft rules:

**409-060-0150**

**Coverage Guidances**

OAR 409-060-0120(3) does not apply to this section. Instead, if the Subcommittee responsible for development of the report lacks sufficient expertise in the relevant field, or a request is received from an interested outside party the Subcommittee shall solicit an ad hoc expert to provide additional information as requested. Requests from interested parties to appoint ad hoc experts must be submitted fourteen days prior to the subcommittee's first review of the initial draft coverage guidance. The subcommittee may appoint ad hoc experts based on requests that arrive after this point. Candidates wishing to serve as ad hoc experts shall disclose conflicts of interest according to HERC bylaws. The OHPR administrator shall appoint ad hoc experts. Ad hoc experts shall answer technical questions and provide clinical context during the review of the evidence.

- 7) **Concern:** Providers are often unaware of what is going on, resulting in feedback that occurs after the coverage guidances have been approved. Should there be a different outreach plan?

**HERC Staff Recommendations:**

- a. Discuss if some level of early outreach strategy is indicated to professional associations, either as an initial introduction to the process (how to sign up for public meeting notices) or an updated specific outreach with each topic. This latter approach would potentially play into expert selection as well.

**8) Concern:** What should be the initial approach to developing a recommendation for a topic?

**HERC Staff Recommendations:**

- a. Rely on the algorithm as a structured guide
- b. Consider if the algorithm needs to have values/preferences added in or if it is fine as it stands without exactly adhering to GRADE domains

**9) Concern:** Should there be additional explanation of the committee deliberations for the final coverage recommendations including in the Coverage Guidance document?

**HERC Staff Recommendations:**

- a. Consider adding a section towards the end of the Coverage Guidance document that summarizes the major issues considered (evidence and GRADE domains and other issues such as implementation) leading to the final recommendations.

## **Feedback on coverage guidance process from perinatal collaborative group**

Question: As HERC is modifying its coverage guidance process, what types of responses or changes are indicated based on public comments received, including the feedback received from the Perinatal Collaborative meeting

Question Source: Perinatal Collaborative Group (feedback predominantly from participating OB/GYNs)

Issue: On December 3, 2012, HERC staff was invited to attend a Perinatal Collaborative meeting in order to provide information about the coverage guidance process and also receive feedback about major concerns by the present OB/GYN community. This is presented as parts of the coverage guidance process are currently under flux, and the feedback is opportune.

This is a HERC staff summary of the key concerns raised.

- 1) General concern that the language about individualized decision making and key indications for IOL (such as fetal demise, preeclampsia) are located in a footnote. This feels nonsupportive of clinicians and makes them wonder if plans will try to not offer coverage for what are clearly appropriate indications for induction
- 2) Concerns that this is not what ACOG recommends and unlike other specialties, they practice exactly in line with this one professional organization which is the single most important factor in determining standard of care/malpractice. To have something different than what ACOG/standard of care would subject them to liability.
- 3) There is potential harm in not permitting elective induction of labor during the 39-41 weeks time period, with increased rates of stillbirth. This should be an option for patients.
- 4) They have been working hard across many hospital systems to create this hard stop at 39 weeks and have made tremendous progress in decreasing early elective inductions. They would really like to see greater alignment and have 39 weeks be the cutoff to ensure efforts are all simultaneous
- 5) The level of disgruntlement varied across providers. One stressed that the HERC has no right to go against ACOG in determining that elective cesarean sections should not be covered, while others disagreed.
- 6) There were concerns about having a nonstandard form of implementation.
- 7) There were concerns about a two-tiered system, where those with OHP would get different care than those without OHP.
- 8) Need to acknowledge that “insufficient evidence” doesn’t really describe what may be the best available or possible evidence for a specific group (e.g. placenta previa and CS). Should have some qualifications about the best level of evidence supporting a recommendation, but can also

make a recommendation to support when evidence is not of RCT quality if it is the best to be expected or would be unethical to do an RCT.

- 9) They strongly believe expert input was indicated

**HERC Staff responses**

<b>OG/GYN concerns</b>	<b>HERC response</b>
<p>Concern about discrepancies between professional guidelines and coverage guidances</p>	<p>Sometimes varying professional guidelines exist with opposing recommendations. The HERC coverage guidances are based on the best evidence, which may or may not be what a specific guideline is based on. An individual provider has the right to choose how that they are going to approach an individual patient, regardless of the population-based plan coverage. With the adoption of the GRADE based methodology, additional concerns beyond the quality of the evidence will also be taken into account.</p>
<p>Individualized decision making language being nonsupportive</p>	<p>This language is currently being reviewed and alternate language, such as “coverage should not be limited,” may be adopted.</p> <p>Footnotes are also being recommended to largely be moved to within the box.</p>
<p>Two-tiered system concerns</p>	<p>Right now OHP patients do get a different benefit package than, for example, commercially insured patients. The intent of the coverage guidances is to be more consistent with what will improve health outcomes and decrease unnecessary care. Improving health outcomes, decreasing harms, and containing costs would be a desirable outcome for all health plans.</p>

<p>Concern that the quality of evidence assessment does not take into account the real level of evidence that may be obtainable for a specific condition-treatment (e.g. no RCT for placenta previa and CS)</p>	<p>HERC is actively reviewing this issue and the adoption of a modified GRADE- framework would allow for a more comprehensive and transparent process for addressing quality of evidence as well as other factors.</p>
<p>Implementation concerns</p>	<p>HERC has felt that implementation should be up to individual plans. However, HERC is discussing adding a “policy landscape” section that would incorporate relevant national quality metrics and potentially national/state-wide efforts related to the specific issue that would be considered during the coverage guidance development process.</p>
<p>Involvement of experts</p>	<p>This is an active area of discussion. HERC’s proposed administrative rule (public comments to be accepted through January 18th) states that if outside expertise is not present on the subcommittee or is requested by an interested party, it shall be solicited.</p> <p>HERC will discuss whether the outreach strategy shall be changed.</p>
<p>Specific concerns about IOL coverage guidance</p>	<p>This particular coverage guidance is being used as an example of the new “GRADE-lite” process and will likely see modifications. Specific concerns about the language can be dealt with by the EbGS subcommittee.</p>

# BMJ

## GRADE: an emerging consensus on rating quality of evidence and strength of recommendations

Gordon H Guyatt, Andrew D Oxman, Gunn E Vist, Regina Kunz, Yngve Falck-Ytter, Pablo Alonso-Coello, Holger J Schünemann and for the GRADE Working Group

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## RATING QUALITY OF EVIDENCE AND STRENGTH OF RECOMMENDATIONS

# GRADE: an emerging consensus on rating quality of evidence and strength of recommendations

Guidelines are inconsistent in how they rate the quality of evidence and the strength of recommendations. This article explores the advantages of the GRADE system, which is increasingly being adopted by organisations worldwide

Guideline developers around the world are inconsistent in how they rate quality of evidence and grade strength of recommendations. As a result, guideline users face challenges in understanding the messages that grading systems try to communicate. Since 2006 the *BMJ* has requested in its "Instructions to Authors" on [bmj.com](http://bmj.com) that authors should preferably use the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for grading evidence when submitting a clinical guidelines article. What was behind this decision?

In this first in a series of five articles we will explain why many organisations use formal systems to grade evidence and recommendations and why this is important for clinicians; we will focus on the GRADE approach to recommendations. In the next two articles we will examine how the GRADE system categorises quality of evidence and strength of recommendations. The final two articles will focus on recommendations for diagnostic tests and GRADE's framework for tackling the impact of interventions on use of resources.

GRADE has advantages over previous rating systems (box 1). Other systems share some of these advantages, but none, other than GRADE, combines them all.<sup>1</sup>

## What is "quality of evidence" and why is it important?

In making healthcare management decisions, patients and clinicians must weigh up the benefits and downsides of alternative strategies. Decision makers will be influenced not only by the best estimates of the expected

### Box 1 | Advantages of GRADE over other systems

- Developed by a widely representative group of international guideline developers
- Clear separation between quality of evidence and strength of recommendations
- Explicit evaluation of the importance of outcomes of alternative management strategies
- Explicit, comprehensive criteria for downgrading and upgrading quality of evidence ratings
- Transparent process of moving from evidence to recommendations
- Explicit acknowledgment of values and preferences
- Clear, pragmatic interpretation of strong versus weak recommendations for clinicians, patients, and policy makers
- Useful for systematic reviews and health technology assessments, as well as guidelines

**Gordon H Guyatt** professor, Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, ON, Canada L8N 3Z5

**Andrew D Oxman** researcher, Norwegian Knowledge Centre for the Health Services, PO Box 7004, St Olavs Plass, 0130 Oslo, Norway

**Gunn E Vist** researcher, Norwegian Knowledge Centre for the Health Services, PO Box 7004, St Olavs Plass, 0130 Oslo, Norway

**Regina Kunz** associate professor, Basel Institute of Clinical Epidemiology, University Hospital Basel, Hebelstrasse 10, 4031 Basel, Switzerland

**Yngve Falck-Ytter** assistant professor, Division of Gastroenterology, Case Medical Center, Case Western Reserve University, Cleveland, OH 44106, USA

**Pablo Alonso-Coello** researcher, Iberoamerican Cochrane Center, Servicio de Epidemiología Clínica y Salud Pública (Universidad Autónoma de Barcelona), Hospital de Sant Pau, Barcelona 08041, Spain

**Holger J Schünemann** professor, Department of Epidemiology, Italian National Cancer Institute Regina Elena, Rome, Italy for the GRADE Working Group

**Correspondence to:** G H Guyatt, CLARITY Research Group, Department of Clinical Epidemiology and Biostatistics, Room 2C12, 1200 Main Street, West Hamilton, ON, Canada L8N 3Z5 [guyatt@mcmaster.ca](mailto:guyatt@mcmaster.ca)

**This is the first in a series of five articles that explain the GRADE system for rating the quality of evidence and strength of recommendations.**

advantages and disadvantages but also by their confidence in these estimates. The cartoon depicting the weather forecaster's uncertainty captures the difference between an assessment of the likelihood of an outcome and the confidence in that assessment (figure). The usefulness of an estimate of the magnitude of intervention effects depends on our confidence in that estimate.

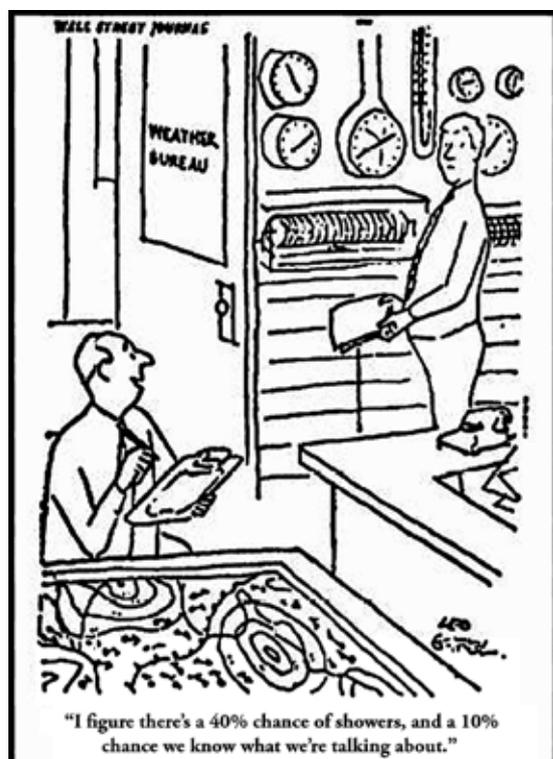
Expert clinicians and organisations offering recommendations to the clinical community have often erred as a result of not taking sufficient account of the quality of evidence.<sup>2</sup> For a decade, organisations recommended that clinicians encourage postmenopausal women to use hormone replacement therapy.<sup>3</sup> Many primary care physicians dutifully applied this advice in their practices.

A belief that such therapy substantially decreased women's cardiovascular risk drove this recommendation. Had a rigorous system of rating the quality of evidence been applied at the time, it would have shown that because the data came from observational studies with inconsistent results, the evidence for a reduction in cardiovascular risk was of very low quality.<sup>4</sup> Recognition of the limitations of the evidence would have tempered the recommendations. Ultimately, randomised controlled trials have shown that hormone replacement therapy fails to reduce cardiovascular risk and may even increase it.<sup>5 6</sup>

The US Food and Drug Administration licensed the antiarrhythmic agents encainide and flecainide for use in patients on the basis of the drugs' ability to reduce asymptomatic ventricular arrhythmias associated with sudden death. This decision failed to acknowledge that because arrhythmia reduction reflected only indirectly on the outcome of sudden death the quality of the evidence for the drugs' benefit was of low quality. Subsequently, a randomised controlled trial showed that the two drugs increase the risk of sudden death.<sup>7</sup> Appropriate attention to the low quality of the evidence would have saved thousands of lives.

Failure to recognise high quality evidence can cause similar problems. For instance, expert recommendations lagged a decade behind the evidence from well conducted randomised controlled trials that thrombolytic therapy achieved a reduction in mortality in myocardial infarction.<sup>8</sup>

Insufficient attention to quality of evidence risks inappropriate guidelines and recommendations that may lead clinicians to act to the detriment of their



patients. Recognising the quality of evidence will help to prevent these errors.

#### How should guideline developers alert clinicians to quality of evidence?

A formal system that categorises quality of evidence—for example, from high to very low—represents an obvious strategy for conveying quality of evidence to clinicians. Some limitations, however, do exist. Quality of evidence is a continuum; any discrete categorisation involves some degree of arbitrariness. Nevertheless, advantages of simplicity, transparency, and vividness outweigh these limitations.

#### What is “strength of recommendation” and why is it important?

A recommendation to offer patients a particular treatment may arise from large, rigorous randomised controlled trials that show consistent impressive benefits with few side effects and minimal inconvenience and cost. Such is the case with using a short course of oral steroids in patients with exacerbations of asthma. Clinicians can offer such treatments to almost all their patients with little or no hesitation.

