



Health Evidence Review Commission

May 7, 2015

1:30 PM

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

Section 1.0

Call to Order

AGENDA
HEALTH EVIDENCE REVIEW COMMISSION

Wilsonville Training Center, Rooms 111-112

May 7, 2015

1:30-4:30 pm

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

#	Time	Item	Presenter	Action Item
1	1:30 PM	Call to Order	Som Saha	
2	1:35 PM	Approval of Minutes (3-12-2015)	Som Saha	X
3	1:40 PM	Director's Report	Darren Coffman	
4	1.50 PM	Value-based Benefits Subcommittee Report	Kevin Olson Ariel Smits Cat Livingston	X
6	2:15 PM	Revascularization for Chronic Stable Angina <ul style="list-style-type: none"> • EbGS coverage guidance recommendation • VbBS Prioritized List recommended changes 	Cat Livingston Robyn Liu	X
8	2:45 PM	Biennial Report	Darren Coffman	
9	3:00 PM	Coverage Guidance Development Process <ul style="list-style-type: none"> • Algorithm 	Wiley Chan	X
10	4:25 PM	Next Steps <ul style="list-style-type: none"> • Schedule next meeting – 8/13/15 Wilsonville Training Center, Rooms 111-112 	Som Saha	
11	4:30 PM	Adjournment	Som Saha	

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

Minutes

HEALTH EVIDENCE REVIEW COMMISSION
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
March 12, 2015

Members Present: Susan Williams, MD, Chair Pro Tempore; Beth Westbrook, PsyD; Wiley Chan, MD; Vern Saboe, DC; Mark Gibson; Leda Garside, RN, MBA; Gerald Ahmann, MD, PhD; Holly Jo Hodges, MD; Chris Labhart.

Members Absent: Som Saha, MD, MPH, Chair; James Tyack, DMD; Irene Crosswell, RPh.

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Wally Shaffer, MD; Denise Taray, RN; Jason Gingerich; Daphne Peck.

Also Attending: Marty Carty, Perverserance Strategies; Jane Stephen & Karen Campbell, Allergan; Susan Bamberger & Mary Hlday, Oregon Physical Therapy Association; Robyn Liu, MD & Valerie King, MD, Center for Evidence-based Policy; Nora Stern, Providence.

Call to Order

Susan Williams, MD, Chair Pro Tempore of the Health Evidence Review Commission (HERC), called the meeting to order. Role was called.

Minutes Approval

MOTION: To approve the minutes of the 1/8/2015 meeting as presented. CARRIES 9-0.

Director's Report

[Meeting materials](#), pages 44-46

Coffman shared recruitment for the DO vacancy is on hold until review by the new Governor. We are expecting an appointment in the next month.

The subcommittee restructuring approved at the last meeting is in transition. In addition to the new members who were seated in January, Saha will join HTAS, as chair, in June. To create a more even balance in subcommittees between physician and non-physicians, Coffman proposed to move:

- Dr. George Waldman from HTAS to EbGS
- Leda Garside, RN, from EbGS to HTAS

MOTION: To approve the proposed subcommittee member restructuring. CARRIES: 8-0. (Garside absent).

Coffman announced Dr. Wally Shaffer's retirement. Dr. Shaffer had been serving as lead clinical staff to HTAS.

Dr. Livingston noted a change to the coverage guidance evidence presentation process. VbBS will now hear the full evidence presentation, as the subcommittee's primary function is to review evidence related to Prioritized List changes. HERC members will still hear evidence, but in a less formal way, though the materials will be available in the meeting packet. This new process should theoretically bring more informed recommendations to HERC.

Jason Gingerich presented proposed changes to the Commission's public comment webpage; there is no content or process change, just a different way to present the information.

Value-based Benefits Subcommittee (VbBS) Report on Prioritized List Changes
[Meeting materials](#), pages 47-99

Drs. Kevin Olson, Ariel Smits and Cat Livingston reported the VbBS met earlier in the day, March 12, 2015. Each helped to summarize a number of topics discussed.

Recommended code movement (effective 10/1/2015):

- Add straightforward coding changes and corrections
- Delete two dental procedure codes for sealant repair and cleaning of removable appliances and place on the *Services Not Recommended for Coverage Table*
- Add the procedure code for inferior vena cava (IVC) filters to three lines with deep vein thrombosis (DVT) and pulmonary embolism (PE) codes
- Add various procedures for treatment of lower urinary tract symptoms resulting from benign prostatic hypertrophy (BPH) to the covered BPH line, and delete several treatment codes, bringing the Prioritized List into agreement with the coverage guidance on treatments for BPH.

Recommended guideline changes (effective 10/1/15):

- Add a new guideline indicating that unilateral hearing loss treatment is only covered for children through age 20 and outlining what treatments are available for various levels of unilateral hearing loss
- Modify the guideline regarding bone anchored hearing aids (BAHAs) to reflect that BAHAs are only covered for children up to age 20 with normal hearing in the contralateral ear with or without hearing aids
- Add a new guideline allowing up to 8 weeks of proton pump inhibitor (PPI) treatment for gastroesophageal reflux (GERD). Failure of medication is a step in diagnostic evaluation for Barrett's esophagus.
- Add a new ancillary guideline which specifies that inferior vena cava (IVC) filters are covered for trauma patients requiring prolonged hospitalization when medically appropriate
- Add a new guideline regarding coverage of treatments for benign prostatic hypertrophy (BPH)
- Modify the guideline regarding intraocular steroid injections to include coverage criteria for use in diabetic macular edema

Recommended Biennial Review Changes (Effective 1/1/16):

- Merge and modify the cochlear implant guidelines to
 - allow hearing loss of 70dB or greater as the threshold to consider implantation for both children and adults
 - change the benefit received from hearing aids from “little or no” to “limited”
 - define what limited benefit means
- Merge the two cochlear implant lines and accept scoring that indicates placement into the funded region of the Prioritized List
- Add a new line for bone and joint conditions as high risk for complications and accept scoring that indicates placement into the funded region of the Prioritized List, with a guideline specifying when these conditions are eligible for treatment.
 - Accept rescoring the existing unfunded benign bone and joint conditions line to an appropriate lower priority position

MOTION: To accept the VbBS recommendations on Prioritized List changes not related to coverage guidances, as stated. See the VbBS minutes of 3/12/15 for a full description. Carries: 9-0.

Smits mentioned two ICD-10 codes were omitted from her earlier presentation and asked the Commission to consider adding ICD-10-CM codes KO9.0 and KO9.1 to the lower bone and joint condition line.

MOTION: To accept recommendation as stated. CARRIES: 9-0.

Recommendations of the Back Pain Line Reorganization Task Force

[Meeting materials](#), page 100-169

Under the current line structure, patients with a radiculopathy (nerve pain, pain radiating from the spine) may receive various treatments including medication, surgery (if needed), chiropractic care, acupuncture, and physical and occupational therapy. Patients without symptoms of radiculopathy theoretically receive no care without applying the comorbidity rule, though in reality, they would receive primary care office visits and medication, including opioids.

Oregon has seen a dramatic increase in the number of opioid overdose deaths and hospitalizations over the past few years. High-level meetings have been convened around the state to determine a root cause; one cause addressed was the Oregon Health Plan not providing treatment for back pain. Recent studies on opioid use show insufficient evidence for long term benefit and significant evidence of dose-dependent risk of harms.

Jason Gingerich gave an overview of certain statistics about OHP patients who have had treatment for back pain. The data sample was taken from the All Payer All Claims (APAC) database for calendar year 2013. The data has certain exclusions and does not account for every scenario, including patients moving on and off OHP and the differences in benefits between OHP Standard and OHP Plus at that time.

- Of 47,000 patients who had a primary diagnosis of back pain, there were:
 - 9,500 emergency department visits
 - 1,500 surgeries performed

- Costs break down for patients who did not have surgery:
 - Prescription costs: \$4.3M were spent on opioids, for all patients, not just those reporting back pain (at least a portion of this was related to surgeries). This amount does not include patients with a cancer diagnosis.
 - \$11.2 M Other, including emergency department, imaging, nursing, home health
 - Office visits: ~\$5.7M
 - Less than \$100K for chiropractic, acupuncture, OMT combined
 - ~\$300K for PT/OT

Smits reported that the Back Pain Lines Reorganization Task Force, which includes representation from many fields (physicians, chiropractor, physiatrist, mental health professionals, etc), met a couple more times since she last reported in January. They propose a new emphasis on conservative care which focuses on timely treatment with a bio-psycho-social approach, encouraging patient activation and functional improvements:

- Those in a *low risk* category would receive office visits, up to 4 physical therapy (PT), occupational therapy (OT), osteopathic manipulation (OMT), chiropractic, or acupuncture treatments and certain over-the-counter medication and muscle relaxers.
- Those in the *high risk* category receive office visits, cognitive behavior therapy, up to 30 PT/OT/OMT/chiropractic/acupuncture treatments, certain over-the-counter medication and muscle relaxers, limited opioids, steroid injections and, if available, yoga, interdisciplinary rehab, supervised exercise and massage.
- Surgery would only be available for certain high risk conditions with good evidence that surgery helps more than conservative therapy
 - No coverage for non-urgent conditions
 - Scoliosis surgery limited to adolescents only

Proposal, to be effective January 1, 2016:

- Four back pain lines (see Appendix A), including:
 - One medical line prioritized approximately on Line 405
 - Combines conditions on current lines 374,412,545,588 as well as several diagnoses currently in the MAP Diagnostic Workup File (sciatica, lumbago, etc.). Procedures on this line include primary care and specialty office visits, emergency department (ED) visits, skilled nursing facility (SNF) care, patient education, medications, OMT/CMT, acupuncture, PT/OT, and cognitive behavioral therapy
 - Three surgical lines, all including office visits, medications, ED visits, inpatient and ICU care and SNF care
 - Prioritized approximately on Line 350: diagnoses with urgent/emergent surgical indications with good evidence that surgery is an effective treatment
 - Prioritized approximately on Line 364: scoliosis surgery for adolescents
 - Prioritized approximately on Line 535: diagnoses without good evidence of effective surgical treatment, or with evidence that surgery is equally effective to non-surgical care but with greater expense and/or risk
- Four new guidelines (see Appendix B):
 - Non-Interventional Treatments for Conditions of the Back and Spine – Outlines bio-psycho-social approach, encouraging patient activation and functional improvements.
 - **Discussion:**
Westbrook asked if the task force considered group therapy.

- Smits assured her the CPT code is included on the line, but was not specifically called out in the guideline language
- Chan asked if we should recommend a specific evaluation tool.
 - The task force encouraged use of STarT Back but others can be used
 - Livingston shared information about an ARC study, pointing to inconsistencies in tools with no best tool recommendation
 - Smits said staff will work with the Transformation Center to disseminate a toolbox
- Opioid Prescribing for Conditions of the Back and Spine – Restricts opioid prescribing to acute cases where conservative drugs have failed or are contraindicated and no more than 90 days for chronic cases
 - **Discussion**
 - Chan asked for examples of tools to evaluation function.
 - Hodges shared there are several available and did not think it appropriate to name one in the guideline
 - Hodges will send a list of tools to HERC staff
 - Taray added the tool selection depends on the population served
 - Surgical Interventions for Conditions of the Back and Spine Other Than Scoliosis – Outlines when surgery is appropriate
 - Scoliosis – Surgery only available for children and adolescents with spinal curvature greater than 45 degrees
 - Revisions to existing guidelines (see Appendix C)
 - Diagnostic Guideline D4, Advanced Imaging for Low Back Pain
 - Guideline Note 92, Acupuncture
 - Percutaneous Interventions
 - Lumbar epidural steroid injections – available for radicular pain, 1-2 injections only
 - Cervical epidural steroid injections and facet joint radiofrequency neurotomy – not available
 - Delete now obsolete guideline notes (see Appendix D)
 - Relevant coding changes (see Appendix E)

Gibson called attention to the evidence summary ([meeting materials](#), pages 121-125) which breaks down interventions and their efficacy, provided a crosswalk from research to reached conclusions. He observed the task force had a broad cross-section of professionals who work on back pain issues and even though this proposal is a departure from the way back pain has been handled in the past, this recommendation came with a very high degree of consensus.

MOTION: To adopt the VbBS proposal as presented (see Appendices A-E for details).
CARRIES: 9-0.

Coverage Guidance: Alternatives to Transurethral Resection of the Prostate (TURP)
[Meeting materials](#), page 171 | [Handout](#), pages 10-27

Wally Shaffer, MD, presented a summary of the evidence. Dr. Eugene Fuchs (not present), of OHSU, was the appointed ad-hoc expert on this topic.

Lower Urinary Tract Syndrome happens when an enlarged prostate causes urinary retention symptoms. The treatment involves destroying prostate tissue, or lifting it out of the way. Transurethral Resection of the Prostate (TURP) is the established treatment, but requires hospitalization and has risk of transurethral resection (TUR) syndrome, a serious complication.

Evidence Summary:

- TURP has significantly better symptomatic outcomes (symptoms, flow rate, QoL) than most of the alternative procedures
 - at the expense of a higher rate of transfusions, and in some cases, other adverse outcomes
- TURP alternatives where symptomatic outcomes are similar or better, resulting in strong recommendation of coverage:
 - Bipolar resection of the prostate (Bipolar TURP)
 - Photoselective Vaporization of the Prostate (PVP, also know as “Greenlight”)
 - Laser Enucleation of Prostate, including Holmium (HoLEP)
 - TUIP (Transurethral Incision of the Prostate)
- TURP alternatives where outcomes are not as good as alternatives but risks are less or other considerations resulted in weaker recommendation:
 - Transurethral Needle Ablation of Prostate (TUNA)
 - Transurethral Microwave Thermotherapy (TUMT)
- TURP alternatives where outcomes/risks are similar but quality of evidence not as good, resulting in weaker recommendation:
 - Thulium vaporization/laser resection
- TURP alternatives where outcomes are better in short-term but not long-term, resulting in weaker recommendation:
 - Bipolar TUVP (Transurethral Electro vaporization of Prostate) or “Button procedure”
- TURP alternatives where evidence is insufficient to recommend coverage:
 - Botulinum toxin
 - HIFU (High Intensity Focused Ultrasound)
 - TEAP (Transurethral Ethanol Ablation of the Prostate)
 - Prostatic urethral lifts
- TURP alternatives where evidence is insufficient to recommend coverage:
 - Laser coagulation
 - Prostatic artery embolization

MOTION: To approve the proposed coverage guidance for Alternatives to Transurethral Resection of the Prostate (TURP) as presented. Carries 9-0.

MOTION: To approve the proposed coding changes and new guideline, Treatments for Benign Prostate Enlargement with Lower Urinary Tract Symptoms, for the Prioritized List as proposed. Carries 9-0.