Alternatively, treatment recommendations may arise from observational studies and may involve appreciable harms, burdens, or costs. Deciding whether to use antithrombotic therapy in pregnant women with prosthetic heart valves involves weighing the magnitude of reduction in valve thrombosis against inconvenience, cost, and risk of teratogenesis. Clinicians offering such treatments must help patients to weigh up the desirable and undesirable effects carefully according to their values and preferences.

Guidelines and recommendations must therefore

indicate whether (a) the evidence is high quality and the desirable effects clearly outweigh the undesirable effects, or (b) there is a close or uncertain balance. A simple, transparent grading of the recommendation can effectively convey this key information.

There are limitations to formal grading of recommendations. Like the quality of evidence, the balance between desirable and undesirable effects reflects a continuum. Some arbitrariness will therefore be associated with placing particular recommendations in categories such as “strong” and “weak.” Most organisations producing guidelines have decided that the merits of an explicit grade of recommendation outweigh the disadvantages.

#### What makes a good grading system?

Not all grading systems separate decisions regarding the quality of evidence from strength of recommendations. Those that fail to do so create confusion. High quality evidence doesn't necessarily imply strong recommendations, and strong recommendations can arise from low quality evidence.

For example, patients who experience a first deep venous thrombosis with no obvious provoking factor must, after the first months of anticoagulation, decide whether to continue taking warfarin long term. High quality randomised controlled trials show that continuing warfarin will decrease the risk of recurrent thrombosis but at the cost of increased risk of bleeding and inconvenience. Because patients with varying values and preferences will make different choices, guideline panels addressing whether patients should continue or terminate warfarin should—despite the high quality evidence—offer a weak recommendation.

Consider the decision to administer aspirin or paracetamol (acetaminophen) to children with chicken pox. Observational studies have observed an association between aspirin administration and Reye's syndrome.<sup>9</sup> Because aspirin and paracetamol are similar in their analgesic and antipyretic effects, the low quality evidence regarding the association between aspirin and Reye's syndrome does not preclude a strong recommendation for paracetamol.

Systems that classify “expert opinion” as a category of evidence also create confusion. Judgment is necessary for interpretation of all evidence, whether that evidence is high or low quality. Expert reports of their clinical experience should be explicitly labelled as very low quality evidence, along with case reports and other uncontrolled clinical observations.

Grading systems that are simple with respect to judgments both about the quality of the evidence and the strength of recommendations facilitate use by patients, clinicians, and policy makers.<sup>1</sup> Detailed and explicit criteria for ratings of quality and grading of strength will make judgments more transparent to those using guidelines and recommendations.

Although many grading systems to some extent meet these criteria,<sup>1</sup> a plethora of systems makes their use difficult for frontline clinicians. Understanding a variety of systems is neither an efficient nor a realistic use of clinicians' time. The GRADE system is used

widely: the World Health Organization, the American College of Physicians, the American Thoracic Society, UpToDate (an electronic resource widely used in North America, [www.uptodate.com](http://www.uptodate.com)), and the Cochrane Collaboration are among the more than 25 organisations that have adopted GRADE. This widespread adoption of GRADE reflects GRADE's success as a methodologically rigorous, user friendly grading system.

### How does the GRADE system classify quality of evidence?

To achieve transparency and simplicity, the GRADE system classifies the quality of evidence in one of four levels—high, moderate, low, and very low (box 2). Some of the organisations using the GRADE system have chosen to combine the low and very low categories. Evidence based on randomised controlled trials begins as high quality evidence, but our confidence in the evidence may be decreased for several reasons, including:

- Study limitations
- Inconsistency of results
- Indirectness of evidence
- Imprecision
- Reporting bias.

Although observational studies (for example, cohort and case-control studies) start with a “low quality” rating, grading upwards may be warranted if the magnitude of the treatment effect is very large (such as severe hip osteoarthritis and hip replacement), if there is evidence of a dose-response relation or if all plausible biases would decrease the magnitude of an apparent treatment effect.

### How does the GRADE system consider strength of recommendation?

The GRADE system offers two grades of recommendations: “strong” and “weak” (though guideline panels may prefer terms such as “conditional” or “discretionary” instead of weak). When the desirable effects of an intervention clearly outweigh the undesirable effects, or clearly do not, guideline panels offer strong recommendations. On the other hand, when the trade-offs are less certain—either because of low quality evidence or because evidence suggests that desirable and undesirable effects are closely balanced—weak recommendations become mandatory.

In addition to the quality of the evidence, several other factors affect whether recommendations are strong or weak (table 1).

#### Box 2 | Quality of evidence and definitions

**High quality**— Further research is very unlikely to change our confidence in the estimate of effect

**Moderate quality**— Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate

**Low quality**— Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate

**Very low quality**— Any estimate of effect is very uncertain

### Factors that affect the strength of a recommendation

Factor	Examples of strong recommendations	Examples of weak recommendations
Quality of evidence	Many high quality randomised trials have shown the benefit of inhaled steroids in asthma	Only case series have examined the utility of pleurodesis in pneumothorax
Uncertainty about the balance between desirable and undesirable effects	Aspirin in myocardial infarction reduces mortality with minimal toxicity, inconvenience, and cost	Warfarin in low risk patients with atrial fibrillation results in small stroke reduction but increased bleeding risk and substantial inconvenience
Uncertainty or variability in values and preferences	Young patients with lymphoma will invariably place a higher value on the life prolonging effects of chemotherapy than on treatment toxicity	Older patients with lymphoma may not place a higher value on the life prolonging effects of chemotherapy than on treatment toxicity
Uncertainty about whether the intervention represents a wise use of resources	The low cost of aspirin as prophylaxis against stroke in patients with transient ischemic attacks	The high cost of clopidogrel and of combination dipyridamole and aspirin as prophylaxis against stroke in patients with transient ischaemic attacks

### SUMMARY POINTS

Failure to consider the quality of evidence can lead to misguided recommendations; hormone replacement therapy for post-menopausal women provides an instructive example. High quality evidence that an intervention's desirable effects are clearly greater than its undesirable effects, or are clearly not, warrants a strong recommendation.

Uncertainty about the trade-offs (because of low quality evidence or because the desirable and undesirable effects are closely balanced) warrants a weak recommendation.

Guidelines should inform clinicians what the quality of the underlying evidence is and whether recommendations are strong or weak.

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach provides a system for rating quality of evidence and strength of recommendations that is explicit, comprehensive, transparent, and pragmatic and is increasingly being adopted by organisations worldwide.

Details of the GRADE working group, contributors, and competing interests appear in the version on [bmj.com](http://bmj.com)

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## **Applying GRADE to Coverage Decisions**

Principal Investigator and Team Members: Philipp Dahm (PI), Benjamin Djulbegovic, Gordon Guyatt, Andrew Oxman, Holger Schünemann, Shahnaz Sultan

Organization: University of Florida

Inclusive Dates of Project: 07/01/2011—06/30/2012

Federal Project Officer: Stephanie Chang

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## **I. Abstract**

**Purpose:** The overarching goal of the AHRQ-funded conference was to develop a rational framework for coverage decision-making based on the GRADE framework that is acceptable to all major stakeholders.

**Scope:** Policy decision-making about coverage is a complex process with profound implications for beneficiaries' access to medical treatments and new health technologies. There is a critical need for a well-defined, transparent, and ideally unified and widely applicable system for coverage decision-making.

**Methods:** We conducted the workshop "Applying GRADE to Coverage Decisions" on April 3-4, 2012, preceded by an open GRADE workshop. A total of 42 individuals representing various national and international stakeholder organizations and the GRADE Working Group attended the meeting. Participants were requested to participate in a pre-workshop survey. The workshop used an interactive format that consisted of large and small group sessions and provided participants the opportunity to discuss the GRADE framework based on five examples that were prepared prior to the meeting.

**Results:** The workshop very effectively engaged a group of stakeholders with different backgrounds yet a common goal of developing a transparent, methodologically rigorous approach to coverage decision-making. Working through the examples of GRADE frameworks of moving from evidence to coverage decisions, stakeholders provided commentary on the strengths of the GRADE framework, specific guidance on how to further improve the framework as well as contextual issues and barriers that play an important role in the implementation of a coverage decision framework.

**Key Words:** Health policy, coverage decisions, evidence-based decision-making, clinical practice guidelines

## II. Purpose

The overarching goal of the proposed conference was to develop a rational framework for coverage decision-making that would be acceptable to all major stakeholders. The specific aims of this workshop were as follows:

1. To engage key stakeholder organizations involved in coverage decision-making in the adaptation and application of GRADE
2. To define how GRADE evidence profiles should be adapted to best suit the information needs of people making coverage decisions
3. To develop a framework on how to move from evidence to coverage decisions, analogous to the GRADE framework for making judgments about clinical recommendations
4. To develop and disseminate guidance documents on the use of GRADE for decisions about coverage

## III. Scope

**III. 1. Background:** Decision-making about coverage for clinical interventions is a complex process with important implications for beneficiaries' access to effective interventions, their exposure to ineffective or harmful interventions, and how limited resources for healthcare are used. Ideally, decisions about coverage require an estimate of the 'true' effectiveness of a given healthcare intervention, which should be based on sound scientific evidence. Unfortunately, high quality and definitive evidence to help with coverage decisions is frequently lacking. For example, a study by Neumann *et al* which reviewed all national coverage decisions (n=119) for new technologies made by Medicare from 1999 – 2007 found that the Centers for Medicare and Medicaid Services (CMS) considered the supporting evidence as only 'poor' or 'fair' for 85% of the technologies evaluated.[1] Despite the absence of high quality evidence, CMS made favorable decisions in about 60% of the cases, although almost always with conditions placed on the populations or settings to which coverage applied.

These findings underscore the importance of an explicit and transparent system for coverage decisions to facilitate complex judgements about the relative benefits and harms underlying a given coverage decision and to ensure that these judgements are well informed. An editorial by Neumann and Tunis has further emphasized the need for stricter evidentiary standards as well as "a more transparent, timely, and participatory process" for health policy decision-making.[2] At present, a variety of approaches to coverage decisions are used in the United States (US), all of which could be improved.

**III. 2. Context:** GRADE had previously developed a methodologically rigorous and transparent framework that allows the developers of guidance documents to grade the quality of evidence and rate the strength of recommendations. Based on two previous conferences organized by the Agency for Healthcare Research and Quality (AHRQ) exploring the use of GRADE for coverage decisions, it appeared that few changes would be required in the GRADE framework for assessing the quality of evidence to apply it to health coverage decisions. However, GRADE evidence profiles appeared not ideally suited to meet the information needs of individuals making health policy decisions. Also, most importantly, the GRADE framework for grading the strength of recommendations is not directly applicable to coverage decisions. This aspect of the GRADE framework – going from the evidence to a recommendation or decision – in the context of coverage decisions was therefore the main focus of the conference.

**III. 3. Setting:** The focus of the conference was coverage decision-making within the context of the US healthcare system.

**III. 4. Participants:** Invited participants were mainly US-based stakeholder representatives affiliated with CMS as well as the United States Department of Veterans Affairs (VA). Healthcare policy experts from outside the US as well as select members of the GRADE Working Group supplemented this group.

#### **IV. Methods**

**IV. 1. Study Design:** In accordance with our funding proposal, we designed a 2-day workshop with the title “Applying GRADE to Coverage Decisions,” which was held in Clearwater Beach, Florida on April 3-4, 2012. This workshop was by invitation only but preceded by a half-day GRADE course that was designed to not only provide an in-depth introduction to GRADE methodology to invited workshop participants, but was also open to the interested public.

**IV. 2. Data Sources:** We invited meeting participants with the goal of achieving a broad and ideally representative selection of key stakeholders primarily from the United States. In addition, we invited select individuals representing corresponding international organizations and agencies as well as members of the GRADE leadership.

We identified the core group of US-based stakeholder representatives initially through the participant roster of two previous AHRQ-sponsored meetings of GRADE members with health decision-makers in Baltimore (July 13, 2009) and Washington, DC (September 14, 2009). In addition, the AHRQ program officer, Stephanie Chang, identified key stakeholder representatives whom she had interacted with on related health policy issues as well as by sending an announcement to the national directors for CMS through a list-server. We identified international participants primarily through recommendations of members of the GRADE leadership, in particular Andrew Oxman, who had previously worked extensively in this arena. Lastly, GRADE membership representation included its leadership (Holger Schünemann and Gordon Guyatt) as well as members with a dedicated interest in health policy that responded to an email announcement per list-server.

**IV. 3. Interventions:** We planned this meeting through a number of initial face-to-face meetings of members of the Local Planning Committee (Benjamin Djulbegovic, Shahnaz Sultan and Philipp Dahm), followed by several conference calls of the entire Planning Committee, which in addition to the Local Planning Committee members included Gordon Guyatt, Andrew Oxman and Holger Schünemann. We also sought input from recognized thought leaders by scheduled conference calls with Sean Tunis from the Center for Medical Technology Policy in Baltimore, Maryland, and J. Mark Gibson and Pamela Curtis, Director and Deputy Director, respectively, of the Center for Evidence-based Policy at Oregon Health & Science University. We included Stephanie Chang, as AHRQ program officer, on selected conference calls for her input and guidance.

To develop suitable and practically relevant examples to evaluate the GRADE framework for moving from evidence to coverage decisions, we reached out to prospective participants and the GRADE membership. Ultimately, we developed five examples of coverage decisions (contributors), which were circulated among the participants in advance of the meeting in conjunction with a set of related articles about the GRADE Working Group [3-5] and related studies about coverage decisions [6, 7]:

1. Should low molecular weight heparin (LMWH) be offered to patients with advanced solid cancer who have no standard indication for anticoagulation? (Holger Schünemann and Elie Akl)
2. Should screening followed by targeted interventions for hepatitis C be covered for the US population born between 1945 and 1965? (Yngve Falck-Ytter)

3. Should apixaban, dabigatran or rivaroxaban be covered for patients with atrial fibrillation? (Vijay Shukla, Karen Lee and Andy Oxman)
4. Should ipilimumab be covered for patients with advanced melanoma? (Yngve Falck-Ytter)
5. Should transurethral radiofrequency collagen denaturation be covered for women with stress urinary incontinence? (Philipp Dahm)

In preparation for the conference, we developed and sent out a survey to those participants that were stakeholders of organizations that make coverage decisions. Questions asked in the survey were directed towards obtaining information on the current status of the coverage decision-making process within various organizations. We therefore asked questions about the use of systematic reviews, rating of the quality of evidence, the availability of explicit criteria and what implicit factors play a role in the decision-making processes.

To ensure a solid understanding of the GRADE framework for rating the quality of evidence and moving from evidence to recommendations, which served as the basis for the framework for moving from evidence to coverage decisions to be discussed at the workshop, we planned an introductory GRADE course on the afternoon of April 2, 2012. The development of this interactive course relied heavily on the extensive experience of the GRADE membership in conducting similar educational activities and was therefore able to capitalize on existing learning materials.

To promote an active exchange of ideas, we developed a meeting agenda (Appendix 1) that alternated lecture-style presentations with large group discussions and small group breakout sessions. The focus of the three small group breakout sessions was placed on three key issues:

1. Understanding the confidence in estimates of effect (quality of evidence) and resource use in the context of coverage decisions
2. Moving from evidence to coverage decisions
3. Applying the GRADE framework for moving from evidence to a coverage decision

**IV. 4. Measures:** In preparation for the workshop, we invited input into the workshop organization from multiple individuals including Sean Tunis from the Center for Medical Technology Policy in Baltimore, Maryland, and J. Mark Gibson and Pamela Curtis, Director and Deputy Director, respectively, of the Center for Evidence-based Policy at Oregon Health & Science University as well as other GRADE members who were not part of the planning committee. Prior to the workshop's adjournment, we scheduled a formal session to solicit summative feedback about the GRADE framework, recommendations for improvement and suggested next steps in its further development and dissemination. We have also planned a post-workshop survey of participants to assess the impact the workshop has had on their process of coverage decision-making at the different stakeholder organizations that were represented. Finally, we are planning a manuscript to be published in the peer-reviewed literature to summarize the workshop findings.

**IV. 5. Limitations:** Potential limitations of the workshop towards meeting its objectives lay in the lack of familiarity of the participants with the GRADE framework for rating the quality of evidence and moving from evidence to recommendations in the setting of clinical practice guidelines as well as non-representative selection of participants. We sought to address the first limitation by distributing articles discussing the key features of GRADE to invited participants in advance. In addition, we offered a half-day GRADE course on the afternoon immediately preceding the workshop that was well-utilized (see also below). Second, although somewhat limited by both funding as well as logistic constraints that are inherent to an effective workshop, we attempted to be inclusive with regards to the individual stakeholder representatives and organizations we invited. The workshop was widely announced using the GRADE website and list-server as well

as through AHRQ. Ultimately, nobody who expressed a legitimate interest in attending this workshop was declined.

## **V. Results**

**V. 1. Principal Findings/Outcomes:** The workshop took place from April 3-4, 2012. Principal findings and outcomes are summarized below.

**V. 1.1 Pre-workshop GRADE course:** Twenty-eight individuals attended the half-day, open pre-workshop course that was offered in conjunction with the workshop on coverage decisions. Among these, 12 individuals were not invited to the subsequent workshop; 16 individuals were invited workshop participants who took the opportunity to receive an introduction to the GRADE framework on rating the quality of evidence and moving from evidence to recommendations. Based on participant feedback, this session was perceived as very valuable both by subsequent workshop participants as well as the other attendees.

**V. 1.2. Workshop Participation:** A total of 42 individuals participated in the Applying GRADE to Coverage Decisions workshop (Appendix 2). Among these, 19 participants represented US-based stakeholder organizations making coverage decisions, namely contractor medical directors for CMS and directors from private insurance providers. Four participants represented international organizations (Canadian Agency for Drugs and Technologies in Health (CADTH), National Institute for Health and Clinical Excellence (NICE) and the Australian Pharmaceutical Benefits Advisory Committee). The remaining participants represented the Centers for Disease Control and Prevention (CDC), AHRQ, the Cochrane Collaboration, the Institute for Clinical and Economic Review and the GRADE Working Group.

**V. 1.3. Pre-workshop Survey:** The results of the pre-workshop survey were reported at the conference. It was completed by 20 (87%) of 23 eligible stakeholder representatives. Analysis focused on the responses of the 14 representatives of US-based stakeholder organizations and found the following:

- 13/14 organizations used systematic reviews as the basis for coverage decisions; among these, only 2 organizations developed systematic reviews themselves whereas all others relied on systematic reviews from external sources.
- 9/14 organizations rated the quality of evidence internally. The system used was different for most organizations. The single most commonly identified rating systems were past or present rating systems recommended by AHRQ (n=4). Four participants referred to an internally developed system for rating the quality of evidence within their organization; one participant indicated the recent implementation of GRADE.
- A single US stakeholder representative reported the use of formal cost-effectiveness analysis prepared by an internal medical policy team.
- Approximately 20% (3/14) indicated some form of internal process for reviewing the quality of the systematic reviews being used; one participant reported this to be the role of a sister organization.
- All representatives indicated playing a key role (frequently in conjunction with others) in either making recommendations for or against coverage to the actual decision-makers or being responsible for that decision themselves.
- All representatives indicated using a process that considered a varying degree of stakeholder involvement from (among others) advisory committees, specialty societies, community physicians etc.
- 7/14 organizations reported explicit criteria for moving from evidence to coverage decisions; all CMS-affiliated stakeholders pointed towards the definition of “reasonable and necessary” as guidance. Additional implicit criteria mentioned were considerations

of accepted standards of care, position papers and other policies as well as a track record of previous national and local coverage decisions.

In the ensuing discussion, participants expressed strong agreement about the value of an organized, systematic way of reviewing and summarizing the best available evidence coverage decisions should be based upon. A rigorous, robust and transparent system would offer great value to all users. It would be important that any system be sufficiently user-friendly and ultimately receives public buy-in. It was emphasized that coverage decision-makers have limited resources at their disposal and mostly rely on access to high quality evidence in the form of systematic reviews from external sources; this also speaks to the value of a unified system for rating the quality of evidence (such as GRADE) and the tremendous value of resources such as Cochrane reviews as authoritative sources of evidence.

A suitable system would have to accommodate contextual issues and withstand the influence of public politics. It must accommodate stakeholder engagement from the public and legislature, which may be extensive and may be more important than the quality of evidence. With regards to the applicability to the United States, it is relevant to note that CMS is currently prohibited from formal considerations of costs in its decision-making, although this regulation does not apply to the VA or private insurers.

**V. 1.4. GRADE framework for rating the quality of evidence:** A presentation by Gordon Guyatt was followed by a discussion about its value within the context of frameworks for coverage decision-making. Several GRADE characteristics were thereby clarified as summarized below:

- GRADE's outcome-specific nature that accounts for the fact that the confidence in an estimate of effect will frequently differ by outcome
- The distinction GRADE makes between the confidence in estimate of effect and magnitude of effect as two separate issues; can be confident or lacking confidence about big or small events
- GRADE's emphasis on transparency in reaching judgments about quality of evidence (preferred terminology: confidence in estimates of effect)
- The importance of absolute (versus relative) measures of effect size for decision-making
- GRADE's approach to subpopulations/groups, which is to investigate subgroup effects if there is compelling evidence to suggest that the magnitude of effect differs in some populations; GRADE also recognizes that patient values and preferences may diverge
- GRADE rates observational studies as "low" quality evidence and the underlying rationale; GRADE does not rate up confidence in observational studies for consistency because there is no reason to think that biases are not going to show up again in other studies

**V. 1.5. Consideration of resource use in decision-making about coverage:** A presentation by Suzanne Hill from the perspective of the Australian Pharmaceutical Benefits Advisory Committee was followed by a discussion about the difficulties of appropriately capturing resource utilization that ideally should capture both direct and indirect costs (i.e. time out of work). Quality adjusted life-years (QALYs) as used by NICE, was recommended as a consistent measure of comparison. It was once again emphasized that CMS is currently prevented by law from formally considering costs in its decision-making framework. Additional discussions centered around the thoughtful consideration of the "right" price for a healthcare intervention which needs to be aligned with that of other similar services/tests to avoid unforeseen consequences and wrong incentives; if the cost is too high, uptake of a good medical service (for example HPV vaccination in young girls) may be low.

#### **V. 1.6. Summary feedback from breakout session with regards to evidence presentation:**

The first of three breakout sessions asked participants to focus on how the necessary evidence for coverage decision-making was presented within the GRADE framework. Participants commented on the tremendous value of having structured evidence profiles at their finger-tips that are based on systematic reviews of the current best evidence and described that actual coverage decisions were often not based on up-to-date, high quality systematic reviews, in large part due to limited resources. Specific comments about the GRADE framework centered around two issues:

- Surrogate endpoints: Where surrogate endpoints are reported, it should be made explicit that this lowers the confidence in the estimates of effect for the outcomes that patients actually care about. Ideally, coverage decision-makers should make an a priori determination of which outcomes they care about, which would be in analogy to the GRADE framework for moving from evidence to recommendations in the guideline setting.
- Subgroup analysis: Participants emphasized the need and requirements for subgroup analyses to demonstrate the particular effectiveness (or lack thereof) of a given medical service and identify potential for harms/increased risk for adverse effects. Subgroup analyses may result in restricted coverage (with price reduction) and thereby provide an option for escaping the most intense pressure that frequently accompanies determinations of non-coverage. GRADE members provided clarification that the confidence in the estimate of effect associated with a subgroup analysis was captured under “indirectness”. There was consensus among the group that subgroups were so important that it would need to be brought more into the foreground, potentially by providing a separate evidence profile for each subgroup. Valuable information would also be whether the subgroup analysis was one of many and whether it was determined a priori or post-hoc.

**V. 1.7. Going from evidence to recommendations:** A presentation by Holger Schünemann on the GRADE framework (given on behalf of and prepared by Andrew Oxman) for moving from evidence to recommendations was followed by a discussion that mainly served to clarify elements of the GRADE approach: First, although GRADE includes a category in its framework for guidance development of “no decision”, this should be rarely used since the patient and physician usually have to reach a decision. Second, there are conceptual differences between saying “outcomes are uncertain” versus “equally balanced”, and lastly, when considering patients’ preferences, GRADE stipulates that these patients are well-informed of their options.

#### **V. 1.8. Summary feedback from breakout session on moving from evidence to recommendations:**

The second of three breakout sessions asked participants to focus on the usefulness of the framework for arriving at coverage decisions. The participants’ constructive feedback and the outcomes of the discussion as relevant to the various criteria are summarized below:

- Severity: Different wording is recommended to distinguish between prevalence, mortality and morbidity of the condition
- Appropriate use: Would have separate considerations about inappropriate use as it relates to safety and indication creep; move before consideration of health equity
- Equity:
  - Change wording of inequities to disparities
  - Important to recognize that this question is very context-dependent (for example, will there be a co-payment by patients)
- Effect size of desirable and undesirable effects:

- The evidence profile implies some judgments (for example, which outcomes are most important); consider comment section for coverage decision-makers to comment on whether they agree or disagree with underlying assumptions or judgments of the evidence profile
- For the criteria that focus on the best estimates of desirable effects and undesirable effects, should limit judgments to “yes” and “no” and leave out “uncertain”; certainty is separate issue that is addressed in the subsequent questions about certainty of anticipated effects
- Certainty of anticipated effects:
  - Certainty (confidence in estimates of effect) should come first before size of effect
  - Criteria should address overall effect and address whether there are credible subgroup effects; decision-makers will look at this even when confidence is very low
- Do benefits outweigh harms (values):
  - For questions of whether benefits outweigh harms: Both “uncertain” and “closely balanced” are needed and, while they are based on different considerations, they likely lead to the same consequences
  - Add section that would allow labeling the fact that information about important outcomes (such as quality of life) is not available; maybe have entirely own dedicated section in evidence profile. Putting it into the “values” section is not ideal/misleading
  - Benefits outweighing harms should be based on a combination of benefits and harms and the associated patient values and preferences; may need footnote that, at times, patient perspective may be different than societal perspective; i.e. length and type of antibiotic use
  - Helpful to provide additional details of what assumptions we are making about patients’ values and preferences, what the source of information is and how these may vary between patients
  - Judgments about balance of benefits to harms/downsides should not be classified under term “values”
- Cost-effectiveness: Should be considered from societal perspective; clarify
- Budget: Include both resource use and cost per procedure; consider overall budget impact (i.e. put into relationship to overall budget)
- Overall balance of consequences: Not clear what consequences this includes (does it include costs?); will likely depend on context of coverage decision
- Coverage decision: Suggestion to make coverage question dichotomous: coverage yes/no; if yes then consider with/without restriction or make assumptions about pricing; an alternative option would be one of three choices: No, yes, yes/with restrictions
- Restrictions: see above
- Justification: no issues
- Implementation: no issues

Additional comments were related to the importance of burden and inconvenience to both the patient as well as the healthcare system; the latter is addressed under resource use. There should be three separate criteria: Benefits, Harms, Burdens/inconvenience; answers should be yes/no: any uncertainty clarified in comments. Also, when more than two interventions are being addressed (for example in “Should apixaban, dabigatran or rivaroxaban be covered for patients with atrial fibrillation?”) these could be presented more clearly.