Approved Coverage Guidance:

HERC Coverage Guidance

For men with lower urinary tract symptoms (LUTS) due to benign prostate enlargement, coverage of surgical procedures is recommended only if symptoms are severe, and if drug treatment and conservative management options have been unsuccessful or are not appropriate. (*strong recommendation*)

The following are coverage recommendations regarding surgical alternatives to transurethral resection of the prostate (TURP):

Recommended for coverage (*strong recommendation*):

- Bipolar TURP
- Photoselective vaporization of the prostate (PVP)
- Laser enucleation; HoLEP (Holmium Laser Enucleation of Prostate)
- TUIP (Transurethral Incision of the Prostate)

Recommended for coverage (*weak recommendation*):

- TUNA (Transurethral Needle Ablation of Prostate)
- TUMT (Transurethral Microwave Thermotherapy)
- Bipolar TUVP (Transurethral Electrovaporization of Prostate) (Button procedure)
- Thulium laser vaporization/resection of the prostate

Not recommended for coverage (*weak recommendation*):

- Botulinum toxin
- HIFU (High Intensity Focused Ultrasound)
- TEAP (Transurethral Ethanol Ablation of the Prostate)
- Prostatic urethral lifts

Not recommended for coverage (*strong recommendation*):

- Laser coagulation (for example, VLAP/ILC)
- Prostatic artery embolization

Changes Approved to the Prioritized List of Health Services:

Coding changes to the Prioritized List:

- 1) *Prostatic urethral lifts*: Remove 52441 (Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant), 52442 (each additional implant), C9739 and C9740 (Cystourethroscopy, with insertion of transprostatic implant) from line 331 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION and add to the Services Recommended for Non-Coverage Table
- 2) *Laser coagulation*: Remove 52647 (Laser coagulation of prostate, including control of postoperative bleeding, complete) from line 331 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION and add to the Services Recommended for Non-Coverage Table

- 3) *Transurethral incision of prostate (TUIP)*: Add 52450 to lines 331 and 576
 - Advise MAP to remove 52450 from the Ancillary File
- 4) *Transurethral microwave thermoplasty (TUMT)* Add 53850 to line 331
 - Advise MAP to remove 53850 from the Non-Covered File
- 5) *Transurethral needle ablation of the prostate (TUNA)* 53852 (Transurethral destruction of prostate tissue; by radiofrequency thermotherapy) to line 331
 - Advise MAP to remove 53852 from the Non-Covered File

New guideline note:

GUIDELINE NOTE XXX, TREATMENTS FOR BENIGN PROSTATE ENLARGEMENT WITH LOWER URINARY TRACT SYMPTOMS

Line 331

For men with lower urinary tract symptoms (LUTS) due to benign prostate enlargement, coverage of surgical procedures is recommended only if symptoms are severe, and if drug treatment and conservative management options have been unsuccessful or are not appropriate.

The following interventions for benign prostate enlargement are not included on line 331 due to lack of evidence of effectiveness:

- Botulinum toxin
- HIFU (High Intensity Focused Ultrasound)
- TEAP (Transurethral Ethanol Ablation of the Prostate)
- Prostatic urethral lifts
- Laser coagulation. For example, visual laser ablation of prostate (VLAP)/Interstitial Laser Coagulation (ILC)
- Prostatic artery embolization

Coverage Guidance Topic: Inferior Vena Cava (IVC) Filters for Prevention of Pulmonary Emboli

[Meeting materials](#), page 236

[Handout](#), pages 1-9

Cat Livingston provided clinical background on the topic. She said filters are recommended for proximal deep venous thrombosis (DVT) and/or pulmonary embolism (PE) and when anticoagulation too dangerous. Filters are placed in vena cava, mechanically trap emboli before reaching heart and lungs. Filters may be permanent or retrievable. IVC filters are standard of care so lack of clinical equipoise makes study difficult.

Livingston gave a high level summary of the evidence:

IVC filter for proximal (DVT) with anticoagulation

- Insufficient evidence on efficacy of IVC filters to prevent PE or impact mortality
- Evidence that long-term use of IVC filters increase risk of DVT (low strength of evidence (SOE))

Hospitalized patients with trauma

- IVC filter associated with lower incidence of PE in general and a lower incidence of fatal PE in particular compared with no filter (low SOE)
- No statistically significant impact on overall mortality (insufficient SOE)

Cat Livingston reviewed each element in the GRADE table with the committee including the EbGS recommendations (see [Meeting materials](#) page 229).

Chan wondered if “retrieval of removable IVC filters” should be listed in a separate row on the GRADE table. Members felt that kind of re-working should happen in the research phase, rather than the meeting. Dr. Valerie King, OHSU, mentioned some patients might be too ill to undergo a procedure to remove a filter within an appropriate window, and a decision is made to leave the filter in place. Discussion centered on adding a footnote about IVC filter removal, settling instead on the following statement in the box language:

Retrieval of removable IVC filters is recommended for coverage if the benefits of removal outweigh harms (weak recommendation)

MOTION: To approve the proposed coverage guidance for Inferior Vena Cava Filters for Prevention of Pulmonary Emboli as amended. Carries 9-0.

MOTION: To approve the proposed IVC Filters For Active PE/DVT Guideline, IVC Filters for Trauma Ancillary guideline and coding changes for the Prioritized List as proposed. Carries 9-0.

Approved Coverage Guidance:

HERC COVERAGE GUIDANCE

Inferior vena cava (IVC) filters are recommended for coverage in:

- Patients with active deep vein thrombosis/pulmonary embolism (DVT/PE) for which anticoagulation is contraindicated (*strong recommendation*)
- Some hospitalized patients with trauma* (*weak recommendation*)

Retrieval of removable IVC filters is recommended for coverage if the benefits of removal outweigh harms (*weak recommendation*)

IVC filters are not recommended for coverage for patients with DVT who are candidates for anticoagulation (*strong recommendation*)

*Examples of trauma for which IVC filters may be indicated include patients with severe trauma and prolonged hospitalization.

Changes approved to the Prioritized List of Health Services:

Coding changes to the Prioritized List:

- 1) Add CPT 37191-37193 (Insertion, repositioning and removal of IVC filter) to lines 1 PREGNANCY, 217 ACUTE PULMONARY HEART DISEASE AND PULMONARY EMBOLI, and 285 BUDD-CHIARI SYNDROME AND OTHER VENOUS EMBOLISM AND THROMBOSIS
- 2) Adopt a new guideline of IVC filters for PE/DVT (deep vein thrombosis) as shown below
- 3) Adopt a new ancillary guideline for IVC filters for trauma/prolonged hospitalization as shown below

- There are multiple lines with conditions that may represent severe trauma and require prolonged hospitalization. IVC filter CPT codes would not be practical on all of these lines.

New guideline notes:

GUIDELINE NOTE XXX, IVC FILTERS FOR ACTIVE PE/DVT

Lines 1, 83, 217, 285, 290

Inferior vena cava (IVC) filter placement (CPT 37191) is included on these lines for patients with active deep vein thrombosis/pulmonary embolism (DVT/PE) for which anticoagulation is contraindicated. IVC filter placement is not included on these lines for patients with DVT who are candidates for anticoagulation.

Retrieval of removable IVC filters (CPT 37193) is included on these lines when the benefits of removal outweigh the harms.

ANCILLARY GUIDELINE AXX, IVC FILTERS FOR TRAUMA

It is the intent of the Commission that inferior vena cava (IVC) filter placement (CPT 37191) and subsequent repositioning and removal (CPT 37192, 37193) are covered when medically indicated for hospitalized patients with severe trauma resulting in prolonged hospitalization.

Review of Topics Nominated for Coverage Guidance Development

[Meeting materials](#), page 262

Gingerich stated that in January HERC solicited topic nominations through an open survey. Six topics were nominated through public solicitation; three were suggested by members. Staff evaluated and scored the nominations using their established criteria. Livingston reviewed the details of each topic.

- Nitrous oxide use for labor pain management (Score: 30)
- Smoking cessation interventions in pregnancy and postpartum care (Score: 26)
- Telepsychiatry and telecounseling (Score: 26)
- Transitional care interventions to prevent readmissions for people with heart failure (Score: 30)
- Treatments for acquired nontraumatic cognitive impairment/dementia (Score: 30)
 - Members expressed interest in this topic, partially because the medications are expensive and not particularly useful. The “Meaningful Coverage Guidance” score was changed from 1 to 2, which doubled the original score of 15.
- Bariatric surgery for obesity with comorbidities other than type 2 diabetes (Score: 45)
- Hypofractionated whole breast irradiation (Score: 28)
- Nitric oxide for the diagnosis and management of asthma (Score: 33)
- Skin substitutes for diabetic foot ulcers or venous leg ulcers (Score: 20)
- Myriad MyRisk™ hereditary cancer test (Score: 0)
- Removal of torus mandibularis for patients needing lower dentures or partials (Score: 0)

MOTION: To add the nine new topics with a score of 20 or higher to the list of potential future new coverage guidance topics. Carries: 9-0.

Retreat Follow-up

[Meeting materials](#), pages 274-278

Gingerich discussed recent staff work to implement the process improvements identified at the October 2014 retreat. Many areas identified were implemented (a full list is available on pages 277-78), such as:

- Topic nomination survey
- Engaging experts and stakeholder groups early in the process
- Remove two-month delay between VbBS and HERC reviews
- Subcommittee restructuring
- A plan to handle subcommittee disagreements

Work still to come includes:

- Finalize the searchable Prioritized List, addressing:
 - Questions between the roles of coverage guidances, List, MAP rules for CCOs
 - Services recommended for non-coverage
 - Optimizing web presence
- Orientation materials/training
- Improving expert input process by learning from other groups conducting HTAs
- Patient decision tools
- Changes to the coverage guidance development framework (algorithm)

Coffman asked for feedback on the changes to the coverage guidance process resulting in VbBS hearing a topic in the morning, then HERC hearing it the same afternoon. Gibson offered the change is helpful for him, as a person who sits on both groups, keeping him immersed in the process through both discussions, with less possibility of forgetting what was discussed two months ago.

Chan introduced two coverage guidance development framework (algorithm) proposals, one more simple in concept, though both leading to the same outcome (meeting materials pages 275-76). One begins with the question of strength of evidence and is more complicated. The other begins with the question of net benefit.

Gibson remarked he favors the framework that begins with a question of evidence quality but questioned grouping low and very low evidence together, as they are not the same thing. There were suggestions to add a branch for very low evidence, leading directly to an uncertain conclusion.

King expressed concern in the algorithm that begins with a question of net benefit, cautioning that a process which appears to put a higher emphasis on justifying cost might inspire more political/ethical discussion than we might wish.

Coffman shared a discussion about this topic he had with HERC Chair Som Saha. Saha expressed a desire to see the algorithm used as a tool that informs the process as opposed to an actual appendix in the coverage guidance document, as it currently is.

The group agreed this was a good introduction to the topic but more discussion is needed than the remaining meeting time would allow.

Public Comment

There was no public comment at this time.

Adjournment

Meeting adjourned at 4:45 pm. Next meeting will be from 1:30-4:30 pm on Thursday, May 7, 2015 at Clackamas Community College Wilsonville Training Center, Rooms 111-112, Wilsonville, Oregon.

DRAFT

Appendix A New Lines

Line: MMM
 Condition: CONDITIONS OF THE BACK AND SPINE
 Treatment: RISK ASSESSMENT, PHYSICAL MODALITIES, COGNITIVE BEHAVIORAL THERAPY, MEDICAL THERAPY
 ICD-9: 336.0,344.60-344.61,349.2,720.2,720.81,721.0-721.9,722.0-722.9,723.0,723.1, 723.4,723.6-723.9, 724.0-724.9,731.0,732.0,737.0-737.2,737.40-737.42,737.8-737.9,738.4-738.5,739.0-739.9,742.59, 754.2,756.10-756.19,839.20-839.21,847.0-847.9,V57.1,V57.2x,V57.81-V57.89
 ICD-10: F45.42 (Pain disorder with related psychological factors),G83.4,G95.0,M24.08,M25.78,M40.x,M42.0x, M43.00-M43.28,M43-M43.9,M45.0-M45.8,M46.1,M46.40-M46.49,M46.81-M46.89,M46.91-M46.99, M47.011-M47.16,M47.20-M47.28,M47.811-M47.9,M48.00-M48.27,M48.30-M48.38,M48.9,M49.80- M49.89,M50.00-M50.93,M51.04-M51.9,M53.2x1-M53.2x8, M53.3,M53.80-M53.9,M54.0,M54.11- M54.6,M54.81-M54.9,M62.830,M96.1,M96.2-M96.5,M99.00-M99.09,M99.12-M99.13,M99.20- M99.79,M99.83-M99.84,Q06.0-Q06.3,Q06.8-Q06.9,Q67.5,Q76.0-Q76.4,Z47.82,S13.0xxA- S13.0xxD,S13.4xxA-S13.4xxD,S13.8xxA-S13.8xxD,S13.9xxA-S13.9xxD,S16.1xxA-S16.1xxD, S23.0xxA-S23.0xxD, S23.100A-S23.100D,S23.101A-S23.101D,S23.110A-S23.110D,S23.111A- S23.111D,S23.120A-S23.120D,S23.121A-S23.121D,S23.122A-S23.122D,S23.123A-S23.123D, S23.130A-S23.130D,S23.131A-S23.131D,S23.132A-S23.132D,S23.133A-S23.133D,S23.140A- S23.140D,S23.141A-S23.141D,S23.142A-S23.142D,S23.143A-S23.143D,S23.150A-S23.150D, S23.151A-S23.151D,S23.152A-S23.152D,S23.153A-S23.153D,S23.160A-S23.160D,S23.161A- S23.161D,S23.162A-S23.162D,S23.163A-S23.163D,S23.170A-S23.170D,S23.171A-S23.171D, S23.3xxA-S23.3xxD,S23.8xxA- S23.8xxD,S23.9xxA-S23.9xxD,S33.0xxA-S33.0xxD, S33.100A- S33.100D,S33.101A-S33.101D,S33.110A-S33.110D,S33.111A-S33.111D,S33.120A-S33.120D, S33.121A-S33.121D,S33.130A-S33.130D,S33.131A-S33.131D,S33.140A-S33.140D,S33.141A- S33.141D,S33.5xxA-S33.5xxD,S33.9xxA-S33.9xxD,S34.3xxA-S34.3xxD, S39.092A-S39.092D, S39.82xA-S39.82xD,S39.92xA-S39.92xD
 CPT: 62311,64483,64484,90785,90832-90838,90853 (mental health visits, counseling),96150-4 (health and behavior assessment codes),97001-97004,97022,97110-97124,97140, 97150, 97530, 97535 (PT/OT evaluation and treatment),97810-97814 (acupuncture),98925-98929, 98940-98942 (OMT/CMT),98966-98968,98969,99051,99060,99070,99078,99201-99215 (outpatient medical visits),99281-99285 (ER),99304-99337 (SNF care),99340-99359, 99366-99404 (risk factor reduction intervention),99408,99409,99411,99412,99441-99449, 99487-99490,99605-99607
 HPCPS: G0157-G0160 (PT/OT),G0396-G0397 (SBRT),G0425-G0427 (telehealth),G0463,G0466, G0467,G0469,G0470 (FQHC)