**V. 1.9. Contextual factors that impact coverage decisions:** Participants of the meeting made frequent references to contextual factors that influenced coverage decision-making yet were not yet explicitly captured in the GRADE framework; their discussion took up a large part of the third breakout session. It was emphasized that these could not be readily summarized as positive or negative, although small group work suggested that some were undesired for evidence-based decision-making. The following list of contextual factors was generated:

- Resource availability (to decision-makers) to search/rate evidence
- Medical legal environment/court decisions/risk of providing/denying coverage (impact)
- Local factors (state regulation)
- Influence by:
  - Patient advocacy groups
  - Industry/lobbyists
  - Politicians
  - Professional societies
  - Prominent individuals
  - Media and press
- Related regulatory decisions from other agencies (such as FDA)
- Coverage decisions by other providers
- Past/historical decisions about drug coverage or recommendations (cultural/normative factor that drives decision-making)
- Societal disease priorities
- Special considerations of:
  - Life-threatening conditions
  - Rare diseases
- Time horizon being used (i.e. short-term cash flow impact versus long-term benefit of preventive health measures)
- Incentives and disincentives of coverage decision; making sure ultimate utilization is aligned with patient welfare
- Realities of system of care and ability to understand the process
- Consideration of technical aspects of coding and claim submissions (credentialing of providers, administrative burden); may require changes in system
- Absence or presence of alternatives
- Likelihood of new research becoming available and in what time period
- Alternate access to the same service (i.e. self-pay) or not

**V. 2. Discussion:** As witnessed by its excellent attendance and participants' feedback at the meeting, the AHRQ-funded GRADE workshop on coverage decisions was highly successful in engaging a large group of US-based stakeholders (**see aim #1**) in a constructive dialogue about the applicability of a GRADE-based framework for coverage decision-making. The GRADE system of rating the quality of evidence and presenting it in a structured format as evidence profiles (**see aim #2**) was well-received, with participants acknowledging the great value in a transparent, methodologically rigorous and unified system of rating the quality of evidence. The workshop provided concrete feedback on how the presentation of evidence criteria that influence coverage decision-making could find better presentation. With regards to moving from evidence to coverage decisions (**see aim #3**), several important considerations became clear. These included the constraints of all CMS-affiliated coverage decision-makers in their ability to formally consider costs in their determinations. Second, the critical role that subgroup analyses play in the context of coverage decision-making not only in determining vulnerable populations but also for identifying individuals more likely to benefit from a given intervention even when the confidence that the overall benefits of a coverage decision outweigh the burdens and harms for

the overall population is low, thereby providing a rationale for niche indications and avoidance of a “do not cover” determination. Third, the meeting was very helpful in shedding light on a large number of contextual factors that impact coverage decision-making yet cannot necessarily be categorized as positive or negative. Once again, the application of a robust, transparent and methodologically well-grounded framework, which is able to withstand external scrutiny and ultimately garner broad public support, was viewed as beneficial. To address the aim to develop and disseminate guidance documents on the use of GRADE for decisions about coverage (**aim #4**), a peer-reviewed publication based on the conference results is in preparation.

**V. 3. Conclusions:** The GRADE workshop on coverage decision-making was successful at meeting most of its objectives. It successfully engaged a large number of US-based stakeholders in a constructive dialogue on evidence-based coverage decision-making and was able to obtain critical feedback for future development of the GRADE framework. In addition, international stakeholders were engaged and provided important information about the international context.

**V. 4. Significance:** The AHRQ-sponsored meeting represents an important milestone in on-going efforts towards developing an explicit and transparent system for coverage decisions to facilitate complex judgements about the relative benefits and harms. It successfully engaged a large number of stakeholders who provided critical feedback about the GRADE framework for moving from evidence to coverage decisions. It also established a network of direct personal contacts that will be invaluable for future pilot projects to formally assess the framework in practice.

**V. 5. Implications:** The GRADE workshop on coverage decisions represented a critical step towards the development of a methodologically rigorous, transparent and robust system for coverage decision-making. It has furthered a dialogue between healthcare methodologists and decision-makers, which is expected to be the seed for projects in which the framework is pilot-tested in practice. Several stakeholders have expressed interest in such future collaboration in which the GRADE Working Group provides methodological expertise and guidance. The results of this workshop will also help inform the forthcoming meeting at the New York Academy of Medicine with the topic Evidence-Based Guidelines Affecting Policy, Practice and Stakeholders (E-GAPPS; <http://www.nyam.org/events/2012/evidence-based-guidelines-conference.html>) as well as enrich on-going efforts of the work package 2 of the DECIDE Collaboration (<http://www.decide-collaboration.eu/project-partners>) and its closely related aims of promoting evidence-based decision-making among health policy-makers.

## **VI. List of Publications and Products**

None to date.

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## VIII. Appendices

### VIII. 1. Appendix 1:

#### Agenda

**Applying GRADE to Coverage Decisions  
April 3 - 4, 2012  
Clearwater Beach, Florida**

#### April 3

#### **07:00-12:30 Morning Session (Chair: Holger Schünemann)**

- 07:30 Introductions and overview of conference objectives and agenda
- 08:00 “What is the GRADE Working Group” (Holger Schünemann)
- 08:20 Presentation of survey results of participants (Philipp Dahm) followed by brief structured overviews by participants of how coverage decisions are made by the different organizations that are represented:
- Who reviews the evidence and how?
    - Are systematic reviews used?
    - How are judgements made about the quality of the evidence?
  - Who makes coverage decisions and how?
    - Are the criteria that are used explicit or implicit?
    - What criteria are used?
  - What role do considerations of resource use (costs) and cost-effectiveness play in decisions?
    - Are cost-effectiveness analyses used? If so, how?
    - Is total cost to the payer considered? If so, how?
- 09:30 Break
- 10:00 “Confidence in estimates of effects (quality of evidence)” (Gordon Guyatt)  
“GRADE’s approach to resource use” (Sue Hill)  
Introduction to examples and small group work (Holger Schünemann)
- 11:00 Small group breakout session #1: Confidence in estimates of effect and resource use in the context of coverage decisions
- What is currently being done?
  - What, if anything, is missing from the GRADE approach?
  - What are the comparative advantages of GRADE and other approaches?
- 12:30 Break

**13:30-17:00 Afternoon Session (Chair: Holger Schünemann)**

- 13:30 Feedback from small groups and discussion
- 14:30 “Going from evidence to coverage decisions” (Holger Schünemann)
- 15:00 Break
- 15:30 Small group breakout session #2: Going from evidence to coverage decisions
- What is currently being done?
  - What do people like about the framework and how could it be improved?
  - What are the comparative advantages of using an evidence-to-decision framework and other approaches?
- 16:30 “Coverage - intersection between judgments & social policy” (Benjamin Djulbegovic) and discussion
- 17:00 Adjourn for day

**April 4**

**07:00-13:00 Morning Session (Chair: Holger Schünemann)**

- 07:30 Feedback from small groups and discussion  
Introduction to small group work (Holger Schünemann)
- 08:30 Small group breakout session #3: Making a coverage decision using the framework (each group to make a coverage decision using one of the examples)
- 10:00 Break
- 10:30 Feedback + discussion
- What about the process worked well?
  - What problems were encountered?
- 11:30 Brief overview of how the different organizations that are represented currently communicate coverage decisions to clinicians and patients
- What information is communicated to clinicians and patients when a decision is made and how?
  - What, if any, information about the rationale for the decision is communicated and how?
- “Communicating coverage decisions to stakeholders” (Holger Schünemann)  
Discussion
- 12:30 Feedback from participants about meeting

- How big a change would it be for their organization to use an approach similar to what we have discussed?
- How likely is it that their organizations will make any changes?
- How might the GRADE Working Group, AHRQ or others best support such changes?
- Other feedback on the workshop?

13:00      Adjourning of meeting (Philipp Dahm)

## VIII. 2. Appendix 2:

### Participants

Akl, Elie	Associate Professor, Department of Medicine, University at Buffalo
Amato, Laura	Department of Epidemiology, Lazio Regional Health Service; Cochrane Drugs and Alcohol Group
Andrews, Jeff	Associate Professor of Obstetrics and Gynecology, Sr Scientist in the Vanderbilt Evidence-based Practice Center; Assoc Editor for the Effective Health Care Program, AHRQ
Becker, Lorne	The Cochrane Collaboration
Brozek, Jan	Assistant Professor, Department of Clinical Epidemiology & Biostatistics, McMaster University
Chang, Stephanie	Agency for Healthcare Research and Quality (AHRQ)
Chin, Joseph	Medical Officer, DHHS Centers for Medicare and Medicaid Services (CMS)
Clark, Larry	Contractor Medical Director, National Government Services
Corcoran, James	Medical Director, First Coast Service Options, Inc. - traditional Medicare Contractor
Cunningham, Carolyn	Contractor Medical Director, National Government Services
Dahm, Philipp	Professor, Department of Urology, University of Florida
Deshmukh, Uday	Senior Medical Director, Blue Cross and Blue Shield of Florida
Djulgovic, Ben	Distinguished Professor of Medicine and Oncology, University of South Florida
Falck-Ytter, Yngve	Associate Professor of Medicine, Case Western Reserve University; Chief, Division of Gastroenterology, Louis Stokes VA Medical Center
Gallagher, Catherine	Director, The Cochrane Collaboration College for Policy, George Mason University
Guyatt, Gordon	Distinguished Professor, Department of Clinical Epidemiology & Biostatistics, McMaster University
Hill, Suzanne	Chair, Pharmaceutical Benefits Advisory Committee, Australia
Jeter, Elaine	J11 Medical Director, Palmetto GBA (a Medicare MAC contractor)
Justman, Richard	National Medical Director for Medical Policy Development, UnitedHealthCare
Kosloff, Thomas	Director of Clinical Policy, Physical Health; OptumHealth (a subsidiary of UnitedHealth Group)
Lawrence, Janet	Contractor Medical Director, National Government Services
Lee, Karen	Director of Health Economics, HTA organization, Canadian Agency for Drugs and Technologies in Health
Lerner, Phillip	Senior Medical Director, Office of the Chief Medical Officer, Aetna
Lotz, Doris	Medicaid Medical Director, New Hampshire Department of Health and Human Services
Lurvey, Arthur	Contractor Medical Director J-1, Palmetto GBA Medicare MAC Contractor
Morgan, Rebecca	Health Scientist, Prevention Branch, Division of Viral Hepatitis, Centers for Disease Control and Prevention
Patterson, Debra	Medical Director for the J4 Medicare Administrative Contract, Trailblazer Health Enterprises LLC
Pearson, Steven	President, Institute for Clinical and Economic Review
Pilley, Mark	CMO Palmetto GBA - J11 - Part A, HHH, Palmetto GBA
Pregno, Silvia	Italian Cochrane Centre; Department of Haematology and Oncology, University of Modena and Reggio Emilia
Rosenberg, Alan	VP of Medical & Clinical Pharmacy Policy, WellPoint Inc.
Ruiz, Francis	Senior Adviser (Health Economics), NICE International
Schafer, Jyme	Director of the Division of Medical and Surgical Services, Centers for Medicare and Medicaid Services
Schünemann, Holger	Professor and Chair, Department of Clinical Epidemiology & Biostatistics, McMaster University; Professor, Department of Medicine, McMaster University
Sedrakyan, Art	Associate Professor, Director of Patient-Centered Comparative Effectiveness Program, Weill Cornell Medical College and New York Presbyterian Hospital
Shukla, Vijay	Canadian Agency for Drugs and Technology in Health (CADTH)
Singh, Jasvinder	Associate Professor of Medicine, Division of Clinical Immunology and Rheumatology, Department of Medicine, University of Alabama at Birmingham
Sultan, Shahnaz	Assistant Professor of Medicine, Division of Gastroenterology, Hepatology, and Nutrition,

	University of Florida College of Medicine and NF/SGVHS
Turner, Becke	Palmetto GBA - Project Manager MoDx
Whitten, Richard	Medicare Contractor Medical Director, DME Jurisdiction D, Noridian Administrative Services
Yeh, Yu-Chen	Senior Pharmacist, Center for Drug Policy, Partners Healthcare
Zerzan, Judy	Chief Medical Officer/Deputy Medicaid Director, Colorado Department of Health Care Policy and Financing

### **Criteria for applying or using GRADE**

One of the aims of the GRADE Working Group is to reduce unnecessary confusion arising from multiple systems for grading evidence and recommendations. To avoid adding to this confusion by having multiple variations of the GRADE system we suggest that the criteria below should be met when saying that the GRADE system was used. Also, while users may believe there may be good reasons for modifying the GRADE system, we discourage the use of “modified GRADE approaches” that differ substantially from the approach described by the GRADE Working Group.

On the other hand, we encourage and welcome constructive criticism of the GRADE approach, suggestions for improvements, and involvement in the GRADE Working Group. As most scientific approaches to advancing healthcare, the GRADE approach will continue to evolve in response to new evidence and to meet the needs of systematic review authors, guideline developers and other users.

Suggested criteria for stating that the GRADE system was used:

1. “Quality of evidence” should be defined consistently with one of the two definitions (for guidelines or for systematic reviews) used by the GRADE Working Group.
2. Explicit consideration should be given to each of the GRADE criteria for assessing the quality of evidence (risk of bias/study limitations, directness, consistency of results, precision, publication bias, magnitude of the effect, dose-response gradient, influence of residual plausible confounding and bias “antagonistic bias”) although different terminology may be used.
3. The overall quality of evidence should be assessed for each important outcome and expressed using four (e.g. high, moderate, low, very low) or, if justified, three (e.g. high, moderate, and very low and low combined into low) categories based on definitions for each category that are consistent with the definitions used by the GRADE Working Group.
4. Evidence summaries (narrative or in table format) should be used as the basis for judgements about the quality of evidence and the strength of recommendations. Ideally, full evidence profiles suggested by the GRADE Working Group should be used and these should be based on systematic reviews. At a minimum, the evidence that was assessed and the methods that were used to identify and appraise that evidence should be clearly described. In particular, reasons for up and downgrading should be described transparently.
5. Explicit consideration should be given to each of the GRADE criteria for assessing the strength of a recommendation (the balance of desirable and undesirable consequences, quality of evidence, values and preferences, and resource use) and a general approach should be reported (e.g. if and how costs were considered, whose values and preferences were assumed, etc.).
6. The strength of recommendations should be expressed using two categories (weak/conditional and strong) for or against a management option and the definitions for each category should be consistent with those used by the GRADE Working Group. Different

terminology to express weak/conditional and strong recommendations may be used, although the interpretation and implications should be preserved.

7. Decisions about the strength of the recommendations should ideally be transparently reported.

## HERC COVERAGE GUIDANCE USING GRADE

### GRADE Determinants of Strength of Recommendation

Factor	Description
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Costs (resource allocation)	The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted

#### Strong recommendation

***In Favor:*** The subcommittee is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects.

***Against:*** The subcommittee is confident that the undesirable effects of adherence to a recommendation outweigh the desirable effects.

#### Weak recommendation

***In Favor:*** the subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, but is not confident.

***Against:*** the subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, but is not confident.

#### Quality of evidence across studies for the treatment/outcome

High = Further research is very unlikely to change our confidence in the estimate of effect.

Moderate = Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low = Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low = Any estimate of effect is very uncertain.

## HEALTH EVIDENCE REVIEW COMMISSION (HERC)

### COVERAGE GUIDANCE: INDUCTION OF LABOR

DATE: 06/14/2012

#### 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 breach 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)**  
**COVERAGE GUIDANCE: INDUCTION OF LABOR**  
**NEW DRAFT GRADE FORMAT FOR HERC**

HERC COVERAGE GUIDANCE

Induction of labor **is recommended for coverage** for the following indications (*strong recommendation*):

- Gestational age beyond 41 0/7 weeks
- Prelabor rupture of membranes at term

Induction of labor **is recommended for coverage** for the following indications (*weak recommendation*):

- Diabetes, pre-existing and gestational
- Fetal demise

Induction of labor **is not recommended for coverage** for the following indications (*weak recommendation*):

- Macrosomia (in the absence of maternal diabetes)
- Elective purposes (without a medical or obstetrical indication)
- Breech
- Intrauterine growth restriction/Small for gestational age
- Severe preeclampsia at less than 34 weeks gestation (however IOL is superior to cesarean section)

There is insufficient evidence to make a recommendation regarding induction of labor for the following indications. **However, because these conditions may lead to significant disability and/or death, and delivery of some form is inevitable, it is recommended coverage should not be restricted.**

- Strong Recommendation
  - Cholestasis of pregnancy
  - Placental abruption
  - Fetal demise
  - Chorioamnionitis
- Weak Recommendation
  - Mild preeclampsia
  - Severe preeclampsia at term
  - Preterm, prelabor rupture of membranes;
  - Gastroschisis
  - Twin gestation
  - 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)

- Severe preeclampsia in preterm women <34 weeks

Note: Definitions for strength of recommendation are provided in the “GRADE Framework Description” section.

## RATIONALE FOR GUIDANCE DEVELOPMENT

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- 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
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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.

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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.

[\[Evidence Source\]](#)

### GRADE FRAMEWORK – \*NEW\*

The HERC develops recommendations by using a modified version of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are four elements that determine the strength of a recommendation, as listed in the table below. The HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box.

Indication	Balance between desirable and undesirable effects	Quality of evidence	Costs	Values and preferences	Recommendation
Post-term pregnancy (gestational age >41 weeks)	Net benefit (May reduce perinatal mortality and meconium aspiration syndrome. IOL not found to increase cesarean delivery.)	High	Likely cost-saving given benefit/harm ratio	Limited variability, most women would choose in favor of induction	IOL is recommended for post-term pregnancy (gestational age beyond 41 and 0/7 weeks) <i>Strong recommendation</i>
PROM (term)	Net benefit (reduces maternal infections and neonatal admission to NICU)	High	Likely cost-saving given benefit/harm ratio	Limited variability, most women would choose in favor of induction	IOL is recommended from PROM at term <i>Strong recommendation</i>
PPROM (preterm)	Uncertain tradeoffs (may reduce	Moderate	IOL would shorten maternal	Large variability	IOL is recommended for PPRM

Indication	Balance between desirable and undesirable effects	Quality of evidence	Costs	Values and preferences	Recommendation
	chorioamnionitis, but RCTs did not incorporate interventions now considered standard for this condition)		hospitalization but prolong NICU hospitalization, likely cost-saving		<i>Weak recommendation</i>
Suspected macrosomia	Net harm - Does not improve outcomes and increases Cesarean deliveries)	Moderate	Increased costs	Moderate variability	IOL is not recommended for suspected macrosomia <i>Weak recommendation</i>
Twin gestation	Uncertain tradeoffs (a single RCT underpowered to detect benefit or harm)	Low	Likely less costly on average than elective cesarean, although multiple IOL would result in CS.	Large variability in preferences. 50% likelihood that second twin will require CS even if first is vaginally delivered.	IOL is recommended for twin gestation <i>Weak recommendation</i>
Oligohydramnios	Uncertain tradeoffs	Low	More costly	Limited variability	IOL is recommended for oligohydramnios <i>Weak recommendation</i>
Gestational diabetes	Uncertain tradeoffs (MED report - 1 RCT found reduced macrosomia, but no diff in patient oriented outcomes. NICE reports decreased risk of stillbirth and shoulder dystocia, without increased harms (e.g. CS rate)	Moderate	More costly	Limited variability, most women would choose IOL given risk of shoulder dystocia and stillbirth.	IOL is recommended for gestational diabetes <i>Weak recommendation</i>
Intrahepatic cholestasis of pregnancy	Uncertain tradeoffs 1 case-control study found reduced intrauterine death	Very low	More costly	Limited variability. Most women would choose IOL given risk of fetal demise.	IOL is recommended at 38 weeks for intrahepatic cholestasis of pregnancy <i>Strong</i>

Indication	Balance between desirable and undesirable effects	Quality of evidence	Costs	Values and preferences	Recommendation
					<i>recommendation</i>
Cardiac disease	Uncertain tradeoffs	Very low	More costly	Moderate variability	No recommendation or weak recommendation
Mild preeclampsia	---	No evidence	Likely cost-neutral. Balance between increased monitoring and IOL costs	Moderate variability	No recommendation or weak recommendation
Severe preeclampsia (preterm, IOL vs. EM)	Uncertain tradeoffs (2 RCTs found improved neonatal outcomes (not specified) with expectant management (up to 34 weeks, not beyond))	Moderate	More costly	Moderate variability	IOL is not recommended in patients with severe preeclampsia prior to 34 weeks gestation. However it appears to be preferable to cesarean section. <i>Weak recommendation</i>
Severe preeclampsia (preterm, IOL vs. Cesarean)	Uncertain tradeoffs (7 case series found that IOL at 30-34 wks was commonly associated with a cesarean delivery, but that the IOL may help to improve fetal lung maturity compared to cesarean without labor.)	Very low	Less costly	Limited variability	IOL is recommended above cesarean section for preterm severe preeclampsia, however is not generally recommended above expectant management. <i>Weak recommendation</i>
Eclampsia (IOL vs. Cesarean)	Uncertain tradeoffs (1 small RCT found reduced maternal length of stay, underpowered, developing country setting)	Low	Less costly		No recommendation. should not be restricted.
Suspected IUGR/SGA (preterm)	Tradeoffs (1 large RCT found that IOL does not	High	More costly	Moderate variability	IOL is not recommended for suspected

Indication	Balance between desirable and undesirable effects	Quality of evidence	Costs	Values and preferences	Recommendation
	reduce perinatal mortality or longer term disability. Cesarean delivery is reduced with EM)				IUGR/SGA in preterm infants <i>Weak recommendation</i>
Suspected IUGR/SGA (term)	Uncertain tradeoffs (1 RCT underpowered)	Low	More costly	Limited variability	IOL is not recommended for IUGR/SGA <i>Weak recommendation</i>
Gastroschisis	Uncertain tradeoffs (1 RCT underpowered)	Low	More costly	Moderate variability	<b>No recommendation</b>
Elective	Net harm – increased risk of C/S in nullips up to 41 weeks, increase in NICU up to 39 weeks	Low	More costly	Moderate variability. some women and clinicians prefer elective deliveries for convenience or comfort.	IOL is not recommended for elective purposes <i>Weak recommendation</i>
Breech	Presumed harm exceeds benefit	Insufficient	Less costly than cesarean but risk of major morbidity increasing costs	Limited variability, against	IOL is not recommended for breech presentation <i>Strong recommendation</i>
Fetal Demise	Presumed potential benefit (decreased risk of maternal morbidity and mortality, psychosocial considerations)	Insufficient	Slightly more costly	Limited variability. Most women would choose to have IOL.	IOL is recommended for fetal demise <i>Strong recommendation</i>

### GRADE Framework Descriptions – \*NEW\*

Element	Description
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted

Element	Description
Costs (resource allocation)	The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted

### Strong recommendation

**In Favor:** The subcommittee is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects.

**Against:** The subcommittee is confident that the undesirable effects of adherence to a recommendation outweigh the desirable effects.

### Weak recommendation

**In Favor:** the subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, but is not confident.

**Against:** the subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, but is not confident.

### Quality of evidence across studies for the treatment/outcome

**High** = Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate** = Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low** = Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low** = Any estimate of effect is very uncertain.

### POLICY LANDSCAPE – \*NEW\*

There is a current quality measure developed by the Joint Commission for Accreditation of Hospitals Organization that pertains to elective induction of labor. The measure is titled “Perinatal care: percentage of patients with elective vaginal deliveries or elective cesarean sections at greater than or equal to 37 and less than 39 weeks of gestation completed”. This measure is not currently endorsed by the National Quality Forum. No related measures were found from other entities when searching the [National Quality Measures Clearinghouse](#).

### PROCEDURE

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 breach 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, 59614	Vaginal delivery only, after previous cesarean delivery
<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 care
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
<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

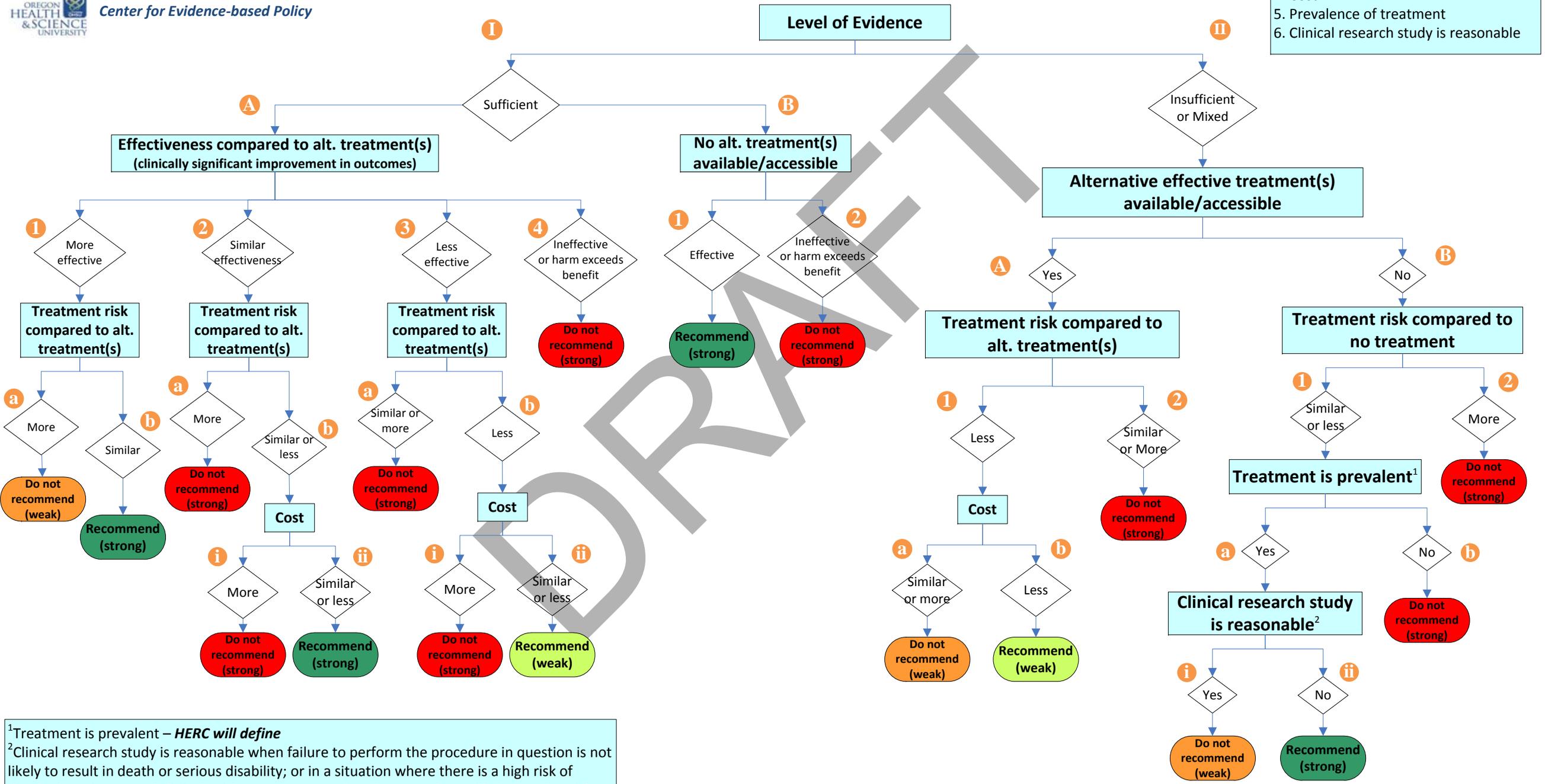
Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers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

# HERC Guidance Development Framework

Refer to *HERC Guidance Development Framework Principles* for additional considerations

- Decision Point Priorities**
1. Level of evidence
  2. Effectiveness & alternative treatments
  3. Harms and risk
  4. Cost
  5. Prevalence of treatment
  6. Clinical research study is reasonable



<sup>1</sup>Treatment is prevalent – HERC will define  
<sup>2</sup>Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk

## HERC Guidance Development Framework Principles

This framework was developed to assist with the decision making process for the Oregon policy-making body, the HERC and its subcommittees. It is a general guide, and must be used in the context of clinical judgement. It is not possible to include all possible scenarios and factors that may influence a policy decision in a graphic format. While this framework provides a general structure, factors that may influence decisions that are not captured on the framework include but are not limited to the following:

- Estimate of the level of risk associated with the treatment, or any alternatives;
- Which alternatives the treatment should most appropriately be compared to;
- Whether there is a discrete and clear diagnosis;
- The definition of clinical significance for a particular treatment, and the expected margin of benefit compared to alternatives;
- The relative balance of benefit compared to harm;
- The degree of benefit compared to cost; e.g., if the benefit is small and the cost is large, the committee may make a decision different than the algorithm suggests;
- Specific indications and contraindications that may determine appropriateness.