Line: S1
 Condition: CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS
 Treatment: SURGICAL THERAPY
 ICD-9: 344.60-344.61 (cauda equina),721.1,721.41-721.42,721.91 (spondylosis with myelopathy), 722.7x (intervertebral disc disorder with myelopathy),723.0 (spinal stenosis),724.0x (spinal stenosis),738.4,756.11-756.12 (spondylolisthesis),V57.1,V57.2x,V57.81-V57.89
 ICD-10: G83.4 (cauda equina),M43.1x (spondylolisthesis),M47.0x,M47.1x (spondylosis with myelopathy),M48.0x (spinal stenosis),M50.0x,M51.0x (intervertebral disc disorder with myelopathy),M53.2x (spinal instabilities),Q76.2 (spondylolisthesis),Z47.82 (aftercare after scoliosis surgery)
 CPT: 20660-20665, 20930-20938,21720,21725,22206-22226,22532-22855,29000-29046,29710-29720, 62287, 62355-62370,63001-63091,63170,63180-63200,63270-63273,63295-63610,63650,63655, 63685, 97001-97004, 97022, 97110-97124, 97140,97150,97530,97535 (PT/OT evaluation and treatment),96150-4 (health and behavior assessment codes), 98966- 98968,98969,99051,99060,99070,99078,99201-99215 (outpatient medical visits), 99217-99239 (hospital),99281-99285 (ER),99304-99337 (SNF care),99401-99404 (risk factor reduction intervention),99408,99409,99411,99412,99441-99444,99446-99449 (critical care),99605-99607
 HPCPS: G0157-G0160 (PT/OT),G0396-G0397 (SBRT),G0406-G0408 (inpatient consultation), G0425-G0427 (telehealth),G0463,G0466,G0467 (FQHC),S2350-S2351 (discectomy with decompression of spinal cord)

Line: S2
 Condition: CONDITIONS OF THE BACK AND SPINE
 Treatment: SURGICAL THERAPY

Appendix A New Lines

ICD-9: 336.0, 349.2, 720.81, 721.0, 721.2, 721.3, 721.5-721.8, 721.90, 722.0, 722.10-722.2, 722.4-722.6, 722.8-722.93, 723.0, 723.1, 723.4-723.9, 724.0x, 731.0, 732.0, 737.0-737.2, 737.40-737.42, 737.8-737.9, 738.4-738.5, 742.59, 754.2, 756.10-756.12, 839.20-839.21, V57.1, V57.2x, V57.81-V57.89

ICD-10: G95.0, M40.xx, M42.xx, M43.0x, M43.1x, M43.2x, M43.5x, M43.8x, M45.x, M46.0x- M46.9x, M47.2x, M47.8x, M47.9, M48.0x (spinal stenosis), M48.1, M48.3, M48.8, M48.9, M49.8x, M50.1x- M50.9x, M51.1x-M51.9, M53.8x, M53.9, M54.1x, M96.1-M96.5, M99.2x-M99.8x, Q67.5, Q76.0-Q76.3, Q76.4x, S13.0x, S23.0x, S23.1x, S33.0x, S33.1x, S34.3x

CPT: 20660-20665, 20930-20938, 21720, 21725, 22206-22226, 22532-22865, 27035, 29000-29046, 29710-29720, 62287, 62355-62370, 63001-63091, 63170, 63180-63200, 63270-63273, 63295-63610, 63650, 63655, 63685, 96150-96154 (health and behavior assessment codes), 97001-97004, 97022, 97110-97124, 97140, 97150, 97530, 97535 (PT/OT evaluation and treatment), 98966-98968, 98969, 99051, 99060, 99070, 99078, 99201-99215 (outpatient medical visits), 99217-99239 (hospital), 99281-99285 (ER), 99304-99337 (SNF care), 99401-99404 (risk factor reduction intervention), 99408, 99409, 99411, 99412, 99441-99444, 99446-99449 (critical care), 99605-99607

HPCPS: G0157-G0160 (PT/OT), G0396-G0397 (SBRT), G0406-G0408 (inpatient consultation), G0425-G0427 (telehealth), G0463, G0466, G0467 (FQHC), S2350-S2351 (discectomy with decompression of spinal cord)

Line: S3
 Condition: SCOLIOSIS
 Treatment: MEDICAL AND SURGICAL THERAPY
 ICD-9: 737.3x, 737.43, V57.1, V57.2x, V57.81-V57.89
 ICD-10: M41.xx
 CPT: 20660-20665, 20930-20938, 21720, 21725, 22206-22226, 22532-22865, 29000-29046, 29710-29720, 62287, 62355-62370, 63001-63091, 63170, 63180-63200, 63210, 63295-63610, 63650, 63655, 63685, 96127, 96150-96154 (health and behavior assessment codes), 97001-97004, 97022, 97110-97124, 97140, 97150, 97530, 97535 (PT/OT evaluation and treatment), 97760, 97762, 98966-98968, 98969, 99051, 99060, 99070, 99078, 99201-99215 (outpatient medical visits), 99217-99239 (hospital), 99281-99285 (ER), 99304-99337 (SNF care), 99401-99404 (risk factor reduction intervention), 99408, 99409, 99411, 99412, 99441-99444, 99446-99449 (critical care), 99605-99607
 HPCPS: G0157-G0160 (PT/OT), G0396-G0397 (SBRT), G0406-G0408 (inpatient consultation), G0425-G0427 (telehealth), G0463, G0466, G0467 (FQHC)

Scoring—Line MMM medical treatments

Category: 7
 HL: 4
 Suffering: 3
 Population effects: 0
 Vulnerable population: 0
 Tertiary prevention: 2
 Effectiveness: 3
 Need for service: 0.8
 Net cost: 2
 Score: 432
 Approximate line placement: 405

Scoring—Line S1 urgent surgical

Category: 7
 HL: 5
 Suffering: 4
 Population effects: 0
 Vulnerable population: 0
 Tertiary prevention: 4
 Effectiveness: 3
 Need for service: 1
 Net cost: 2
 Score: 780
 Approximate line placement: 350

Scoring—Line S2 surgical

Category: 7
 HL: 4
 Suffering: 3
 Population effects: 0
 Vulnerable population: 0
 Tertiary prevention: 0
 Effectiveness: 1
 Need for service: 0.8
 Net cost: 2
 Score: 112
 Approximate line placement: 535

Scoring—Line S3 scoliosis

Category: 7
 HL: 5
 Suffering: 3
 Population effects: 0
 Vulnerable population: 0
 Tertiary prevention: 3
 Effectiveness: 3
 Need for service: 1
 Net cost: 2
 Score: 660
 Approximate line placement: 364

Appendix B New Guidelines

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

Line MMM

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

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

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

For patients who are determined to be high risk on the validated assessment tool, the following treatments are included on this line:

- Office evaluation, consultation and education
- Cognitive behavioral therapy. The necessity for cognitive behavioral therapy should be re-evaluated every 90 days and coverage will only be continued if there is documented evidence of decreasing depression or anxiety symptomatology, improved ability to work/function, increased self-efficacy, or other clinically significant, objective improvement.
- Prescription and over the counter medications, opioid medications subject to the limitations on coverage of opioids in Guideline Note YYY OPIOID PRESCRIBING FOR CONDITIONS OF THE BACK AND SPINE. See evidence table.
- The following evidence-based therapies, when available, are encouraged: yoga, massage, supervised exercise therapy, intensive interdisciplinary rehabilitation
- A total of 30 visits per year of any combination of the following evidence-based therapies when available and medically appropriate. These therapies are only covered if provided by a provider licensed to provide the therapy and when there is documentation of measurable clinically significant progress toward the therapy plan of care goals and objectives using evidence based objective tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).
 - 1) Rehabilitative therapy (physical and/or occupational therapy), if provided according to GUIDELINE NOTE 6, REHABILITATIVE SERVICES. Rehabilitation services provided under this guideline also count towards visit totals in Guideline Note 6
 - 2) Chiropractic or osteopathic manipulation
 - 3) Acupuncture

These coverage recommendations are derived from the State of Oregon Evidence-based Guideline on the Evaluation and Management of Low Back Pain available here:

<http://www.oregon.gov/oha/herc/Pages/blog-low-back-non-pharmacologic-intervention.aspx>

Appendix B New Guidelines

Intervention Category*	Intervention	Acute < 4 Weeks	Subacute & Chronic > 4 Weeks
Self-care	Advice to remain active	●	●
	Books, handout	●	●
	Application of superficial heat	●	
Nonpharmacologic therapy	Spinal manipulation	●	●
	Exercise therapy		●
	Massage		●
	Acupuncture		●
	Yoga		●
	Cognitive-behavioral therapy		●
	Progressive relaxation		●
Pharmacologic therapy <small>(Carefully consider risks/harms)</small>	Acetaminophen	●	●
	NSAIDs	●(▲)	●(▲)
	Skeletal muscle relaxants	●	
	Antidepressants (TCA)		●
	<i>Benzodiazepines</i> **	●(▲)	●(▲)
	<i>Tramadol, opioids</i> **	●(▲)	●(▲)
Interdisciplinary therapy	Intensive interdisciplinary rehabilitation		●
<ul style="list-style-type: none"> Interventions supported by grade B evidence (at least fair-quality evidence of moderate benefit, or small benefit but no significant harms, costs, or burdens). No intervention was supported by grade "A" evidence (good-quality evidence of substantial benefit). <p>▲ Carries greater risk of harms than other agents in table.</p>			

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

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

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

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

Lines MMM, S1, S2, S3

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

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

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

Appendix B New Guidelines

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

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

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

Lines S1, S2

Surgical consultation/consideration for surgical intervention are included on these lines only for patients with neurological complications, defined as showing objective evidence of one or more of the following:

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

Spondylolithesis (ICD-9 738.4, 756.11-756.12 / ICD-10 M43.1x, Q76.2) is included on line S1 only when it results in spinal stenosis with signs and symptoms of neurogenic claudication. Otherwise, these diagnoses are included on line S2.

Appendix B New Guidelines

Surgical correction of spinal stenosis (ICD-9 721.1, 723.0, 724.0x / ICD-10 M48.0x) is only included on lines S1 for patients with:

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

Only decompression surgery is covered for spinal stenosis; spinal fusion procedures are not covered for this diagnosis. Otherwise, these diagnoses are included on line S2.

For conditions on line S2, surgical interventions may only be considered after the patient has completed at least 6 months of conservative treatment, provided according to Guideline Note XXX NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE.

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

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

GUIDELINE NOTE AAA, SCOLIOSIS

Line S3

Non-surgical treatments of scoliosis (ICD-9 737.3x,737.43/ICD-10 M41.xx) are included on line CCC when

- 1) the scoliosis is considered clinically significant, defined as curvature greater than or equal to 25 degrees or
- 2) there is curvature with a documented rapid progression.

Surgical treatments of scoliosis are included on line S3

- 1) only for children and adolescents (age 20 and younger) with
- 2) a spinal curvature of greater than 45 degrees

Appendix C
Revised Guidelines

DIAGNOSTIC GUIDELINE D4, ADVANCED IMAGING FOR LOW BACK PAIN

In patients with non-specific low back pain and no “red flag” conditions [see Table D4], 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.

Table D4. 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"> • History of cancer with new onset of LBP 	MRI	ESR
	<ul style="list-style-type: none"> • Unexplained weight loss • Failure to improve after 1 month • Age >50 years • Symptoms such as painless neurologic deficit, night pain or pain increased in supine position 	Lumbosacral plain radiography	
	<ul style="list-style-type: none"> • Multiple risk factors for cancer present 	Plain radiography or MRI	
Spinal column infection	<ul style="list-style-type: none"> • Fever • Intravenous drug use • Recent infection 	MRI	ESR and/or CRP
Cauda equina syndrome	<ul style="list-style-type: none"> • Urinary retention • Motor deficits at multiple levels • Fecal incontinence • Saddle anesthesia 	MRI	None
Vertebral compression fracture	<ul style="list-style-type: none"> • History of osteoporosis • Use of corticosteroids • Older age 	Lumbosacral plain radiography	None
Ankylosing spondylitis	<ul style="list-style-type: none"> • Morning stiffness • Improvement with exercise • Alternating buttock pain • Awakening due to back pain during the second part of the night • Younger age 	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"> • Back pain with leg pain in an L4, L5, or S1 nerve root distribution present < 1 month • Positive straight-leg-raise test or crossed straight-leg-raise test 	None	None
	<ul style="list-style-type: none"> • Radiculopathic** signs present >1 month • Severe/progressive neurologic deficits (such as foot drop), progressive motor weakness 	MRI***	Consider EMG/NCV
Spinal stenosis	<ul style="list-style-type: none"> • Radiating leg pain • Older age • Pain usually relieved with sitting (Pseudoclaudication a weak 	None	None

**Appendix C
Revised Guidelines**

Possible cause	Key features on history or physical examination	Imaging*	Additional studies*
	predictor)		
	<ul style="list-style-type: none"> • Spinal stenosis symptoms present >1 month 	MRI**	Consider EMG/NCV

* Level of evidence for diagnostic evaluation is variable

** Radiculopathic signs are defined for the purposes of this guideline [as the objective evidence of as in Guideline Note 37 with](#) any of the following:

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

*** 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.

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

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,207,374,414,468,545,546,MMM

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

Line 1 PREGNANCY

Hyperemesis gravidarum

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

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

Breech presentation

ICD-10-CM code: O32.1xx0, O32.8xx0

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

Back and pelvic pain of pregnancy

ICD-10-CM code: O33.0

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

Line 207 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE

Appendix C Revised Guidelines

Acupuncture is paired with the treatment of post-stroke depression only. Treatments may be billed to a maximum of 30 minutes face-to-face time and limited to 15 total sessions, with documentation of meaningful improvement.

~~Line 374 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT~~

~~Acupuncture is included on Line 374 YYY only for pairing with disorders of the spine with myelopathy and/or radiculopathy represented by the diagnosis codes G83.4, M47.1x, M47.2x, M50.0x, M50.1x, M51.1x, M54.1x, with referral, for up to 12 sessions.~~

Line MMM-CONDITIONS OF THE BACK AND SPINE

Acupuncture is included this line with visit limitations as in Guideline Note XXX.

Line 414 MIGRAINE HEADACHES

Acupuncture pairs on Line 414 for ICD-10-CM code G43.9 Migraine, when referred, for up to 12 sessions.

Line 468 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 468 for osteoarthritis of the knee only, when referred, for up to 12 sessions.

~~Line 545 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT~~

~~Acupuncture pairs on Line 545 with the low back diagnoses G83.4, M47.1x, M47.2x, M50.0x, M50.1x, M51.1x, M54.1x, when referred, for up to 12 sessions. Acupuncture pairs with chronic (>90 days) neck pain diagnoses (-), when referred, for up to 12 sessions.~~

Line 546 TENSION HEADACHES

Acupuncture is included on Line 546 for treatment of tension headaches G44.2x, when referred, for up to 12 sessions

GUIDELINE NOTE 105, EPIDURAL STEROID INJECTIONS, ~~OTHER PERCUTANEOUS INTERVENTIONS FOR LOW BACK PAIN~~

Lines ~~75, 159, 297, MMM~~

Epidural lumbar steroid injections (CPT 62311, 64483, 64484) are included on this line for patients with persistent radiculopathy due to herniated disc, where radiculopathy is ~~as~~ defined in ~~in~~ Guideline Note 37 as showing objective evidence of one or more of the following:

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

One epidural steroid injection is included on these lines; a second epidural steroid injection may be provided after 3-6 months only if objective evidence of 3 months of sustained pain relief was provided by the first injection. 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. Epidural lumbar steroid injections are not included on these lines for spinal stenosis or for patients with low back pain without radiculopathy.