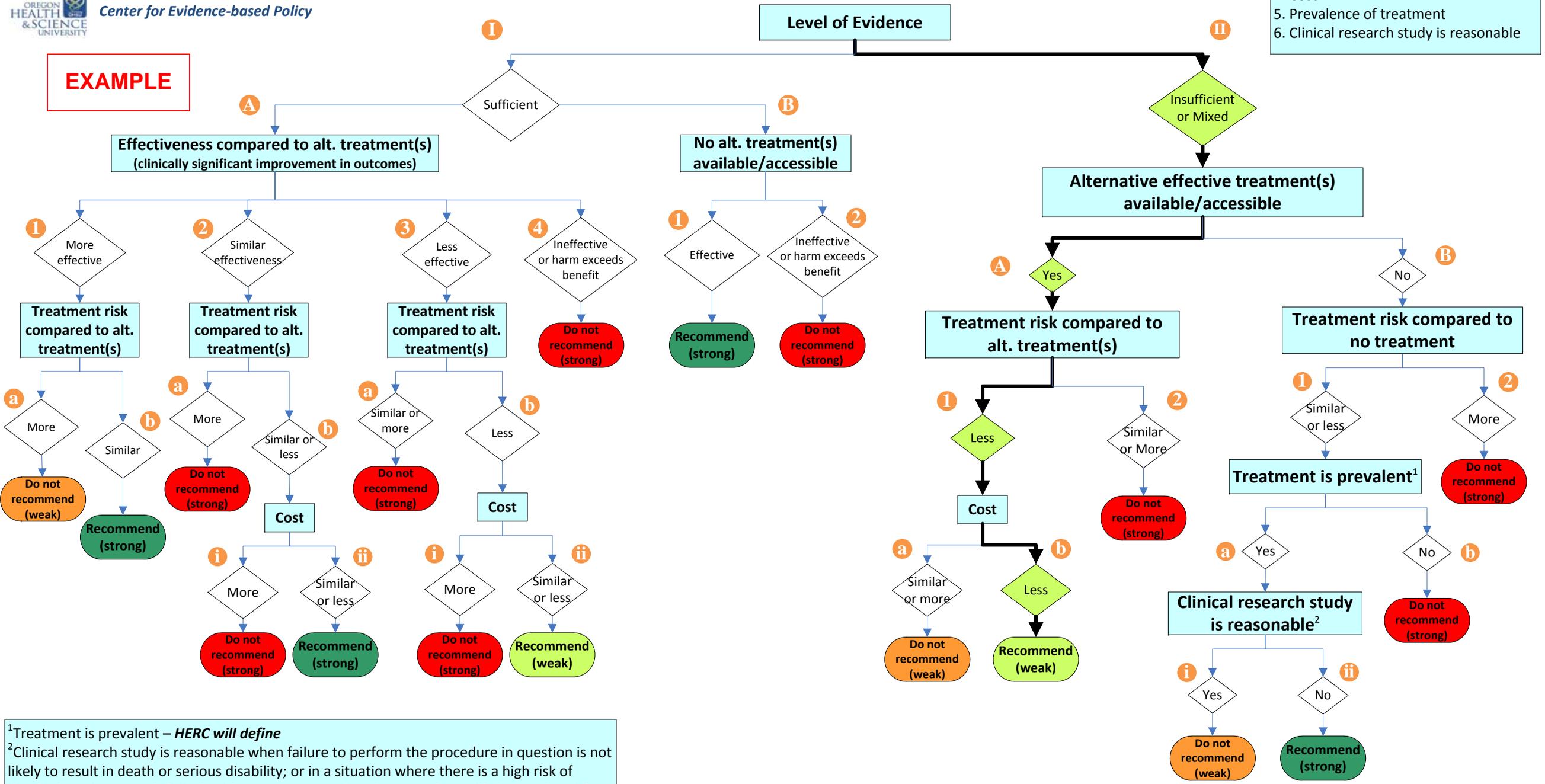
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# HERC Guidance Development Framework Induction of Labor – Fetal Demise

Refer to *HERC Guidance Development Framework Principles* for additional considerations

- Decision Point Priorities**
1. Level of evidence
  2. Effectiveness & alternative treatments
  3. Harms and risk
  4. Cost
  5. Prevalence of treatment
  6. Clinical research study is reasonable

EXAMPLE



<sup>1</sup>Treatment is prevalent – HERC will define  
<sup>2</sup>Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk

# HERC Guidance Development Framework

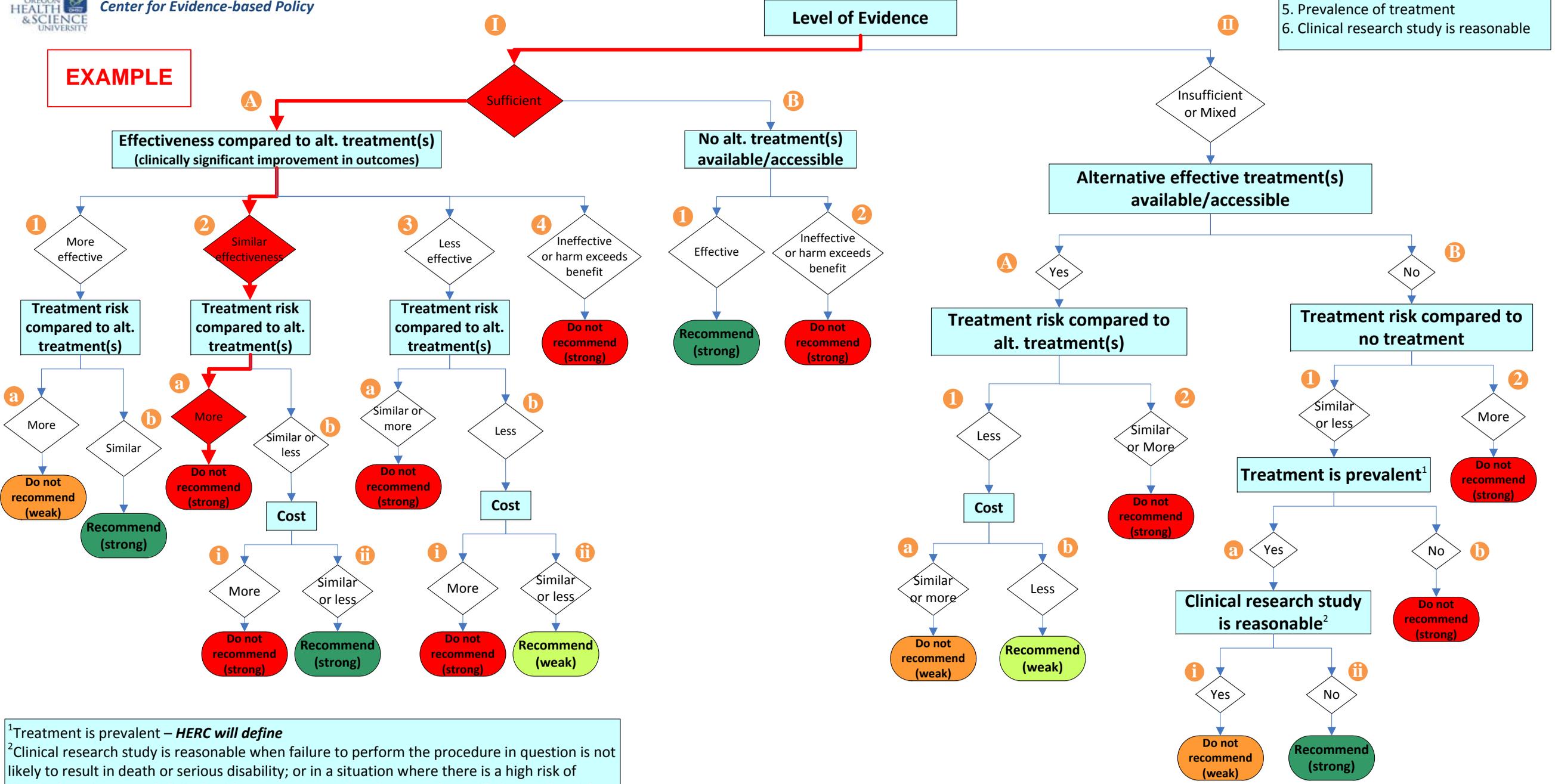
## Induction of Labor vs. Spontaneous Delivery – Macrosomia

Refer to *HERC Guidance Development Framework Principles* for additional considerations

- Decision Point Priorities**

  1. Level of evidence
  2. Effectiveness & alternative treatments
  3. Harms and risk
  4. Cost
  5. Prevalence of treatment
  6. Clinical research study is reasonable

EXAMPLE



<sup>1</sup>Treatment is prevalent – HERC will define  
<sup>2</sup>Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk

**Health Technology  
Assessment  
Subcommittee Report**

## MINUTES

Health Technology Assessment Subcommittee  
Meridian Park Community Health Education Center  
19300 SW 65th Avenue, Tualatin, OR  
November 26, 2012  
1:00-4:00 pm

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**Members Present:** Alissa Craft, DO, MBA; Gerald Ahmann, MD (by phone, left after PET scans topic); George Waldmann, MD (Arrived after approval of prior minutes); James MacKay, MD; Timothy Keenen, MD (arrived for review of final draft coverage guidance on vertebroplasty, sacroplasty and kyphoplasty).

**Members Absent:** None

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

**Also Attending:** Alison Little, MD (CEBP); Shannon Vandergriff (CEBP); Dena Searce & Joanie Cosgrove (Medtronic); Bill Struyk (Johnson and Johnson); Denise Taray (DMAP); Ann Demaree, RN.

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### 1. CALL TO ORDER

Alissa Craft called the meeting of the Health Technology Assessment Subcommittee (HTAS) to order at 1:00 pm. The order of the agenda was revised so that Dr. Keenen could be present for the discussion of Vertebroplasty, Sacroplasty and Kyphoplasty.

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### 2. MINUTES REVIEW

No changes were made to the September 24, 2012 minutes. **Approved 3-0 (Ahmann, Craft, MacKay).**

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### 3. COVERAGE GUIDANCE PROCESS

Coffman reported that at the Health Evidence Review Commission's October meeting there was lengthy discussion generated by the EbGS Femoroacetabular Impingement (FAI) guidance. The subcommittee found ambiguous evidence, and the guidance says there is insufficient proof of efficacy, without recommending coverage or noncoverage. Some OHP medical directors provided feedback requesting a clearer coverage determination in cases like this where evidence is not sufficient; otherwise they need to make decisions as Medical Directors of individual plans. Making such decisions can be time consuming and could be inconsistent. They feel that the Commission and subcommittees are the correct bodies to make these decisions. In light of this feedback, the Commission has requested a re-review of FAI. Staff and chairs are discussing possible changes to the coverage guidance process to better deal with areas where there is ambiguous evidence as well as clarifying the roles the various subcommittees. Staff and chairs are also discussing possible changes to the format in which guidances are presented,

including the GRADE format as well as a format developed by staff that would provide ratings similar to the Consumer Reports magazine.

Coffman asked the subcommittee members whether they are comfortable in the role of making specific coverage recommendations or GRADE-style recommendations. After discussions the consensus of the group was that it will be making a clear yes or no coverage recommendation on topics that are presented, using “may cover” in certain cases where absolutely necessary.

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#### 4. REVIEW OF PUBLIC COMMENTS

##### A) Continuous Blood Glucose Monitoring in Diabetes Mellitus

Craft reviewed the coverage guidance from the meeting materials. Alison Little reviewed the public comments and the CEbP’s recommended responses.

Craft offered an opportunity for public comment, but no one wished to testify.

No changes were made to the draft coverage guidance, as shown below:

HERC COVERAGE GUIDANCE

Real-time continuous glucose monitoring systems should be covered for Type 1 diabetes mellitus patients with HbA1c levels greater than 8.0% or a history of recurrent hypoglycemia, for whom insulin pump management is being considered, initiated, or utilized.

Real-time continuous glucose monitoring systems should not be covered for Type 2 diabetes mellitus patients.

Retrospective continuous glucose monitoring systems should be covered for Type 1 diabetes mellitus and should not be covered for Type 2 diabetes mellitus.

A motion was made to approve the draft coverage guidance as written and forward to HERC. **Motion approved 4-0 (Ahmann, Craft, MacKay, Waldmann).**

##### B) Diagnosis of Sleep Apnea in Adults

Craft reviewed the coverage guidance from the meeting materials. The subcommittee did not receive public comments during the public comment period.

Craft offered an opportunity for verbal public comment, but no one wished to testify.