Appendix C Revised Guidelines

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
- radiofrequency denervation

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

**Appendix D
Deleted Guidelines**

Deleted Guideline Notes:

- GUIDELINE NOTE 37, DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT
- GUIDELINE NOTE 41, SPINAL DEFORMITY, CLINICALLY SIGNIFICANT
- GUIDELINE NOTE 56, ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT
- GUIDELINE NOTE 60, SPINAL DEFORMITY, NOT CLINICALLY SIGNIFICANT
- GUIDELINE NOTE 94, EVALUATION AND MANAGEMENT OF LOW BACK PAIN

DRAFT

Appendix E Coding Changes

Related coding changes required:

- 1) Advise MAP to remove ICD-9 724.3 (Sciatica), ICD-10 M41.40 (Neuromuscular scoliosis, site unspecified), M41.50 (Other secondary scoliosis, site unspecified), M54.3-M54.4 (Sciatica) from the Diagnostic Workup File
- 2) Advise MAP to remove 22830 (Exploration of spinal fusion) from the Diagnostic File
- 3) Advise MAP to remove 63210 (Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; cervical or thoracic) from the Ancillary File
- 4) Remove ICD-9 754.1/ICD-10 Q68.0 (Congenital musculoskeletal deformities of sternocleidomastoid muscle) from line 545 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT and ICD-9 756.3/ICD-10 Q76.6-Q76.9 (Other anomalies of ribs and sternum) and ICD-10 Q68.0 (Congenital musculoskeletal deformities of sternocleidomastoid muscle) from lines 412 SPINAL DEFORMITY, CLINICALLY SIGNIFICANT and 588 SPINAL DEFORMITY, NOT CLINICALLY SIGNIFICANT and place on line 534 DEFORMITIES OF UPPER BODY AND ALL LIMBS
- 5) HERC did not approve coverage of facet joint injections for the cervical or lumbar spine.
 - a. Keep 64490-64492 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (flouro or CT), cervical) and 64633 and 64634 (Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single or additional facet joints) on the Non-Covered File
 - b. Lumbar facet joint injection currently is on the Non-Covered File

Value-based Benefits Subcommittee Recommendations Summary For Presentation to: Health Evidence Review Commission on March 12, 2015

*For specific coding recommendations and guideline wording,
please see the text of the 3-12-2015 VbBS minutes.*

RECOMMENDED CODE MOVEMENT (effective 10/1/15)

- Various straightforward coding changes
- Two dental procedure codes for sealant repair and cleaning of removable appliances were removed from the Prioritized List and placed on the Services Recommended for non-Coverage Table
- The procedure code for IVC filters was added to three lines with lower extremity or lung blood clot diagnostic codes
- Various procedures for treatment of lower urinary tract symptoms resulting from benign prostatic hypertrophy (BPH) were added to the funded BPH line, and several treatments were removed.

RECOMMENDED GUIDELINE CHANGES (effective 10/1/15)

- The cochlear implant guidelines were merged and modified to allow hearing loss of 70dB or greater as the threshold to consider implantation for both children and adults and to change the benefit received from hearing aids from “little or no” to “limited” and define what limited benefit means
- A new guideline was adopted indicating that unilateral hearing loss treatment is only included on funded lines for children through age 20 and outlines what treatments are available for various levels of unilateral hearing loss
- The guideline regarding bone anchored hearing aids (BAHAs) was modified to reflect that BAHAs are only included on funded lines for children up to age 20 with normal hearing in the contralateral ear with or without hearing aids
- A new guideline was adopted allowing up to 8 weeks of proton pump inhibitor (PPI) treatment for gastroesophageal reflux (GERD)
- A new guideline was adopted which specifies that IVC filters are included on covered lines only when a patient has an active peripheral or lung clot and is not a candidate for anti-coagulation medication
- A new ancillary guideline was adopted which specifies that IVC filters are covered for trauma patients requiring prolonged hospitalization when medically appropriate
- A new guideline was adopted regarding coverage of treatments for BPH
- The guideline regarding intraocular steroid injections was modified to include coverage criteria for use in diabetic macular edema

BIENNIAL REVIEW CHANGES (effective 1/1/16)

- The two cochlear implant lines were merged and re-scored, resulting in continued placement in the funded region of the Prioritized List

- A new line for bone and joint conditions at high risk for complications was created along with a guideline specifying when these conditions were eligible for treatment. Scoring of the new line placed it in the funded region, while the existing unfunded benign bone and joint conditions line was rescored to a lower priority position on the List.
- The four current back conditions lines were restructured into four new lines. The new medical treatment line will contain all back pain diagnoses and will include a variety of medical therapies, including lumbar epidural steroid injections. A new guideline was adopted for this medical line. Scoring of the new medical line placed it in the funded region. A new surgical line for urgent surgical conditions was also scored and prioritized in the funded region, with a new guideline. Scoring for a new surgical line for non-urgent surgical conditions placed it in the unfunded region, with the new surgical guideline applying to this line as well. The fourth line is a scoliosis line, whose scoring placed it in the funded region, which has a guideline limiting surgical therapies to children through age 20. A new guideline was adopted which restrict opioid therapy for the treatment of pain associated with back conditions, allowing limited use for 90 days after an acute injury or exacerbation of chronic pain, but not allowing opioid therapy after 90 days. Patients on chronic opioid therapy for back conditions will need to be tapered off. Five current guidelines for back conditions were deleted as they have been incorporated into the new guidelines. The acupuncture guideline was modified to refer to the new back condition medical guideline. The epidural steroid injection guideline was modified to specify what symptoms are required to qualify for the injection and limiting the injections to once, with a second if the first injection provided substantial pain relief for 3 months. The back pain diagnostic guideline was modified to remove the reference to a deleted guideline.

VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
March 12, 2015
8:30 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair; David Pollack, MD; Susan Williams, MD; Mark Gibson; Holly Jo Hodges, MD; Laura Ocker, LAc.

Members Absent: James Tyack, DMD; Irene Crosswell, RPh.

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

Also Attending: Wally Shaffer, MD and Bruce Austin, DMD, OHA; Valerie King MD, MPH, OHSU Center for Evidence Based Policy; Mary Hlady PT, Oregon PT Association; Nora Stern PT, Providence; Gary Allen, DMD, Advantage Dental; Laura McKeane, AllCare; Frank Warren, MD, The Oregon Clinic; Jane Stephen and Karen Campbell, Allergan; Eric Davis, PK Melethil, and Donald Leary, MS, DC, JD, Health and Wellness; Fiona Clement, USCF; Kevin Wilson, ND.

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

The meeting was called to order at 8:55 am and roll was called. Minutes from the January, 2015 VbBS meeting were reviewed and approved. Due to the delay in starting the meeting, staff report was not given.

➤ **Topic: Straightforward/Consent Agenda**

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

Recommended Actions:

- 1) Remove 45378 (Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed) from line 526 FOREIGN BODY IN GASTROINTESTINAL TRACT WITHOUT RISK OF PERFORATION OR OBSTRUCTION
 - i. Affirm with MAP that 45378 is on the Diagnostic File
- 2) Remove ICD-10 Q77.2 (Cervical rib) from lines 412 SPINAL DEFORMITY, CLINICALLY SIGNIFICANT and 588 SPINAL DEFORMITY, NOT CLINICALLY SIGNIFICANT
 - a. Add Q77.2 to line 668 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENT

- 3) Affirm 15777 (Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (ie, breast, trunk)) placement on the Services Recommended for Non-Coverage List.
- 4) Remove 26045 (Fasciotomy, palmar (eg, Dupuytren's contracture); open, partial) from line 362 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS
 - a. Add 26045 to line 420 PERIPHERAL NERVE ENTRAPMENT; PALMAR FASCIAL FIBROMATOSIS
- 5) Add 307.50 (Eating disorder, unspecified) to line 385 BULIMIA NERVOSA and remove from line 153 FEEDING AND EATING DISORDERS OF INFANCY OR CHILDHOOD
- 6) Change the name of line 385 to BULIMIA NERVOSA [AND UNSPECIFIED EATING DISORDERS](#)
- 7) Revise GUIDELINE NOTE 92, ACUPUNCTURE as shown in Appendix A

MOTION: To approve the recommendations stated in the consent agenda. CARRIES 5-0.

➤ **Topic: 2015 CDT code issues**

Discussion: There was no discussion of this topic.

Recommended Actions:

- 1) Remove D1353 (SEALANT REPAIR-PER TOOTH) from line 57 PREVENTIVE DENTAL SERVICES
- 2) Advise DMAP to remove D9219 (evaluation for deep sedation or general anesthesia) from the Exempt File
- 3) Remove D9931 (Cleaning and inspection of a removable appliance) from line 457 DENTAL CONDITIONS (EG. MISSING TEETH, PROSTHESIS FAILURE) and place on the Services Recommended for Non-Coverage Table

MOTION: To recommend the code changes as presented. CARRIES 5-0.

➤ **Topic: Cochlear implant guideline/cochlear implant line merge**

Discussion: Smits reviewed the summary document from the meeting packet. Dr. Frank Warren, ENT, from Portland, answered questions from the subcommittee to clarify the summary material. There was no substantial discussion.

Recommended Actions: (Note: the line merge is effective January 1, 2016)

- 1) Merge lines 283 SENSORINEURAL HEARING LOSS - AGE 5 OR UNDER and 423 SENSORINEURAL HEARING LOSS - OVER AGE OF FIVE into the new line shown below with the line scoring shown below
- 2) Modify GN31 as shown in Appendix A
- 3) Delete current GN49

Line: XXX

Condition: SENSORINEURAL HEARING LOSS (See Guideline Note 31)

Treatment: COCHLEAR IMPLANT

ICD-9: 389.11-389.12,389.14,389.16,389.18

ICD-10: H90.3,H90.41-H90.5,Z01.12,Z45.320-Z45.328

CPT: 64505-64530,69930,92562-92565,92571-92577,92590,92591, 92601-92604, 92626-92633,96127-96145,98966-98969,99051,99060,99070,99078,99201-99215, 99281-99285,99341-99355,99358-99378,99381-99404,99408-99412,99429-99449,99487-99498,99605-99607

HCPCS: G0396,G0397,G0463,G0466,G0467

Scoring—Line XXX

Category: 7

HL: 5 (child weighted)

Suffering: 3 (from 283)

Population effects: 1 (average)

Vulnerable population: 0

Tertiary prevention: 3 (average)

Effectiveness: 4 (evidence/child weighted)

Need for service: 1

Net cost: 2

Score: 960

Approximate line placement: 330

MOTION: To recommend the line merging, line scoring, and guideline note changes as presented. CARRIES 5-0.

➤ **Topic: Unilateral hearing loss/BAHA guideline clarification**

Discussion: Smits reviewed the summary document from the meeting packet. There was discussion about the benefits of treatment of unilateral hearing loss in adults—whether this was a disability that should be treated. Smits reviewed that the literature does not support that there is sufficient evidence for coverage in adults, unlike children. Pollack asked if there was a subpopulation of adults who would benefit more from coverage; Smits responded that adults with sudden hearing loss may benefit more than adults with gradual hearing loss, but there were issues with defining sudden loss, and the benefits would still focus only on quality of life.

There were specific suggestions made regarding the wording of the proposed new guideline—modifying the reference to the cochlear implant guideline to reflect the deletion of one of the two cochlear implant guidelines approved in the preceding section of the meeting. Suggestions were made regarding the wording of GN103 regarding BAHAs. The reference to “SoftBand BAHA” was changed to a generic reference to headband mounted BAHA devices. The requirement for normal hearing in the contralateral ear was noted to be “with or without a hearing aid.”

Recommended Actions:

- 1) Adopt a new guideline regarding treatment of unilateral hearing loss as shown in Appendix B
- 2) Modify GN103 for BAHAs as shown in Appendix A

MOTION: To recommend the guideline note changes as amended. CARRIES 5-0.

➤ **Topic: Ventral hernia guideline**

Discussion: This topic was tabled until the May, 2015 VBBS meeting.

➤ **Topic: Prenatal genetic testing guideline**

Discussion: This topic was tabled until the May, 2015 VBBS meeting.

➤ **Topic: GERD esophagitis/PPI therapy**

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

Recommended Actions:

- 1) Add a new guideline regarding proton pump inhibitor therapy as shown in Appendix B
- 2) Modify the treatment description on line 384: “Treatment: [Short-term medical therapy](#), Surgical treatment”

MOTION: To recommend the guideline note and line treatment description changes as presented. CARRIES 5-0.

➤ **Topic: Biennial review—benign bone and joint conditions**

Discussion: Smits reviewed the summary document in the meeting materials. Williams supported the changes, noting that many of the conditions on the proposed new, covered line are locally destructive and need treatment.

Recommended Actions: (effective January 1, 2016)

- 1) Create a new line for benign bone and joint conditions at high risk of complication with the line and scoring as shown below
- 2) Modify GN137 as shown in Appendix A
 - a. Note: “line 533” will need to be changed to new line number
- 3) Rescore line 533 as shown below
- 4) Miscellaneous coding changes
 - a. Add 214.8 (Lipoma of other specified sites), 228.00 (Hemangioma of unspecified site), 727.02 (Giant cell tumor of tendon sheath), and 727.89 (Other disorders of synovium, tendon, and bursa) to line 533 BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE
 - b. Add D17.79 (Benign lipomatous neoplasm of other sites), D18.09 (Hemangioma of other sites), D48.1 (Neoplasm of uncertain behavior of connective and other soft tissue), and M67.8x (Other disorders of synovium, tendon, and bursa), K09.0 (Developmental odontogenic cysts) and K09.1 (Developmental (nonodontogenic) cysts of oral region) to line 533 BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE
 - i. Note: K09.0, K09.1 were added to line 533 at HERC as they were not shown in the VBBS summary materials correctly
 - c. Remove M67.8x (Other disorders of synovium, tendon, and bursa) from line 51 DEEP ABSCESSSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS
 - d. Remove D16.00-D16.8 (Benign neoplasms of bone) from line 358 CLOSED FRACTURE OF EXTREMITIES (EXCEPT MINOR TOES)
 - e. Remove K09.0 (Developmental odontogenic cysts) and K09.1 (Developmental (nonodontogenic) cysts of oral region) from line 466 BRANCHIAL CLEFT CYST; THYROGLOSSAL DUCT CYST; CYST OF PHARYNX OR NASOPHARYNX and add to line 533

Line: XXX
Condition: BENIGN conditions OF BONE AND Joints at high risk for complications (See Guideline Notes 6,7,11,64,65,100,137)
Treatment: MEDICAL AND SURGICAL TREATMENT, WHICH INCLUDES CHEMOTHERAPY AND RADIATION THERAPY
ICD-9: 213.0-213.9, 214.8, 228.00, 526.0-526.2, 719.2x, 727.02, 727.89, 733.2x

ICD-10: D16.00-16.9, D17.79, D18.09, D48.1, K09.0, K09.1, M12.2xx, M27.1, M27.40, M27.41, M67.8x, M85.40-M85.69

CPT: 11400-11446,12051,12052,13131,17106-17111,20150,20550,20551,20600-20611,20615,20900,20930-20938,20955-20973,21011-21014,21025-21032,21040,21046-21049,21181,21552-21556,21600,21930-21936,22532-22819,22851,23071-23076,23101,23140-23156,23200,24071-24079,24105-24126,24420,24498,25000,25071,25073,25110-25136,25170-25240,25295-25301,25320,25335,25337,25390-25393,25441-25447,25450-25492,25810-25830,26100-26116,26200-26215,26250-26262,26449,27025,27043-27049,27054,27059,27065-27078,27187,27327,27328,27337,27339,27355-27358,27365,27465-27468,27495,27630-27638,27645-27647,27656,27745,28039-28045,28100-28108,28122,28124,28171-28175,28820,28825,32553,36680,49411,63081-63103,64774,64792,77014,77261-77295,77300-77307,77331-77338,77385-77387,77401-77427,77469,77470,79005-79445,96127,96405,96406,96420-96440,96450,96542-96571,97001-97004,97012,97022,97110-97124,97140-97530,97535,97542,97760-97762,98966-98969,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99412,99429-99449,99468-99480,99487-99498,99605-99607

HCPCS: G0157-G0161,G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467,G6001-G6017

Scoring—Line XXX (comparison scores are from line 533)

Category: 7 (7)

HL: 3 (2)

Suffering: 2 (1)

Population effects: 0 (0)

Vulnerable population: 0 (0)

Tertiary prevention: 1 (0)

Effectiveness: 4 (4)

Need for service: 0.9 (0.5)

Net cost: 3 (3)

Score: 432 (120)

Approximate line placement: 405

Rescoring—Line 533

Category: 7 (7)

HL: 1 (2)

Suffering: 1 (1)

Population effects: 0 (0)

Vulnerable population: 0 (0)

Tertiary prevention: 0 (0)

Effectiveness: 4 (4)

Need for service: 0.2 (0.5)

Net cost: 3 (3)

Score: 32

Approximate line placement: 577

MOTION: To recommend the new line creation, new and existing line scoring, code and guideline note changes as presented for 2016 biennial list. CARRIES 5-0.

➤ **Topic: Biennial review—Back condition line reorganization**

Discussion: Smits reviewed the summary document in the meeting materials. Smits and Gingerich presented a PowerPoint outlining the proposed changes, and giving approximate OHP numbers of patients with back diagnoses and approximate costs in 2013 for various treatments for back conditions.

There was no discussion regarding the proposed new lines or line scoring. The medical guideline (GN XXX) was modified to specify that both prescription and non-prescription medications are available for patients who score as high risk on validated assessment tools. There was no discussion regarding the opioid prescribing guideline. The surgical guideline (GN ZZZ) was modified to specify that it did not apply to the scoliosis line, and to specify that the non-included procedures were not covered for any area of the spine (cervical, thoracic, lumbar, or sacral). The scoliosis guideline (GN AAA) was modified to allow surgery for patients age 20 and younger (instead of 21) to align with other guidelines covering children. The modifications to diagnostic guideline D4 were modified slightly to clarify that the radiculopathic findings need to be objectively demonstrated. One miscellaneous coding recommendation, regarding CPT 63210, was not accepted, and was decided to be a part of the percutaneous intervention discussion.

The percutaneous interventions for cervical spine pain as well as lumbar epidural steroid injections were discussed in some detail. Due to the weak level of evidence, the subcommittee did not want to add coverage for cervical epidural steroid injections or for cervical radiofrequency neurotomy. These procedures will be added to the Services Recommended for Non-Coverage Table. The subcommittee desired maintaining the current coverage for lumbar epidural steroid injections, placing that procedure on the upper medical back conditions line, with the guideline restricting it to 1 injection with a second injection if the first gave 3 months of sustained pain relief. The definition for radiculopathy in this guideline will be readdressed at the May, 2015 VBBS meeting, as the subcommittee was not completely satisfied with the current wording. Additionally, the subcommittee asked to have further discussion regarding the requirement of PT or other active therapy for patients undergoing lumbar epidural steroid injections.

Recommended Actions: (effective January 1, 2016)

- 1) Adopt the four new back conditions lines and line scoring as shown below
- 2) Delete current back condition lines 374, 412, 545, and 588
- 3) Adopt the new medical guideline for back conditions, new surgical guideline for back conditions, new guideline for scoliosis, and new guideline for opioid prescribing as shown in Appendix B
- 4) Adopt the modified DIAGNOSTIC GUIDELINE D4, ADVANCED IMAGING FOR LOW BACK PAIN and GUIDELINE NOTE 92, ACUPUNCTURE as shown in Appendix A

- 5) Delete guideline notes 37, 41, 56, 60, and 94 (see Appendix C)
- 6) Advise MAP to remove ICD-9 724.3 (Sciatica), ICD-10 M41.40 (Neuromuscular scoliosis, site unspecified), M41.50 (Other secondary scoliosis, site unspecified), M54.3-M54.4 (Sciatica) from the Diagnostic File
- 7) Advise DMAP to remove 22830 (Exploration of spinal fusion) from the Diagnostic File
- 8) Remove ICD-9 754.1/ICD-10 Q68.0 (Congenital musculoskeletal deformities of sternocleidomastoid muscle) from line 545 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT and ICD-9 756.3/ICD-10 Q76.6-Q76.9 (Other anomalies of ribs and sternum) and ICD-10 Q68.0 (Congenital musculoskeletal deformities of sternocleidomastoid muscle) from lines 412 SPINAL DEFORMITY, CLINICALLY SIGNIFICANT and 588 SPINAL DEFORMITY, NOT CLINICALLY SIGNIFICANT and place on line 534 DEFORMITIES OF UPPER BODY AND ALL LIMBS
- 9) Keep 64490-64492 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (flouro or CT), cervical) and 64633 and 64634 (Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single or additional facet joints) on the Services Recommended for Non-Coverage Table
- 10) Place 63210 ((Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; cervical or thoracic)) on the Services Recommended for Non-Coverage Table
 - a. Advise MAP to remove from the Ancillary File

Line: MMM
 Condition: CONDITIONS OF THE BACK AND SPINE
 Treatment: RISK ASSESSMENT, PHYSICAL MODALITIES, COGNITIVE BEHAVIORAL THERAPY, MEDICAL THERAPY

ICD-9: 336.0,344.60-344.61,349.2,720.2,720.81,721.0-721.9,722.0-722.9,723.0,723.1, 723.4,723.6-723.9,724.0-724.9,731.0,732.0,737.0-737.2,737.40-737.42,737.8-737.9,738.4-738.5,739.0-739.9,742.59,754.2,756.10-756.19,839.20-839.21,847.0-847.9,V57.1,V57.2x, V57.81-V57.89

ICD-10: F45.42 (Pain disorder with related psychological factors), G83.4,G95.0,M24.08,M25.78, M40.x,M42.0x,M43.00-M43.28,M43-M43.9,M45.0-M45.8,M46.1,M46.40-M46.49,M46.81-M46.89,M46.91-M46.99,M47.011-M47.16,M47.20-M47.28,M47.811-M47.9,M48.00-M48.27,M48.30-M48.38,M48.9,M49.80-M49.89,M50.00-M50.93,M51.04-M51.9,M53.2x1-M53.2x8, M53.3,M53.80-M53.9,M54.0,M54.11-M54.6,M54.81-M54.9,M62.830,M96.1, M96.2-M96.5,M99.00-M99.09,M99.12-M99.13,M99.20-M99.79,M99.83-M99.84,Q06.0-Q06.3,Q06.8-Q06.9, Q67.5,Q76.0-Q76.4,Z47.82,S13.0xxA-S13.0xxD, S13.4xxA-S13.4xxD,S13.8xxA-S13.8xxD,S13.9xxA-S13.9xxD,S16.1xxA-S16.1xxD,S23.0xxA-S23.0xxD, S23.100A-S23.100D,S23.101A-S23.101D,S23.110A-S23.110D,S23.111A-S23.111D,S23.120A-S23.120D,S23.121A-S23.121D,S23.122A-S23.122D,S23.123A-S23.123D,S23.130A-S23.130D,S23.131A-S23.131D,S23.132A-S23.132D,S23.133A-S23.133D,S23.140A-S23.140D,S23.141A-S23.141D,S23.142A-S23.142D,S23.143A-S23.143D,S23.150A-S23.150D,S23.151A-S23.151D,S23.152A-S23.152D,S23.153A-S23.153D,S23.160A-S23.160D,S23.161A-S23.161D,S23.162A-S23.162D,S23.163A-S23.163D,S23.170A-S23.170D,S23.171A-S23.171D,S23.3xxA-S23.3xxD,S23.8xxA-

S23.8xxD,S23.9xxA-S23.9xxD,S33.0xxA-S33.0xxD, S33.100A-S33.100D,S33.101A-S33.101D,S33.110A-S33.110D,S33.111A-S33.111D,S33.120A-S33.120D,S33.121A-S33.121D,S33.130A-S33.130D,S33.131A-S33.131D,S33.140A-S33.140D,S33.141A-S33.141D,S33.5xxA-S33.5xxD,S33.9xxA-S33.9xxD,S34.3xxA-S34.3xxD, S39.092A-S39.092D,S39.82xA-S39.82xD,S39.92xA-S39.92xD

CPT: 62311, 64483, 64484, 90785,90832-90838,90853 (mental health visits, counseling), 96150-4 (health and behavior assessment codes), 97001-97004, 97022, 97110-97124, 97140, 97150, 97530, 97535 (PT/OT evaluation and treatment), 97810-97814 (acupuncture), 98925-98929, 98940-98942 (OMT/CMT), 98966-98968, 98969, 99051, 99060, 99070,99078,99201-99215 (outpatient medical visits), 99281-99285 (ER), 99304-99337 (SNF care), 99340-99359, 99366-99404 (risk factor reduction intervention), 99408, 99409, 99411, 99412, 99441-99449, 99487-99490, 99605-99607

HPCPS: G0157-G0160 (PT/OT), G0396-G0397 (SBRT), G0425-G0427 (telehealth), G0463, G0466, G0467, G0469, G0470 (FQHC)

Line: S1

Condition: CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS

Treatment: SURGICAL THERAPY

ICD-9: 344.60-344.61 (cauda equina), 721.1, 721.41-721.42,721.91 (spondylosis with myelopathy); 722.7x (intervertebral disc disorder with myelopathy), 723.0 (spinal stenosis), 724.0x (spinal stenosis), 738.4, 756.11-756.12 (spondylolisthesis), V57.1,V57.2x,V57.81-V57.89

ICD-10: G83.4 (cauda equina), M43.1x (spondylolisthesis), M47.0x, M47.1x (spondylosis with myelopathy), M48.0x (spinal stenosis), M50.0x, M51.0x (intervertebral disc disorder with myelopathy), M53.2x (spinal instabilities), Q76.2 (spondylolisthesis), Z47.82 (aftercare after scoliosis surgery)

CPT: 20660-20665, 20930-20938,21720,21725,22206-22226,22532-22855,29000-29046,29710-29720,62287, 62355-62370, 63001-63091,63170,63180-63200, 63270-63273,63295-63610,63650,63655,63685, 97001-97004, 97022, 97110-97124, 97140, 97150, 97530, 97535 (PT/OT evaluation and treatment), 96150-4 (health and behavior assessment codes), 98966-98968, 98969, 99051, 99060, 99070,99078,99201-99215 (outpatient medical visits), 99217-99239 (hospital), 99281-99285 (ER), 99304-99337 (SNF care), 99401-99404 (risk factor reduction intervention), 99408, 99409, 99411, 99412, 99441-99444, 99446-99449 (critical care), 99605-99607

HPCPS: G0157-G0160 (PT/OT), G0396-G0397 (SBRT), G0406-G0408 (inpatient consultation), G0425-G0427 (telehealth), G0463, G0466, G0467 (FQHC), S2350-S2351 (discectomy with decompression of spinal cord)

Line: S2

Condition: CONDITIONS OF THE BACK AND SPINE

Treatment: SURGICAL THERAPY

ICD-9: 336.0, 349.2,720.81,721.0, 721.2,721.3,721.5-721.8,721.90,722.0,722.10-722.2,722.4-722.6,722.8-722.93, 723.0, 723.1,723.4-723.9, 724.0x,731.0,732.0,737.0-737.2,737.40-737.42,737.8-737.9,738.4-738.5,742.59,754.2,756.10-756.12,839.20-839.21,V57.1,V57.2x,V57.81-V57.89

ICD-10: G95.0, M40.xx,M42.xx,M43.0x, M43.1x, M43.2x, M43.5x, M43.8x, M45.x, M46.0x-M46.9x,M47.2x,M47.8x,M47.9,M48.0x (spinal stenosis), M48.1, M48.3, M48.8, M48.9, M49.8x,M50.1x-M50.9x, M51.1x-M51.9,M53.8x,M53.9,M54.1x,M96.1-M96.5,M99.2x-M99.8x,Q67.5,Q76.0-Q76.3,Q76.4x,S13.0x,S23.0x, S23.1x, S33.0x, S33.1x,S34.3x

CPT: 20660-20665, 20930-20938,21720,21725,22206-22226,22532-22865,27035,29000-29046, 29710-29720,62287,62355-62370,63001-63091,63170,63180-63200, 63270-63273,63295-63610,63650,63655,63685,96150-96154 (health and behavior assessment codes), 97001-97004, 97022, 97110-97124, 97140, 97150, 97530, 97535 (PT/OT evaluation and treatment), 98966-98968, 98969, 99051, 99060, 99070,99078,99201-99215 (outpatient medical visits), 99217-99239 (hospital), 99281-99285 (ER), 99304-99337 (SNF care),

99401-99404 (risk factor reduction intervention), 99408, 99409, 99411, 99412, 99441-99444, 99446-99449 (critical care), 99605-99607
HPCPS: G0157-G0160 (PT/OT), G0396-G0397 (SBRT), G0406-G0408 (inpatient consultation), G0425-G0427 (telehealth), G0463, G0466, G0467 (FQHC), S2350-S2351 (discectomy with decompression of spinal cord)

Line: S3
Condition: SCOLIOSIS
Treatment: MEDICAL AND SURGICAL THERAPY
ICD-9: 737.3x, 737.43, V57.1, V57.2x, V57.81-V57.89
ICD-10: M41.xx
CPT: 20660-20665, 20930-20938, 21720, 21725, 22206-22226, 22532-22865, 29000-29046, 29710-29720, 62287, 62355-62370, 63001-63091, 63170, 63180-63200, 63210, 63295-63610, 63650, 63655, 63685, 96127, 96150-96154 (health and behavior assessment codes), 97001-97004, 97022, 97110-97124, 97140, 97150, 97530, 97535 (PT/OT evaluation and treatment), 97760, 97762, 98966-98968, 98969, 99051, 99060, 99070, 99078, 99201-99215 (outpatient medical visits), 99217-99239 (hospital), 99281-99285 (ER), 99304-99337 (SNF care), 99401-99404 (risk factor reduction intervention), 99408, 99409, 99411, 99412, 99441-99444, 99446-99449 (critical care), 99605-99607
HPCPS: G0157-G0160 (PT/OT), G0396-G0397 (SBRT), G0406-G0408 (inpatient consultation), G0425-G0427 (telehealth), G0463, G0466, G0467 (FQHC)

Scoring—Line MMM medical treatments

Category: 7
HL: 4
Suffering: 3
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 2
Effectiveness: 3
Need for service: 0.8
Net cost: 2
Score: 432
Approximate line placement: 405

Scoring—Line S1 urgent surgical

Category: 7
HL: 5
Suffering: 4
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 4
Effectiveness: 3
Need for service: 1
Net cost: 2
Score: 780
Approximate line placement: 350

Scoring—Line S2 surgical

Category: 7
HL: 4
Suffering: 3
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 0
Effectiveness: 1
Need for service: 0.8
Net cost: 2
Score: 112
Approximate line placement: 535

Scoring—Line S3 scoliosis

Category: 7
HL: 5
Suffering: 3
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 3
Effectiveness: 3
Need for service: 1
Net cost: 2
Score: 660
Approximate line placement: 364

MOTION: To recommend the new back condition lines with line scoring, deletion of current back condition lines, and guideline deletions as

presented for 2016 biennial list. To recommend the new guidelines (medical, surgical, opioid prescribing, and scoliosis), changes to existing guidelines, and miscellaneous code changes as modified for 2016 biennial list. CARRIES 5-0.