No changes were made to the draft coverage guidance, as shown below:

### HERC COVERAGE GUIDANCE

The following diagnostic tests for Obstructive Sleep Apnea (OSA) should be covered for adults:

1. Type I PSG is covered when used to aid the diagnosis of OSA in patients who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.
2. Type II or Type III sleep testing devices are covered when used to aid the diagnosis of OSA in patients who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
3. Type IV sleep testing devices measuring three or more channels, one of which is airflow, are covered when used to aid the diagnosis of OSA in patients who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
4. Sleep testing devices measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are covered when used to aid the diagnosis of OSA in patients who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

A motion was made to approve the draft coverage guidance as written and forward to HERC. **Motion approved 4-0 (Ahmann, Craft, MacKay, Waldmann).**

#### **C) Treatment of Sleep Apnea in Adults**

Craft introduced the topic. Alison Little reviewed the public comments and the CEBP's recommended responses. The subcommittee discussed recent changes to the draft guidance. After discussion, the subcommittee opted to remove the reference to impaired cognition (which may be difficult to assess and costly to document) and elected to keep the other changes.

The following revised draft reflects the changes requested by the subcommittee:

HERC COVERAGE GUIDANCE

Coverage of treatment for Obstructive Sleep Apnea (OSA) in adults should be limited, as follows:

CPAP should be covered initially when all of the following conditions are met:

- 12 week 'trial' period to determine benefit. This period is covered if apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour, or if between 5 and 14 events with additional symptoms including excessive daytime sleepiness (Epworth Sleepiness Scale score > 10), or documented hypertension, ischemic heart disease, or history of stroke;
- Providers must provide education to patients and caregivers prior to use of CPAP machine to ensure proper use; and
- Positive diagnosis through polysomnogram (PSG) or Home Sleep Test (HST).

CPAP coverage subsequent to the initial 12 weeks should be based on documented patient tolerance, compliance, and clinical benefit. Compliance (adherence to therapy) is defined as use of CPAP for at least four hours per night on 70% of the nights during a consecutive 30 day period.

Coverage of mandibular advancement devices (oral appliances) should be provided. Intensive weight loss programs (if provided in the benefit package) should be covered for patients with obesity and obstructive sleep apnea.

Surgical options may be covered for treatment of OSA when a diagnosis has been made, CPAP or other non-invasive treatments are not effective or not tolerated, and patients have been informed of the benefits and risks of surgery.

A motion was made to approve the draft coverage guidance as modified and forward to HERC. **Motion approved 4-0 (Ahmann, Craft, MacKay, Waldmann).**

**D) MRI for Breast Cancer Diagnosis**

Craft reviewed the coverage guidance from the meeting materials. Staff reported that the subcommittee received no written comments during the public comment period.

Craft offered an opportunity for public comment, but no one wished to testify.

No changes were made to the draft coverage guidance, which read as follows:

HERC COVERAGE GUIDANCE

In women with recently diagnosed breast cancer, preoperative or contralateral MRI of the breast should not be a covered service.

A motion was made to approve the draft coverage guidance as written and forward to HERC. **Motion approved 4-0 (Ahmann, Craft, MacKay, Waldmann).**

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## 5. REVIEW OF NEW DRAFT COVERAGE GUIDANCES

### A. PET Scans for Breast Cancer

Wally Shaffer presented the revised evidence summary for PET Scans for Breast Cancer and the new draft coverage guidance was discussed. Shaffer discussed the Choosing Wisely evidence source and that it also includes expert opinion along with an evidence-based review. He also noted that the HTAS review is narrower in scope, as the Choosing Wisely documents include CT as well as PET scanning. No public comments were offered.

The committee discussed the use of the words “routine” and “routinely” in the draft from the meeting materials. After discussion they decided to remove these words, and change “as surveillance testing” to “for surveillance testing.”

The updated draft is as follows:

#### HERC COVERAGE GUIDANCE

PET scanning should not be covered in initial staging of breast cancer at low risk for metastasis (asymptomatic individuals with newly identified ductal carcinoma in situ, or clinical stage I or II disease).

PET scanning should not be covered as a modality to monitor response to treatment of breast cancer.

PET scanning should not be covered for surveillance testing for asymptomatic individuals who have been treated for breast cancer with curative intent.

#### **Action:**

A motion was made to approve and seconded to approve the draft coverage guidance as modified. **Motion approved 4-0 (Ahmann, Craft, MacKay, Waldmann).** The draft guidance will be posted for a 30-day comment period.

After the motion was approved, Craft confirmed that a quorum is likely to be present for the Feb. 25th meeting. Shaffer asked the committee to discuss whether to include quality measures from the National Quality Measures Clearinghouse (NMC) as background information in draft coverage guidances. Craft asked whether providing this information would aid in making decisions. Little clarified that some quality measures are endorsed as evidence-based and others may not be. Little offered to provide the

committee with a summary of the history of the NCMC. The subcommittee decided not to make a decision pending review of that summary.

The group recessed for a few minutes until Keenen could be present for the next topic.

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## **6. REVIEW FINAL DRAFT COVERAGE GUIDANCE ON VERTEBROPLASTY, SACROPLASTY AND KYPHOPLASTY**

Craft reviewed the draft coverage guidance for Vertebroplasty, Sacroplasty, and Kyphoplasty and the accompanying note about malignancy. Dena Searce of Medtronic provided oral and written comment, along with a proposed definition for the word, 'routine'.

The draft she distributed contained the following language:

*An osteoporotic compression fracture is not "routine" if:*

- 1) the patient is hospitalized due to pain that is primarily related to a well-documented acute fracture*
- 2) the severity of the pain prevents ambulation or creates significant impairment to normal activities of daily living (ADLs); or*
- 3) the pain is not adequately controlled with oral medication or the patient is unable to tolerate oral pain medication.*

*In each of the above situations, the patient must have failed an appropriate trial of conservative management.*

Craft used the Medtronic draft as a starting point but in discussion, the committee made several changes and confirmed other language from the draft:

- Changed the "or" to "and" so that both inability to walk and inadequate pain control are needed in order for the condition to not be considered routine.
- Changed "hospitalized" to "hospitalized under inpatient status."
- Decided to strike the phrase "creates significant impairment to normal activities of daily living (ADLs)."
- Affirmed the requirement for a well-documented acute fracture (the group decided that an MRI would not be required for such documentation).
- Changed "ambulation" to "unassisted ambulation"
- Discussed whether to include a time requirement for conservative management, or strike the clause about conservative management. In the end the committee agreed to leave the language without specifying a specific time period, as the appropriate time period may vary for individual patients.
- Added a statement that sacroplasty should not be covered regardless of whether the fracture is considered routine.

The resulting coverage guidance reads:

### HERC COVERAGE GUIDANCE

Vertebroplasty and kyphoplasty should not be covered for routine osteoporotic compression fractures.

An osteoporotic compression fracture is not "routine" if:

1. The patient is hospitalized under inpatient status due to pain that is primarily related to a well-documented acute fracture, and
2. The severity of the pain prevents unassisted ambulation, and
3. The pain is not adequately controlled with oral or transcutaneous medication

The patient must have failed an appropriate trial of conservative management.

Sacroplasty should not be covered.

Note: This coverage guidance does not address vertebral fractures related to malignancy.

A motion was made to approve the draft coverage guidance as modified and forward to HERC. **Motion approved 4-0 (Ahmann, Craft, Keenan, MacKay) .**

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## 7. PUBLIC COMMENT

No additional public comment was offered.

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## 8. ADJOURNMENT

The meeting was adjourned at 3:00 pm. The next meeting is scheduled for February 25, 2013 from 1:00-4:00pm in Room 117B of the Meridian Park Hospital Community Health Education Center in Tualatin.

COVERAGE GUIDANCES CURRENTLY UNDER DEVELOPMENT BY EVIDENCE-BASED GUIDELINES SUBCOMMITTEE					
TOPIC	STATUS	REPORTS AVAILABLE	DRAFT(S) FOR PUBLIC COMMENT	FINAL DRAFT	EARLIEST PROJECTED HERC REVIEW
1 Treatment of Attention Deficit Hyperactivity Disorder	EbGS to continue discussion of this topic 2/7/2013.	<a href="#">AHRQ</a>	<a href="#">5/11/2012 to 6/9/2012</a>		3/14/2013
2 Management of Recurrent Acute Otitis Media in Children	EbGS referred draft coverage guidance to HERC 12/6/2012.	<a href="#">Cochrane Review #1</a>	<a href="#">10/9/2012-11/8/2012</a>	<a href="#">Referred by EbGS 12/6/12</a>	3/14/2013
		<a href="#">Cochrane Review #2</a>			
		<a href="#">AHRQ</a>			
3 Coronary Computed Tomography Angiography	Public comment period 12/24/2012 to 1/22/2013.	<a href="#">Public MED Report</a>	<a href="#">12/24/2012 to 1/22/2013</a>		3/14/2013
		<a href="#">NICE</a>			
		<a href="#">ICER</a>			
4 Coronary Artery Calcium Scoring	EbGS referred draft coverage guidance to HERC 12/6/2012.	<a href="#">Hayes, Inc.</a>	<a href="#">10/9/2012 to 11/8/2012</a>	<a href="#">Referred by EbGS 12/6/12</a>	3/14/2013
		<a href="#">NICE</a>			
		<a href="#">USPSTF</a>			
		<a href="#">WA HTA</a>			
5 Cervical Cancer Screening	EbGS referred draft coverage guidance to HERC 12/6/2012.	<a href="#">AHRQ #1</a>	<a href="#">10/9/2012 to 11/8/2012</a>	<a href="#">Referred by EbGS 12/6/12</a>	3/14/2013
		<a href="#">AHRQ #2</a>			
		<a href="#">USPSTF</a>			
6 Femoroacetabular Impingement Syndrome Surgery (FAI)	Review previously-approved coverage guidance at 2/7/2013 EbGS meeting	<a href="#">WA HTA</a>			5/9/2013
		<a href="#">NICE</a>			
7 Neuroimaging For Headache	Review previously-approved coverage guidance at 2/7/2013 EbGS meeting	<a href="#">MED References</a>			5/9/2013

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See Next Page for Health Technology Assessment Subcommittee

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

TOPIC	STATUS	REPORTS AVAILABLE	DRAFT(S) FOR PUBLIC COMMENT	FINAL DRAFT	EARLIEST PROJECTED HERC REVIEW
1 <b>Vertebroplasty, Kyphoplasty and Sacroplasty</b>	HTAS referred draft coverage guidance to HERC 11/26/12.	<a href="#">WA HTA</a>	<a href="#">5/1/2012 to 5/30/2012</a>	<a href="#">Referred by HTAS 11/26/2012</a>	3/14/2013
2 <b>MRI for Breast Cancer Diagnosis</b>	HTAS referred draft coverage guidance to HERC 11/26/12.	<a href="#">WA HTA</a>	<a href="#">6/1/2012 to 6/30/2012</a>	<a href="#">Referred by HTAS 11/26/2012</a>	3/14/2013
3 <b>Continuous Blood Glucose Monitoring In Diabetes Mellitus</b>	HTAS referred draft coverage guidance to HERC 11/26/12.	<a href="#">Cochrane Review</a>	<a href="#">9/27/2012 to 10/18/2012</a>	<a href="#">Referred by HTAS 11/26/2012</a>	3/14/2013
		<a href="#">AHRQ</a>	<a href="#">7/10/2012 to 8/9/2012</a>		3/14/2013
4 <b>Diagnosis of sleep apnea in adults</b>	HTAS referred draft coverage guidance to HERC 11/26/12.	<a href="#">WA HTA</a>	<a href="#">6/1/2012 to 6/30/2012</a>	<a href="#">Referred by HTAS 11/26/2012</a>	3/14/2013
5 <b>Treatment of sleep apnea in adults</b>	HTAS referred draft coverage guidance to HERC 11/26/12.	<a href="#">WA HTA</a>	<a href="#">7/10/2012 to 8/9/2012</a>	<a href="#">Referred by HTAS 11/26/2012</a>	3/14/2013
6 <b>PET Scan for Breast Cancer</b>	Public comment period 12/11/12-1/10/2012.	<a href="#">Choosing Wisely</a>	<a href="#">12/11/2012 to 1/10/2012</a>		3/14/2013
		<a href="#">HAYES, Inc.</a>			
		<a href="#">NICE</a>			
		<a href="#">NIHR HTA</a>			
7 <b>Self Monitoring of Blood Glucose for Type 1 &amp; 2 Diabetes</b>	Review initial draft coverage guidance at the 2/25/2013 HTAS meeting	<a href="#">MED References</a>			5/9/2013
8 <b>Carotid Endarterectomy</b>	Review initial draft coverage guidance at the 2/25/2013 HTAS meeting	<a href="#">Cochrane Review</a>			5/9/2013

# **Evidence-based Guidelines Subcommittee Report**

## MINUTES

### Evidence-based Guidelines Subcommittee

Meridian Park Room  
Community Health Education Center, Room 117 B&C  
19300 SW 65th Avenue, Tualatin, OR 97062  
December 6, 2012  
2:00pm - 5:00pm

**Members Present:** Wiley Chan, MD, Chair; Vern Saboe, DC; Beth Westbrook, PsyD; Irene Croswell, RPh; Leda Garside, RN (arrived 2:18 pm); Eric Stecker, MD (arrived by phone at 2:08 pm); Bob Joondeph, JD.

**Members Absent:** Som Saha, MD, MPH; Steve Marks, MD, Vice-Chair.

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

**Also Attending:** Alison Little, MD and Shannon Vandegriff, CEBP; Denise Taray, DMAP; Dr. Paul Just, Smith & Nephew; Terese Scollard, Oregon Academy of Nutrition and Dietetics; Ann Demaree, RN; Nan Heim, Oregon Association of Orthopedists; Andrea Herzka, OHSU.