➤ **Topic: Coverage Guidance—IVC filters**

Discussion: Livingston reviewed the evidence and EGBS coverage guidance recommendations regarding IVC filters. Smits reviewed the proposed changes to the Prioritized List based on this draft coverage guidance. There was some discussion about different standards of care for use of IVC filters for use in trauma patients in different health systems in the state; however, it was determined that these filters should be available for use in trauma patients for those systems that chose to use them.

Recommended Actions:

- 1) Add CPT 37191-37193 to lines 1 PREGNANCY, 217 ACUTE PULMONARY HEART DISEASE AND PULMONARY EMBOLI, 285 BUDD-CHIARI SYNDROME, AND OTHER VENOUS EMBOLISM AND THROMBOSIS
- 2) Adopt a new guideline for IVC filters for PE/DVT as shown in Appendix B
 - a. Note: a minor modification replacing the line numbers with “these lines” in the second paragraph was done by HERC at their March 12, 2015 meeting. The guideline shown is as approved by VbBS.
- 3) Adopt a new ancillary guideline for IVC filters for trauma/prolonged hospitalization as shown in Appendix B

MOTION: To approve the recommended changes to the Prioritized List based on the draft inferior vena cava filters for pulmonary embolism prevention coverage guidance scheduled for review by HERC at their March 12, 2015 meeting. CARRIES 5-0.

➤ **Topic: Coverage Guidance—Alternatives to TURP**

Discussion: Shaffer reviewed the evidence and the HTAS coverage guidance for alternatives to TURP. Smits reviewed the proposed changes to the Prioritized List. There was some clarifying discussion.

Recommended Actions:

- 1) Remove 600.01 (Hypertrophy (benign) of prostate with urinary obstruction and other lower urinary tract symptoms (LUTS)), 600.11 (Nodular prostate with urinary obstruction), 600.21 (Benign localized hyperplasia of prostate with urinary obstruction and other lower urinary tract symptoms (LUTS)), and 600.91 (Hyperplasia of prostate, unspecified, with urinary obstruction and

- other lower urinary symptoms (LUTS)) from line 576 UNSPECIFIED URINARY OBSTRUCTION AND BENIGN PROSTATIC HYPERPLASIA WITHOUT OBSTRUCTION
- 2) Remove 52441 (Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant), 52442 (each additional implant), C9739, and C9740 (Cystourethroscopy, with insertion of transprostatic implant) from line 331 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION and add to the Services Recommended for Non-Coverage Table
 - 3) Add 52450 (Transurethral incision of prostate) to lines 218 CANCER OF KIDNEY AND OTHER URINARY ORGANS, 274 CANCER OF BLADDER AND URETER, 331 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION, 333 CANCER OF PROSTATE GLAND, 576 UNSPECIFIED URINARY OBSTRUCTION AND BENIGN PROSTATIC HYPERPLASIA WITHOUT OBSTRUCTION
 - a. Advise MAP to remove 52450 from the Ancillary File
 - 4) Remove 52647 (Laser coagulation of prostate, including control of postoperative bleeding, complete) from lines 331 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION and 333 CANCER OF PROSTATE GLAND and add to the Services Recommended for Non-Coverage Table
 - 5) Remove 52648 (Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy, and transurethral resection of prostate are included if performed) from line 333 CANCER OF PROSTATE GLAND
 - 6) Add 53850 (Transurethral destruction of prostate tissue; by microwave thermotherapy) and 53852 (Transurethral destruction of prostate tissue; by radiofrequency thermotherapy) to line 331 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
 - a. Advise MAP to remove 53830 and 53852 from their Non-Covered File
 - 7) Adopt a new guideline as shown in Appendix B

MOTION: To approve the recommended changes to the Prioritized List based on the draft alternative to TURP coverage guidance scheduled for review by HERC at their March 12, 2015 meeting. CARRIES 5-0.

➤ **Topic: Intraocular steroids for diabetic macular edema**

Discussion: Smits reviewed the summary document in the meeting materials. Testimony was heard from Allergan, Inc. representatives, who testified in support

of the staff recommendations. The Allergan representative gave information on some comparative pricing for various ocular steroid treatments. Williams raised a concern that patients who fail anti-VEGF might not benefit from intraocular steroids. Smits and the Allergan representative pointed to a study of this population that found benefit. There was some discussion about the concern for the high cataract formation rate, with the additional cost of surgeries for these cataracts. Overall, the subcommittee felt that the evidence supported the use of steroids for diabetic macular edema.

Recommended Actions:

- 1) Modify GN116 as shown in Appendix A

MOTION: To approve the guideline note change as presented. CARRIES 5-0.

➤ **Public Comment:**

No additional public comment was received.

➤ **Issues for next meeting:**

- Ventral hernia guideline
- Prenatal genetic testing guideline revisions
- Lumbar epidural steroid injection guideline revisions
- Smoking cessation guideline
- Review of inpatient and outpatient visit codes for “special” lines
- Yttrium for liver cancer and metastases
- Penile anomalies guideline
- Coverage guidance on
 - Planned out-of-hospital birth
- Developmental coordination disorder and sensory integration disorder

➤ **Next meeting:**

May 7, 2015 at Clackamas Community College, Wilsonville Training Center, Wilsonville Oregon, Rooms 111-112.

➤ **Adjournment:**

The meeting adjourned at 1:00 PM.

Appendix A

Revised Guideline Notes

Effective October 1, 2015

GUIDELINE NOTE 31, COCHLEAR IMPLANTATION, ~~AGE 5 AND UNDER~~

Line XXX

Children Patients will be considered candidates for cochlear implants if the following criteria are met:

- 1) Profound sensorineural hearing loss in both ears (defined as 71 94dB hearing loss or greater at 500, 1000 and 2000 Hz)
- 2) Receive ~~little or no~~ limited useful benefit from appropriately fitted hearing aids, defined as a speech discrimination score of <30% on age appropriate testing for children and as scores of 40% or less on sentence recognition test in the best-aided listening condition for adults
- 3) No medical contraindications
- 4) High motivation and appropriate expectations (both ~~child~~ patient, and family when appropriate, ~~and family~~)

Bilateral cochlear implants are ~~covered~~ included on these lines. Simultaneous implantation appears to be more cost-effective than sequential implantation.

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,207,374,414,468,545,546

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

Line 1 PREGNANCY

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

Hyperemesis gravidarum

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

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

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

Breech presentation

ICD-10-CM code: O32.1xx0, O32.8xx0

ICD-9-CM codes: 652.20, 652.23

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

Back and pelvic pain of pregnancy

ICD-10-CM code: O33.0

ICD-9 codes: 648.70, 648.73

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

Appendix A

Line 207 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE

Acupuncture is paired with the treatment of post-stroke depression only.

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

Line 374 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT

Acupuncture is included on Line 374 only for pairing with disorders of the spine with myelopathy and/or radiculopathy represented by the diagnosis codes G83.4, M47.1x, M47.2x, M50.0x, M50.1x, M51.1x, M54.1x/ICD-9-CM ~~344.60, 722.1, 722.2, 722.7 and 724.4~~ [344.6x, 721.1, 721.41, 721.42, 721.91, 722.7x, 723.4, 724.4](#), with referral, for up to 12 sessions.

Line 414 MIGRAINE HEADACHES

Acupuncture pairs on Line 414 for ICD-10-CM code G43.9/ICD-9-CM 346

Migraine, when referred, for up to 12 sessions.

Line 468 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 468 for osteoarthritis of the knee only, when referred, for up to 12 sessions.

Line 545 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT

Acupuncture pairs on Line 545 with the low back diagnoses (ICD-10-CM codes G83.4, M47.1x, M47.2x, M50.0x, M50.1x, M51.1x, M54.1x/ICD-9-CM ~~344.60, 722.1, 722.2, 722.7 and 724.4~~ [344.6x, 721.1, 721.41, 721.42, 721.91, 722.7x, 723.4, 724.4](#), when referred, for up to 12 sessions. Acupuncture pairs with chronic (>90 days) neck pain diagnoses (ICD-10-CM M53.82, M54.2, S13.4XXX, S13.8XXX/ICD-9-CM 723.1, 723.8, 723.9, 847.0), when referred, for up to 12 sessions.

Line 546 TENSION HEADACHES

Acupuncture is included on Line 546 for treatment of tension headaches (ICD-10-CM G44.2x/ICD-9-CM 307.81), when referred, for up to 12 sessions.

The development of this guideline note was informed by a HERC evidence-based guideline.

See <http://www.oregon.gov/oha/herc/Pages/blog-low-back-non-pharmacologic-intervention.aspx>

GUIDELINE NOTE 103, BONE ANCHORED HEARING AIDS

Lines 317,450

Bone anchored hearing aids (BAHA, CPT 69714, 69715) are included on these lines when the following criteria are met:

- 1) The patient is ~~age 5 years or older~~ [aged 5-20 years for implanted bone anchored hearing aids; headband mounted BAHA devices may be used for children under age 5](#)
- 2) Treatment is for unilateral severe to profound hearing loss (defined as 71 dB hearing loss or greater at 500, 1000 and 2000 Hz) when the contralateral ear has normal hearing [with or without a hearing aid](#)
- 3) Traditional air amplification hearing aids and contralateral routing of signal (CROS) hearing aid systems are not indicated or have been tried and are found to be not effective.
- 4) Implantation is unilateral.

Use of BAHA for treatment of tinnitus is not included on these lines.

Appendix A

GUIDELINE NOTE 116, INTRAOCULAR STEROID TREATMENTS ~~IMPLANTS~~ FOR CHRONIC NON-INFECTIOUS UVEITIS

Line 100, 363

Intraocular steroid ~~implants~~ treatments (CPT 67027, 67028) are ~~only~~ included on Line 363 for pairing with uveitis (ICD-9-CM codes 360.12, 363.0x, 363.1x, 363.2x, /ICD-10-CM codes H30.0xx, H30.1xx, H30.89x, H30.9xx, H44.11x), ~~and only~~ when the following conditions are met uveitis is chronic, non-infectious, and there has been appropriate trial and failure, or intolerance of therapy, with local and systemic corticosteroids and/or immunosuppressive agents.

Intraocular steroid treatments (CPT 67027, 67028) are included on line 100 for treating chronic diabetic macular edema (ICD-9 362.07/ ICD-10 E11.311) only when there has been insufficient response to anti-VEGF therapies, and only when FDA approved treatments are utilized.

Effective January 1, 2016

DIAGNOSTIC GUIDELINE D4, ADVANCED IMAGING FOR LOW BACK PAIN

In patients with non-specific low back pain and no “red flag” conditions [see Table D4], 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.

**Table D4
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"> • History of cancer with new onset of LBP 	MRI	ESR
	<ul style="list-style-type: none"> • Unexplained weight loss • Failure to improve after 1 month • Age >50 years • Symptoms such as painless neurologic deficit, night pain or pain increased in supine position 	Lumbosacral plain radiography	
	<ul style="list-style-type: none"> • Multiple risk factors for cancer present 	Plain radiography or MRI	
Spinal column infection	<ul style="list-style-type: none"> • Fever • Intravenous drug use • Recent infection 	MRI	ESR and/or CRP
Cauda equina syndrome	<ul style="list-style-type: none"> • Urinary retention • Motor deficits at multiple levels • Fecal incontinence • Saddle anesthesia 	MRI	None
Vertebral compression fracture	<ul style="list-style-type: none"> • History of osteoporosis • Use of corticosteroids • Older age 	Lumbosacral plain radiography	None
Ankylosing	<ul style="list-style-type: none"> • Morning stiffness 	Anterior-	ESR and/or

Appendix A

Possible cause	Key features on history or physical examination	Imaging*	Additional studies*
spondylitis	<ul style="list-style-type: none"> Improvement with exercise Alternating buttock pain Awakening due to back pain during the second part of the night Younger age 	posterior pelvis plain radiography	CRP, HLA-B27
Nerve compression/ disorders (e.g. herniated disc with radiculopathy)	<ul style="list-style-type: none"> Back pain with leg pain in an L4, L5, or S1 nerve root distribution present < 1 month Positive straight-leg-raise test or crossed straight-leg-raise test 	None	None
	<ul style="list-style-type: none"> Radiculopathic** signs present >1 month Severe/progressive neurologic deficits (such as foot drop), progressive motor weakness 	MRI***	Consider EMG/NCV
Spinal stenosis	<ul style="list-style-type: none"> Radiating leg pain Older age Pain usually relieved with sitting (Pseudoclaudication a weak predictor) 	None	None
	<ul style="list-style-type: none"> Spinal stenosis symptoms present >1 month 	MRI**	Consider EMG/NCV

* Level of evidence for diagnostic evaluation is variable

** Radiculopathic signs are defined for the purposes of this guideline [as the objective evidence of as in Guideline Note 37](#) with any of the following:

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

*** 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.

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

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,207,374,414,468,545,546,MMM

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

Line 1 PREGNANCY

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

Hyperemesis gravidarum

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

Appendix A

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

Breech presentation

ICD-10-CM code: O32.1xx0, O32.8xx0

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

Back and pelvic pain of pregnancy

ICD-10-CM code: O33.0

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

Line 207 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE

Acupuncture is paired with the treatment of post-stroke depression only.

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

~~Line 374 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT~~

~~Acupuncture is included on Line 374 YYY only for pairing with disorders of the spine with myelopathy and/or radiculopathy represented by the diagnosis codes G83.4, M47.1x, M47.2x, M50.0x, M50.1x, M51.1x, M54.1x, with referral, for up to 12 sessions.~~

Line MMM-CONDITIONS OF THE BACK AND SPINE

Acupuncture is included this line with visit limitations as in Guideline Note XXX.

Line 414 MIGRAINE HEADACHES

Acupuncture pairs on Line 414 for ICD-10-CM code G43.9 Migraine, when referred, for up to 12 sessions.

Line 468 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 468 for osteoarthritis of the knee only, when referred, for up to 12 sessions.

~~Line 545 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT~~

~~Acupuncture pairs on Line 545 with the low back diagnoses G83.4, M47.1x, M47.2x, M50.0x, M50.1x, M51.1x, M54.1x, when referred, for up to 12 sessions. Acupuncture pairs with chronic (>90 days) neck pain diagnoses (), when referred, for up to 12 sessions.~~

Line 546 TENSION HEADACHES

Acupuncture is included on Line 546 for treatment of tension headaches G44.2x, when referred, for up to 12 sessions.

GUIDELINE NOTE 105, EPIDURAL STEROID INJECTIONS, ~~OTHER PERCUTANEOUS INTERVENTIONS FOR LOW-BACK PAIN~~

Lines ~~75, 159, 297, MMM~~

Epidural lumbar steroid injections (CPT 62311, 64483, 64484) are included on this line for patients with persistent radiculopathy due to herniated disc, where radiculopathy is ~~as~~ defined in Guideline Note 37 as showing objective evidence of one or more of the following:

A) Markedly abnormal reflexes

Appendix A

- 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~~

One epidural steroid injection is included on these lines; a second epidural steroid injection may be provided after 3-6 months only if objective evidence of 3 months of sustained pain relief was provided by the first injection. 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. Epidural lumbar steroid injections are not included on these lines 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~~
- ~~• radiofrequency denervation~~

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

GUIDELINE NOTE 137, BENIGN BONE TUMORS AND JOINT CONDITIONS AT HIGH RISK FOR COMPLICATIONS

Lines ~~XXX, 154, 358, 484, 496~~, 533

Treatment of benign conditions of joints (ICD-9/ICD-10 727.89/M67.8x synovial chondromatosis, ICD-9/ICD-10 228.00/D18.09 synovial hemangioma, ICD-9/ICD-10 214.8/D17.79 lipoma arborescens, ICD-9/ICD-10 727.02/D48.1 tenosynovial giant cell tumor, and ICD-9/ICD-10 719.2x/ M12.2xx villonodular synovitis) are included on Line XXX for those conditions only when there are significant functional problems of the joint due to size, location, or progressiveness of the disease. Treatment of all other benign joint conditions are included on Line 533.

Treatment of benign tumors of bones (ICD-9 213.0-213.9, 526.0-526.2, 733.2x/ICD-10 D16.00-D16.9, K09.0, K09.1, M27.1, M27.40, M27.49, M85.40-M85.69) are included on ~~Lines 154, 358, 484 and 496~~ Line XXX for those neoplasms associated with pathologic fractures, at high risk of fracture, or which cause function problems including impeding joint function due to size, causing nerve compression, have malignant potential or are considered precancerous. Treatment of all other benign bone tumors are included on Line 533.

Appendix B

New Guideline Notes

Effective October 1, 2015

ANCILLARY GUIDELINE A3, IVC FILTERS FOR TRAUMA

It is the intent of the Commission that inferior vena cava (IVC) filter placement (CPT 37191) and subsequent repositioning and removal (CPT 37192, 37193) are covered when medically indicated for hospitalized patients with severe trauma resulting in prolonged hospitalization.

GUIDELINE NOTE XXX, TREATMENT OF UNILATERAL HEARING LOSS

Lines 317, 450

Unilateral hearing loss treatment is included on these lines only for children aged 20 and younger with the following conditions:

- 1) For mild to moderate sensorineural unilateral hearing loss (defined as 26-70 dB hearing loss at 500, 1000 and 2000 Hz), first line intervention should be a conventional hearing aid, with second line therapy being contralateral routing of signal (CROS) system
- 2) For severe to profound unilateral sensorineural hearing loss (defined as 71 dB hearing loss or greater at 500, 1000 and 2000 Hz), first line therapy should be a contralateral routing of signal (CROS) system with second line therapy being a bone anchored hearing aid (BAHA). BAHA SoftBand therapy may be first line therapy for children under age 5 or patients with severe ear deformities (e.g. microstia, severe canal atresia).

Cochlear implants are not included on these lines for unilateral hearing loss per guideline note 31 COCHLEAR IMPLANTATION.

GUIDELINE NOTE XXX, PROTON PUMP INHIBITOR THERAPY FOR GASTROESOPHAGEAL REFLUX DISEASE (GERD)

Lines 384, 519

Short term treatment (up to 8 weeks) of GERD with proton pump inhibitor therapy is included on line 384. Long term treatment is included on line 519.

GUIDELINE NOTE XXX, IVC FILTERS FOR ACTIVE PE/DVT

Lines 1, 83, 217, 285, 290

Inferior vena cava (IVC) filter placement (CPT 37191) is included on lines 1, 83, 217, 285, 290 for patients with active deep vein thrombosis/pulmonary embolism (DVT/PE) for which anticoagulation is contraindicated. IVC filter placement is not included on these lines for patients with DVT who are candidates for anticoagulation.

Retrieval of removable IVC filters (CPT 37193) is included on these lines when the benefits of removal outweigh the harms.

Appendix B

GUIDELINE NOTE XXX, TREATMENTS FOR BENIGN PROSTATE ENLARGEMENT WITH LOWER URINARY TRACT SYMPTOMS

Line 331

For men with lower urinary tract symptoms (LUTS) due to benign prostate enlargement, coverage of surgical procedures is recommended only if symptoms are severe, and if drug treatment and conservative management options have been unsuccessful or are not appropriate.

The following interventions for benign prostate enlargement are not included on line 331 due to lack of evidence of effectiveness:

- Botulinum toxin
- HIFU (High Intensity Focused Ultrasound)
- TEAP (Transurethral Ethanol Ablation of the Prostate)
- Prostatic urethral lifts
- Laser coagulation (for example, VLAP/ILC)
- Prostatic artery embolization

Effective January 1, 2016

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

Line MMM

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

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

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

For patients who are determined to be high risk on the validated assessment tool, the following treatments are included on this line:

- Office evaluation, consultation and education
- Cognitive behavioral therapy. The necessity for cognitive behavioral therapy should be re-evaluated every 90 days and coverage will only be continued if there is documented evidence of decreasing depression or anxiety symptomatology, improved ability to work/function, increased self-efficacy, or other clinically significant, objective improvement.

Appendix B

- [Prescription and over the counter](#) medications, [opioid medications](#) subject to the limitations on coverage of opioids in Guideline Note YYY OPIOID PRESCRIBING FOR CONDITIONS OF THE BACK AND SPINE. See evidence table.
- The following evidence-based therapies, when available, are encouraged: yoga, massage, supervised exercise therapy, intensive interdisciplinary rehabilitation
- A total of 30 visits per year of any combination of the following evidence-based therapies when available and medically appropriate. These therapies are only covered if provided by a provider licensed to provide the therapy and when there is documentation of measurable clinically significant progress toward the therapy plan of care goals and objectives using evidence based objective tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).
 - 1) Rehabilitative therapy (physical and/or occupational therapy), if provided according to GUIDELINE NOTE 6, REHABILITATIVE SERVICES. Rehabilitation services provided under this guideline also count towards visit totals in Guideline Note 6
 - 2) Chiropractic or osteopathic manipulation
 - 3) Acupuncture

These coverage recommendations are derived from the State of Oregon Evidence-based Guideline on the Evaluation and Management of Low Back Pain available here: <http://www.oregon.gov/oha/herc/Pages/blog-low-back-non-pharmacologic-intervention.aspx>

Intervention Category*	Intervention	Acute < 4 Weeks	Subacute & Chronic > 4 Weeks
Self-care	Advice to remain active	●	●
	Books, handout	●	●
	Application of superficial heat	●	
Nonpharmacologic therapy	Spinal manipulation	●	●
	Exercise therapy		●
	Massage		●
	Acupuncture		●
	Yoga		●
	Cognitive-behavioral therapy		●
	Progressive relaxation		●
Pharmacologic therapy <small>(carefully consider risks/harms)</small>	Acetaminophen	●	●
	NSAIDs	●(▲)	●(▲)
	Skeletal muscle relaxants	●	
	Antidepressants (TCA)		●
	Benzodiazepines**	●(▲)	●(▲)
	Tramadol, opioids**	●(▲)	●(▲)
Interdisciplinary therapy	Intensive interdisciplinary rehabilitation		●
<p>● Interventions supported by grade B evidence (at least fair-quality evidence of moderate benefit, or small benefit but no significant harms, costs, or burdens). No intervention was supported by grade “A” evidence (good-quality evidence of substantial benefit).</p> <p>▲ Carries greater risk of harms than other agents in table.</p>			

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

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

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

Appendix B

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

Lines MMM, S1, S2, S3

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

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

- 1) During the first 6 weeks after the acute injury, flare or surgery, opioid treatment is included on these lines ONLY
 - a. When each prescription is limited to 7 days of treatment, AND
 - b. For short acting opioids only, AND
 - c. When one or more alternative first line pharmacologic therapies such as NSAIDs, acetaminophen, and muscle relaxers have been tried and found not effective or are contraindicated, AND
 - d. When prescribed with a plan to keep active (home or prescribed exercise regime) and with consideration of additional therapies such as spinal manipulation, physical therapy, yoga, or acupuncture, AND
 - e. There is documented lack of current or prior opioid misuse or abuse.
- 2) Treatment with opioids after 6 weeks, up to 90 days, requires the following
 - a. Documented evidence of improvement of function of at least thirty percent as compared to baseline based on a validated tools.
 - b. Must be prescribed in conjunction with therapies such as spinal manipulation, physical therapy, yoga, or acupuncture.
 - c. Verification that the patient is not high risk for opioid misuse or abuse. Such verification may involve
 - i. Documented verification from the state's prescription monitoring program database that the controlled substance history is consistent with the prescribing record
 - ii. Use of a validated screening instrument to verify the absence of a current substance use disorder (excluding nicotine) or a history of prior opioid misuse or abuse
 - iii. Administration of a baseline urine drug test to verify the absence of illicit drugs and non-prescribed opioids.
 - d. Each prescription must be limited to 7 days of treatment and for short acting opioids only
- 3) Further opioid treatment after 90 days may be considered ONLY when there is a significant change in status, such as a clinically significant verifiable new injury or surgery. In such cases, use of opioids is limited to a maximum of an additional 7 days. In exceptional cases, use up to 28 days may be included on these lines, subject to the criteria in #2 above.

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

Appendix B

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

Lines S1, S2

Surgical consultation/consideration for surgical intervention are included on these lines only for patients with neurological complications, defined as showing objective evidence of one or more of the following:

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

Spondylolithesis (ICD-9 738.4, 756.11-756.12 / ICD-10 M43.1x, Q76.2) is included on line S1 only when it results in spinal stenosis with signs and symptoms of neurogenic claudication. Otherwise, these diagnoses are included on line S2.

Surgical correction of spinal stenosis (ICD-9 721.1, 723.0, 724.0x / ICD-10 M48.0x) is only included on lines S1 for patients with:

- 1) MRI evidence of moderate to severe central or foraminal spinal stenosis AND
- 2) A history of neurogenic claudication, or objective evidence of neurologic impairment consistent with MRI findings.
- 3)

~~Otherwise, these diagnoses are included on line S2.~~ Only decompression surgery is covered for spinal stenosis; spinal fusion procedures are not covered for this diagnosis. Otherwise, these diagnoses are included on line S2.

For conditions on line S2, surgical interventions may only be considered after the patient has completed at least 6 months of conservative treatment, provided according to Guideline Note XXX NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE.

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

Appendix B

GUIDELINE NOTE AAA, SCOLIOSIS

Line S3

Non-surgical treatments of scoliosis (ICD-9 737.3x,737.43/ICD-10 M41.xx) are included on line CCC when

- 1) the scoliosis is considered clinically significant, defined as curvature greater than or equal to 25 degrees or
- 2) there is curvature with a documented rapid progression.

Surgical treatments of scoliosis are included on line ~~CCC-S3~~

- 1) only for children and adolescents (age ~~24~~ 20 and younger) with
- 2) a spinal curvature of greater than 45 degrees

DRAFT

Appendix C

Deleted Guidelines

~~GUIDELINE NOTE 37, DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT~~

~~Lines 374,545~~

~~Diagnoses are included on Line 374 when objective evidence of neurologic impairment or radiculopathy is present, as defined as:~~

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

~~Otherwise, disorders of spine not meeting these criteria (e.g. pain alone) fall on Line 545.~~

~~GUIDELINE NOTE 41, SPINAL DEFORMITY, CLINICALLY SIGNIFICANT~~

~~Line 412~~

~~Clinically significant scoliosis is defined as curvature greater than or equal to 25 degrees or curvature with a documented rapid progression. Clinically significant spinal stenosis is defined as having MRI evidence of moderate to severe central or foraminal spinal stenosis in addition to a history of neurogenic claudication, or objective evidence of neurologic impairment consistent with MRI findings (see Guideline Note 37).~~

~~GUIDELINE NOTE 56, ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT~~

~~Line 545~~

~~Disorders of spine without neurologic impairment include any conditions represented on this line for which objective evidence of one or more of the criteria stated in Guideline Note 37 is not available~~

~~GUIDELINE NOTE 60, SPINAL DEFORMITY, NOT CLINICALLY SIGNIFICANT~~

~~Line 588~~

~~Scoliosis not defined as clinically significant included curvature less than 25 degrees that does not have a documented progression of at least 10 degrees~~

~~GUIDELINE NOTE 94, EVALUATION AND MANAGEMENT OF LOW BACK PAIN~~

~~Lines 374,545~~

~~Procedures for the evaluation and management of low back pain are included on these lines when provided subject to the State of Oregon Evidence-based Clinical Guidelines dated 10/2011 located at:~~

~~<http://www.oregon.gov/oha/OHPR/pages/herc/evidence-based-guidelines.aspx>.~~

MINUTES

Evidence-based Guidelines Subcommittee

Meridian Park Community Health Education Center, Room 117B&C

19300 SW 65th Avenue, Tualatin, OR

April 2, 2015

2:00-5:00pm

Members Present: Wiley Chan, MD, Chair; Steve Marks, MD, Vice Chair; Kathryn Lueken, MD; Vern Saboe, DC; Beth Westbrook, PsyD, MBA; Som Saha, MD, MPH; Eric Stecker, MD, MPH.

Members Absent: Bob Joondeph, JD; Leda Garside, RN.

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

Also Attending: George Waldmann (HTAS), Robyn Liu MD, MPH, Val King MD MPH and Jill Scantlan (OHSU Center for Evidence-based Policy); Duncan Neilson (Legacy Health); Melissa Cheyney (OSU); Samie Patnode (Health Licensing); Colleen Forbes (Board of Direct Entry Midwifery); Leigh Hess (OHSU); Edward Toggart (Samaritan Heart and Vascular Institute).

1. CALL TO ORDER

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

2. MINUTES REVIEW

No changes were made to the February 5, 2015 minutes.
Minutes approved 6-0 (Stecker not present).

3. STAFF REPORT

Coffman reported changes to subcommittee membership to be effective in June. Som Saha will serve as chair of the Health Technology Assessment Subcommittee (HTAS). George Waldmann, who attended as an observer, will move from HTAS to EbGS. Steve Marks has resigned from the EbGS. Dr. Mark Bradshaw and Chris Labhart will serve as new members of HTAS. EbGS will require a new vice chair, but that will be decided at its June meeting.

4. Coronary artery revascularization for chronic stable angina

Robyn Liu reported on the results of the literature search requested by the subcommittee at its February meeting. In general revascularization by percutaneous coronary interventions did not show benefit in a network meta-analysis, though two of the third-generation stents showed promise in small studies not deemed generalizable.

Livingston reviewed the other changes shown in the meeting materials. In the summary, there is additional information about the meta-analysis. In the GRADE table, there is now a mention of the evidence suggesting a mortality benefit from the newer stents. Dr. Toggart said that the older stents are seldom used, as the third-generation stents are preferred.

For CABG, Livingston reviewed the addition of numeric descriptions of effect to the GRADE table for CABG. She questioned the importance of repeat revascularization as an outcome but noted the lower rate of myocardial infarction.

She noted that the evidence doesn't stratify between patients who did and did not try optimal medical therapy before revascularization. She noted that the requirement for a trial of medical therapy was added based on the subcommittee's recommendation, not directly from a trial in this population. Chan asked whether the evidence summary's lack of an explicit rationale for doing PCI for people who have failed OMT was bothersome for the subcommittee. He suggested stating the rationale into the summary of evidence. After discussion, the subcommittee agreed that Livingston and Chan should work out some language about the rationale to make clearer that PCI is not recommended without a trial of medical therapy because it does not show a mortality benefit, and that the recommendation for coverage after a trial of medical therapy is based on the evidence of improvement in quality of life and symptoms.