#### Roll Call/Minutes Approval/Staff Report

The meeting was called to order at 2:06 pm and roll was called. Chan reviewed the agenda. Minutes from the October 4, 2012 EbGS meeting were reviewed and approved.

**Action:** HERC staff will post the approved minutes on the website as soon as possible.

Coffman shared that at its October meeting, the HERC discussed some possible changes to the coverage guidance process and requested a more conclusive recommendation for the topic of Femoroacetabular Impingement (FAI) Syndrome surgery. In addition, HERC wanted further thought and possible modification to the coverage guidance process, particularly in areas in which there is weak or insufficient evidence. The OHP Medical Directors wanted the HERC to make difficult decisions, particularly in areas in which there is insufficient evidence. Staff and HERC leadership have been discussing potential options to update the coverage guidance development process. After discussing a variety of modifications to the process there was general consensus to recommend moving towards a format based on the GRADE methodology.

Chan discussed the GRADE methodology, sharing its strengths as an open international collaboration with involvement of leaders of evidence-based medicine. It specifically makes recommendations based on other factors in addition to the strength

of the evidence. Domains that are incorporated include the balance between desirable and undesirable effects, the quality of evidence, costs (or resource allocation), and values and preferences. A GRADE-based format would allow HERC to make final coverage recommendations that were “strong” or “weak” based these domains. Westbrook asked about how to deal with bias in working with the GRADE methodology. Chan clarified that this would be very different in a full guideline development process compared to how this may be done through the coverage guidance process. Finding independent sources of information about patient values and preferences can be challenging.

Coffman also described the possibility for coverage guidances to go through their originating subcommittee first and then to the Value-based Benefits Subcommittee, prior to going to HERC.

Coffman also shared that a rules advisory committee has been convened to develop administrative rules for the coverage guidance process. The rules address revisiting coverage guidances and interactions with the public and industry. The final rules are being revised and would go into effect in February 2013.

Livingston discussed the question as to whether a “policy landscape” section containing a summary of a search of the National Quality Measures Clearinghouse should be included in coverage guidances. This suggestion was made by an OBGYN who suggested it was important to consider national quality measures as part of our coverage guidance process. Staff presented two examples of coverage guidances with policy landscape sections added. Joondeph shared that on the metrics committee there were a number of discussions about the national standards and how health plan metrics should relate to them. Aligning information may be important. Chan said it was important to be aware of what is going on from a national metrics standpoint, but expressed concern about basing coverage guidances on these metrics, which may not be supported by evidence. If the committee is trying to influence cost-effective, efficient care, we should be challenging some of these metrics. Stecker stated that it is challenging to have opposing recommendations from different bodies which have significant clout nationally. He suggested HERC follow some national quality measures. Chan said that we should not necessarily follow the metrics if they are wrong and may want to ask national bodies to change their metrics in some cases. Overall the group agreed that having guidelines from the National Quality Measures would be helpful as they consider the evidence.

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## REVIEW PUBLIC COMMENT AND FINALIZE RECOMMENDATIONS

### ➤ **Topic: Management of Recurrent Acute Otitis Media In Children**

**Discussion:** Livingston opened discussion of the draft coverage guidance. There were no written or verbal public comments. Discussion was primarily about how

the guidance might change if HERC elects to change to a more GRADE-like format. After discussion the Subcommittee made no changes to the guidance.

**Action:** Approved draft coverage guidance by a vote of 7-0 with no changes from the version which appeared in the meeting materials. The coverage guidance text approved by the committee is shown below:

HERC COVERAGE GUIDANCE

Prophylactic antibiotics should be covered for recurrent acute otitis media.\*

Tympanostomy tubes may be covered for acute otitis media only for recurrent acute otitis media.

Adenoidectomy or adenotonsillectomy should not be covered for the treatment of recurrent acute otitis media.

*\*Recurrent acute otitis media is defined here as three or more episodes in six months or four or more episodes in one year.*

*Note: Coverage guidance for chronic otitis media with effusion is addressed in a separate document.*

➤ **Topic: Cervical Cancer Screening**

**Discussion:**

There were concerns about whether the guidance would prevent a physician from doing a screening after 4 years and 6 months when it is due every 5 years. After discussion the subcommittee decided to add a footnote clarifying that details such as exact intervals should be determined by each payer.

**Actions:** Approved draft coverage guidance by a vote of 7-0 with the following changes from the version which appeared in the meeting materials.

- 1) Add a footnote: "Exact interval limitations are to be decided by individual plans."
- 2) Change the title to "Routine Cervical Cancer Screening"

The coverage guidance text approved by the committee is shown below:

## HERC COVERAGE GUIDANCE

Cervical cancer screening should be covered in women 21 to 29 years old with cytology alone, not more than every 3 years\*\*\*.

- HPV testing with or without cytology should not be covered

Cervical cancer screening should be covered in women 30 to 65 years old either with:

- Co-testing not more than every 5 years\*\*\*
- Cytology alone not more than every 3 years\*\*\*

Cervical cancer screening should be covered in women over 65 years old

- Until adequate screening is achieved\*
- Until 20 years\*\*\* after regression or appropriate management of a high-grade precancerous lesion

Cervical cancer screening should not be covered for the following populations:

- Women less than age 21
- Women who have had a hysterectomy with removal of cervix for non-cervical cancer related (i.e. high grade precancerous lesion, i.e. CIN 2 or 3, or cervical cancer)
- Women over age 65 who have had adequate prior screening and are not otherwise at high risk of cervical cancer

Specific testing considerations:

- Either liquid based cytology or conventional cytology are appropriate and should be covered.
- HPV testing should not be covered for further triaging when low-grade squamous intraepithelial lesions or higher are diagnosed
- The above recommendations also apply to women who have had abnormal testing but whom are indicated to resume routine screening.\*\*

*\* Adequate screening is defined as 3 consecutive negative cytology results or 2 consecutive negative HPV results within 10 years of the cessation of screening, with the most recent test occurring within 5 years.*

*\*\* Management of abnormal cytology and HPV testing is not addressed in this coverage guidance. The United States Preventive Services Task Force refers to the American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology guideline (Saslow 2012) to address management of abnormal results.*

*\*\*\*Exact Interval Limitations are to be decided by individual plans.*

*Note: This guidance does not apply to women who have received a diagnosis of a high-grade precancerous cervical lesion or cervical cancer, women with in utero exposure to diethylstilbestrol, or women who are immunocompromised (such as those who are HIV positive).*

➤ **Topic: Treatment of Attention Deficit Hyperactivity Disorder**

**Discussion:** Little reviewed part of the public comment disposition. Westbrook raised concerns that the guidance doesn't address other forms of therapy, such as group therapy, that she has had success with. Little clarified that AHRQ looked broadly at this topic and did not find evidence to support the long-term effectiveness of other types of therapy. The subcommittee discussed whether it was too limiting to focus on the evidence-supported parenting programs. Members raised concerns about lack of coverage for other modalities such as psychotherapy and group therapy, especially where parent behavioral training is not available or appropriate (e.g. in cases of sexual abuse by a parent). It was noted that these other therapies are currently covered under OHP and would be unlikely to change since this language does not include a recommendation of non-coverage. Several panel members raised discomfort with recommending therapies for which there is no evidence. A number of proposals were made to recommend coverage for group therapy. The decision was made not to vote on the issue at this time. Staff will answer some questions raised in the discussion and consult again with experts in the field.

**Actions:**

- 1) Little to reexamine AHRQ report to ensure that there is no evidence for other forms of behavioral therapy/psychotherapy/group therapy.
- 2) Staff will obtain expert input from two experts with different areas of expertise and bring comments back to the next meeting.
- 3) Staff to bring back two versions of the guidance at the next meeting.
- 4) Subcommittee to complete review of public comment disposition at next meeting.

➤ **Topic: Coronary Artery Calcium Scoring**

**Discussion:** Little reviewed the public comment disposition document. Stecker said the evidence that this technology affects outcomes is weak. He said that the place where most clinicians like to have it as a tool is for asymptomatic patients. For symptomatic patients, he has never heard of a cardiologist using it. Chan said at his institution he has seen it used in the past for patients who present at the emergency department with chest pain, who are at low risk and for whom other diagnostic work returns negative findings, to clear them to be released from the ED. Stecker and Chan agreed that it isn't currently being used for this purpose at present. Stecker said the main use would be for asymptomatic intermediate risk patients, and the evidence and cost effectiveness are not sufficient for him to feel that it should be covered in a resource constrained environment like the Oregon Health Plan.

**Actions:**

- 1) Approved the coverage guidance as it appeared in the meeting materials 7-0. The coverage guidance text approved by the committee is shown below:

HERC COVERAGE GUIDANCE

Coronary artery calcium scoring (CACS) should not be covered.

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**PREVIOUSLY DISCUSSED DRAFT COVERAGE GUIDANCES**

➤ **Topic: Coronary Computed Tomography Angiography (CCTA)**

**Discussion:** Stecker said that CCTA is best studied in the ER in lower risk coronary patients. He said that the most important effect is on clinical logistics (having people discharged from the ER faster) rather than improve health outcomes. There are downsides to CT scans in ERs, that once you allow it for one thing it will start getting used for other indications. It can also be used in the emergency department for medical-legal reasons rather than to improve outcomes. He would be concerned about recommending coverage for this technology based on non-robust evidence, and would support noncoverage. Chan said that according to the table on page 88 of the packet, any male with typical angina would have a 30 percent risk of myocardial infarction, so for typical angina you could only do it on young women. He also doesn't see a lot of utility for this service. Stecker said that from the standpoint of lowering the cost of admissions by discharging people from the emergency room, calcium scoring would be a better option as it is a cheaper test with less radiation. Chan also raised concern about operationalizing option 2—in the emergency department it is unlikely that clinicians would use the criteria from the study to decide when to use the technology.

**Actions:**

- 1) The subcommittee accepted option 1 from the meeting materials on a 7-0 vote, to be posted for public comment. The coverage guidance text approved by the committee is shown below:

HERC COVERAGE GUIDANCE

Coronary Computed Tomography Angiography (CCTA) should not be covered.

➤ **Topic: Femoroacetabular Impingement (FAI) Syndrome Surgery**

**Discussion:** Livingston introduced the topic. The purpose of this discussion was not to discuss the clinical facts but rather to discuss how to deal with this topic,

as HERC requested a re-review. Based on the administrative rule that is being developed, the subcommittee may need to obtain additional expert input in order to come to a clear coverage recommendation. Livingston asked for input from the subcommittee on how to obtain expert opinion on this topic as well as others. Chan pointed out that this kind of issue will be faced on other topics. Livingston suggested that in that case it would be better to wait until the HERC settles on a process before addressing FAI again. Coffman said that one suggestion was to use the eGov subscription notice to announce that we are looking for expert representation for a particular topic. Coffman said we can get more specific on that if HERC so chooses. Chan said that the ideal time to have expert input would be when the subcommittee first addresses the topic. Livingston suggested that staff and chairs could confer as to whether to solicit an expert before the subcommittee meeting. Chan suggested that it might be good to have that discussion with the entire subcommittee rather than just the chairs. Livingston agreed that this is a reasonable approach. No formal action was taken.

**Actions:**

1) Staff to work with HERC to develop rule and procedures and updated process before FAI is reviewed again.

➤ **Topic: Neuroimaging for Headache**

**Actions:** This topic was not discussed and will be discussed at a future meeting.

➤ **Public Comment:**

Three individuals provided public comment.

Dr. Paul Just, Director of Global Healthcare Economics for Smith & Nephew, testified about FAI syndrome. He said that a significant amount of research has taken place since the evidence search relied on for the evidence review. For FAI, he said there are many reports and none say that FAI does not work; this is different than for many other topics where research is inconclusive. He also said that delaying surgery more than six months can result in a higher incidence of complications, including hip arthroplasty. In evaluating the literature (despite the lack of level 1 studies) he said there is no evidence showing a return to activity with conservative care and consistent reports of good outcomes with surgery.

Andrea Herzka, Asst. Professor of Orthopedics at OHSU, testified on FAI syndrome. Regarding conflicts of interests, she has been an instructor on the use of this surgery but no longer is. She said the evidence review in the coverage guidance says that, overall, none of the studies demonstrate that one specific treatment results in better outcomes than the other. She mentioned studies from Chris Larson in Minneapolis showing improved outcomes from newer techniques compared to older techniques. She said that FAI surgery is a relatively safe procedure. She said that there is no level 1 study and it would be unethical to

assign patients to a nonintervention group given the availability of an effective surgical approach, and that these patients often have difficulty walking and sitting and doing other common tasks. The data to date shows that the best available treatment is the surgical approach. Many of them (but not all) do well. Commercial payers have developed strict criteria for the surgery and suggested that the subcommittee create guidelines. She offered to be involved as needed.

Terese Scollard testified on adult disease related malnutrition. She disclosed no conflicts of interest. She said that this condition has been shown to cause high costs in Europe, where they have come up with algorithms and treatment plans. She cited a May 2012 report which defines disease-related malnutrition more precisely, and said that the costs of waiting to treat malnutrition are very high. She said that early intervention inside and outside the hospital is important to effective treatment. She sees this as an opportunity for Oregon to encourage use of these consensus guidelines and screening tools.

Livingston said that this subcommittee is tasked mostly with making coverage guidances and asked Scollard whether there are elements of the needed treatment that typically aren't covered. Scollard said that it's not the coverage; rather it is just practice guidelines and standards that are needed to make sure that the condition is monitored and treated appropriately. Livingston said that this subcommittee looks at guidelines about once a year and could consider this topic and see if it meets the criteria of what kinds of guidelines to develop. Scollard offered to assist in any way she can.

**Actions:**

- 1) Staff to review whether disease related nutrition is a good candidate for a future guideline.

➤ **Issues for next meeting:**

**Next meeting:** February 7, 2012 at Meridian Park Hospital Health & Education Center, room 117, 2-5 pm.

The meeting was adjourned at 5 p.m.