The subcommittee then discussed the coverage guidance development frameworks (algorithms). The subcommittee discussed how they don't match the recommendations exactly because they fail to capture the balance of benefit and harms as presented in the rationale, but made no change since these are simply a tool used to come up with a recommendation, explained in the GRADE table. Chan also expressed concern that the risk reflected in the algorithm for CABG for patients with three-vessel and left main disease should be the risk associated with the treatment itself rather than the patient's net risk of death with or without treatment. Livingston said that a new algorithm has been proposed to address these types of concerns and will be presented at the May HERC meeting, and after discussion the subcommittee made no changes to the Coverage Guidance Development Framework for this coverage guidance.

Livingston said that the subcommittee received no public comment on this coverage guidance during the 30-day comment period. She then reviewed the coverage guidance box language.

Saha expressed concern about patients with three-vessel disease or left-main disease for whom medical therapy has failed but who have contraindications to CABG. There is no statement about whether these patients should have the option for PCI, but this is not clear from the box language, and the consensus is that these patients should get PCI.

Toggart pointed out that angiography isn't performed on people with mild symptoms, so their anatomy may be unknown unless another study is ordered. Chan confirmed with Toggart that for these patients, CABG would be optimal. Toggart agreed in general, but said there are patients with multiple comorbidities (such as cancer and diabetes) making CABG inappropriate

and that shared decisionmaking would be good for these patients. Stecker mentioned other evidence comparing PCI and CABG, but this evidence was not part of this coverage guidance. The subcommittee discussed adding a weak recommendation for PCI in these patients, but as the evidence reviewed in this coverage guidance did not address that specific population, agreed to leave this for medical directors to decide on a case-by case basis, despite concerns about inconsistent decisionmaking by medical directors.

A motion was made to approve the draft coverage guidance with the changes to the GRADE table to be approved by Chan, then forward the draft to HERC for review. **Motion approved 7-0.**

DRAFT COVERAGE GUIDANCE

Coronary revascularization (with percutaneous coronary intervention (PCI) or coronary artery bypass surgery (CABG)) is recommended for coverage in patients with stable angina whose symptoms are not controlled with optimal medical therapy¹ or who cannot tolerate such therapy (*weak recommendation*).

CABG is recommended for coverage for patients with stable angina who have left main coronary artery stenosis or three-vessel coronary artery stenosis, with or without a trial of optimal medical therapy (*strong recommendation*).

¹Optimal medical therapy for angina symptom control prior to PCI is defined as two or more antianginals (with or in addition to standard treatment for coronary artery disease). Antianginals are defined as: beta-blocker, nitrate, calcium channel blocker, or ranolazine.

4. Planned out-of-hospital birth

Livingston directed the subcommittee's attention to the high risk conditions disposition in the meeting materials, synthesizing the issues brought up in public comment. She also explained the changes to the box structure which were made to clear up confusion around absolute contraindications versus criteria for transfer of care. The subcommittee also clarified that the coverage guidance is not defining systems of care, but clarifying the conditions under which planned out-of-hospital birth should be covered.

In the notes below, only issues receiving substantive discussion are included in these minutes; otherwise the staff recommendations were accepted as follows:

Absolute Contraindication

- Prior Cesarean section

Consultation Required

- Gestational, diet- and exercise-controlled only
- Prior third- or fourth-degree laceration
- History of baby >4.5kg or 9lb14oz
- Suspected fetal macrosomia EFW >4.5kg or 9 lbs 14 oz
- Maternal mental illness under outpatient psychiatric care
- History of preterm birth

- History of more than three first trimester spontaneous abortions, or more than one second trimester spontaneous abortion
- Cervical dysplasia requiring evaluation
- History of pre-eclampsia/HELLP syndrome (if did not necessitate preterm birth)
- History of unexplained stillbirth/neonatal death or previous death unrelated intrapartum difficulty
- Confirmed intrauterine death

Transfer Required

- Type I, Type II, uncontrolled gestational, or gestational controlled with medication
- Intrapartum third- or fourth- degree laceration
- Maternal mental illness requiring inpatient care
- Hyperemesis gravidarum
- History of pre-eclampsia/HELLP syndrome (if necessitated preterm birth)
- History of unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty
- History of postpartum hemorrhage requiring additional treatment or blood transfusion
- Complete placenta previa or low lying placenta within 2 cm or less of the cervical os at term; known vasa previa

Neither Consultation Nor Transfer Required:

- Ultrasound between 12-30 weeks
- Having an IUD

For the requirements around gestational age, the subcommittee accepted the staff recommendations to change the limits to allow planned out-of-hospital birth from 37 weeks + 0 days to 41 weeks + 6 days. The latter recommendation takes into account testimony from appointed expert Neilson that some women choosing out-of-hospital birth may not have an accurate gestational age, and the estimates are more likely underestimated than overestimated.

For extremes of maternal age, there is less consistency among the sources reviewed. With input from Cheyney and Neilson, the subcommittee discussed how in many cases the issues around women on the young end of the spectrum are psychosocial and may be dealt with just as well by a home birth attendant, and the issues for older women are about genetic testing and are not really contraindications to out-of-hospital birth. After discussion, the subcommittee decided to strike these recommended criteria for consultation based on lack of evidence that age in of itself is a criterion necessitating consultation in the absence of other factors.

The group discussed the added requirement of fractured clavicle or shoulder dystocia in a prior birth. Cheyney and Neilson said that defining shoulder dystocia is challenging as it can be because of maternal posture on a soft mattress or because of other more serious factors threatening oxygenation for the baby. The NICE guideline does not define it. King suggested making it a requirement for consultation so that severity can be determined. After discussion, the group decided to use the NICE criteria but make it a requirement for consultation rather than transfer because many things can be different from pregnancy to pregnancy, such as fetal size.

After discussion the subcommittee declined to add maternal Jehovah's Witness status as an indication for consultation or transfer as the reason to go to the hospital would be to get blood products, which a Jehovah's Witness would decline anyway.

Regarding maternal seizure disorders, Livingston said core sources have different criteria and so the staff recommendation was in the middle. Medication use may not be a good proxy for risk level, and Neilson said a maternal seizure disorder is seldom triggered by labor. After discussion the subcommittee elected to make history of maternal seizure disorder as a criterion for consultation.

Livingston reviewed the staff recommendation which attempts to capture patients at the highest risk because of inadequate prenatal care. Neilson said that inadequate prenatal care doesn't make sense as an exclusion criteria since women refusing such care will face similar risks regardless of the birth setting, though there may be risk for the baby after the birth. After discussion the subcommittee decided to include unknown HIV or HPV status as a requirement for transfer and to move the language around inadequate care to a requirement for consultation.

For failure to progress, the committee discussed whether to make it a criterion for consultation or transfer, and decided that a transfer would be more appropriate, as a consultation would result in a recommendation to transfer.

The subcommittee discussed family history of heritable genetic disorders, making it an indication for consultation because some of these conditions do require hospital care for the baby in the immediate postpartum period.

For history of postpartum hemorrhage requiring additional pharmacologic treatment or blood transfusion in prior pregnancy, Livingston noted that "additional treatment" is not defined in the NICE guideline. Cheyney asked about whether a shot of pitocin constitutes additional treatment; Livingston said she sees this as active management. King suggested making this a requirement for consultation as there are a variety of scenarios, some of which may not require planned hospital birth. After discussion the subcommittee accepted her recommendation.

For history of retained placenta, Cheyney and Neilson recommended requiring a consultation for manual removal and planned hospital birth if surgical removal was required. The subcommittee accepted their recommendation.

For the requirement for planned hospital birth for women with pre-pregnancy BMI >35, King said that this is another case where when problems develop, the problems are addressed in other places of the coverage guidance, such as diabetes. After brief discussion the subcommittee decided to make it a requirement for consultation as risks are higher for some women and not for others, such as those that have had a number of uncomplicated prior births.

Discussion then shifted to the box language, which was restructured from the previous draft. Saha suggested combining the absolute contraindications with the indications for planned hospital birth. Livingston said the distinction is that the absolute contraindications are those with strong evidence of much higher risks. He suggested separating the conditions requiring planned hospital birth from those requiring transfer and including the currently-listed absolute contraindications in the list of conditions requiring planned hospital birth. After discussion the subcommittee decided to make this change, recognizing that some indications may need to be listed under the planned hospital birth section as well as the section on conditions requiring transfer.

He asked about the second paragraph, whether it is redundant to say planned out-of-hospital birth is not covered in other circumstances. Liu said this is because there is a weak

recommendation to cover planned out-of-hospital birth as described but a strong recommendation not to cover it for women who had one of the listed absolute contraindications. Cheyney questioned whether this is about the strength of the evidence. King said there is strong evidence around those four factors. Combining this list may make the distinction less clear. The subcommittee asked that the strong recommendation be tied to these same conditions in the re-organized draft. Livingston said staff will look for ways to simplify the structure while retaining the distinct strength of recommendations.

Livingston briefly reviewed the other changes regarding distance to hospital and requirement for continued assessment. Other issues, including nulliparity as a contraindication to planned out-of-hospital birth will be discussed at a future meeting. Cheyney asked about the requirement for documentation of a consultation in the medical record. Livingston clarified that the out-of-hospital midwife would make a medical record, not that the provider who was consulted would have to do so. Chan clarified that this is a condition for coverage.

Discussion will continue at the next meeting.

5. ADJOURNMENT

The meeting was adjourned at 5:05 pm. The next meeting is scheduled for June 4, 2015 from 2:00-5:00pm in Room 117B of the Meridian Park Hospital Community Health Education Center in Tualatin.

Section 2.0

Coverage Guidances-EbGS

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: CORONARY ARTERY REVASCULARIZATION FOR STABLE ANGINA

REVISED DRAFT for VbBS/HERC meeting materials 5/7/2015

HERC COVERAGE GUIDANCE

Coronary revascularization (with percutaneous coronary intervention (PCI) or coronary artery bypass surgery (CABG)) is recommended for coverage in patients with stable angina whose symptoms are not controlled with optimal medical therapy¹ or who cannot tolerate such therapy (*weak recommendation*).

CABG is recommended for coverage for patients with stable angina who have left main coronary artery stenosis or three-vessel coronary artery stenosis, with or without a trial of optimal medical therapy (*strong recommendation*).

¹Optimal medical therapy for angina symptom control prior to PCI is defined as two or more antianginals (in addition to standard treatment for coronary artery disease). Antianginals are defined as: beta-blocker, nitrate, calcium channel blocker, or ranolazine.

Note: Definitions for strength of recommendation are provided in Appendix A GRADE Element Description

RATIONALE FOR GUIDANCE DEVELOPMENT

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

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

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

EVIDENCE SOURCES

Trusted sources

- Dolor, R.J., Melloni, C., Chatterjee, R., Allen LaPointe, N.M., Williams, J.B., Coeytaux, R.R., et al. (2012). *Treatment strategies for women with coronary artery disease*. Rockville, MD: AHRQ. Accessed on October 2, 2014, from http://effectivehealthcare.ahrq.gov/ehc/products/218/1227/CER66_Treatment-Coronary-Artery-Disease_FinalReport_20120816.pdf
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The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

EVIDENCE OVERVIEW

Clinical background

Coronary artery disease (CAD) is the presence of atherosclerosis in the epicardial coronary arteries. Atherosclerotic plaques may either rupture and cause acute ischemia or progressively narrow the coronary artery lumen, resulting in chronic stable angina.

Angina resulting from progressive narrowing of the coronary arteries is the initial manifestation of ischemic heart disease in approximately one-half of patients. Angina is a clinical syndrome characterized by discomfort in the chest, jaw, shoulder, back, or arm. It is typically aggravated by exertion or emotional stress and relieved by nitroglycerin. Angina usually occurs in patients with CAD that involves at least one large epicardial artery. However, angina can also occur in patients with valvular heart disease, hypertrophic cardiomyopathy, and uncontrolled hypertension. It can also be present in patients with normal coronary arteries and myocardial ischemia related to spasm or endothelial dysfunction.

Most angina is a sign of significant CAD—defined angiographically as a stenosis with greater than 70 percent diameter in at least one major epicardial artery segment or with greater than 50 percent diameter in the left main coronary artery. However, some angina is caused by stenotic lesions of lesser diameters, which have much less prognostic significance. Chronic stable angina is classified as pain that classically occurs with moderate to severe exertion, is milder in nature, and is relieved with rest or sublingual nitroglycerin.

Indications

Treatment options for secondary prevention include medical therapy (antiplatelet agents, statins, blood pressure reduction if indicated, beta-blockers and angiotensin converting enzyme inhibitors), coronary artery bypass grafting (CABG) and a number of less invasive methods, including percutaneous transluminal coronary angioplasty (PTCA), in which a small elongated balloon is inflated at the site of the plaque, effectively compacting the deposited material against the vessel wall. This is often accompanied by a coronary artery stent.

Technology description

Coronary artery stents are expandable devices resembling a tubular wire mesh used to 'scaffold' vessels open during PTCA procedures to relieve coronary obstructions in patients. The first of these were metal and are referred to as bare metal stents (BMS). Restenosis (re-narrowing of the treated vessel), which may require a repeat intervention, is a significant limitation of PTCA with the use of stents; rates of restenosis are recorded as ranging between 20 and 50 per cent, depending on the size, location and complexity of the lesion. In order to improve results and reduce restenosis, developments in stent design have been augmented by new drug-eluting technologies. Drug-eluting stents (DES) release anti-proliferative agents from their surface with the objective of limiting cell growth around the stent using cytotoxic, cytostatic and other agents (sirolimus, paclitaxel, everolimus, tacrolimus). Percutaneous coronary intervention (PCI) is an umbrella term that includes PTCA, with and without the additional use of stents.

This report is limited to individuals with stable angina or non-acute coronary heart disease (CHD); it does not address coronary interventions used in the setting of acute coronary syndrome. It is also limited to a comparison to optimal medical therapy to either PCI or CABG. There is a large body of evidence comparing PCI to CABG that is not included in this report.

Oregon utilization

Data from the Dartmouth Atlas of Health Care demonstrate that in Oregon, utilization of PCI is low compared to the national average and in proportion to utilization of CABG.

Table 1. Percutaneous Coronary Interventions (PCI) versus Inpatient Coronary Artery Bypass Grafting (CABG) Utilization per 1,000 Medicare Enrollees in 2012

	Male		Female		Overall	
	PCI	CABG	PCI	CABG	PCI	CABG
Oregon	5.6	3.9	2.9	1.2	4.1	2.4
Washington	6.9	3.5	3.4	1.3	4.9	2.3
National Average	8.4	4.1	4.5	1.4	6.2	2.6
90th Percentile	10.7	5.4	6.1	2.0	8.1	3.4
10th Percentile	5.8	3.1	3.0	0.9	4.3	1.9

Adapted from The Dartmouth Atlas of Health Care Website, <http://www.dartmouthatlas.org/>

Evidence review

Percutaneous coronary intervention vs. optimal medical therapy in stable coronary heart disease

It is unclear whether PTCA with or without stenting is more effective than medical treatment alone at reducing mortality, cardiac death, composite outcomes including mortality and cardiovascular morbidity, non-fatal MI, need for revascularization, or heart failure in people with non-acute CHD (low quality evidence). Populations and interventions (particularly the use of stents) varied between trials, and results varied by the specific analysis undertaken, outcome assessed, and population included (low-quality evidence).

Four systematic reviews comparing PTCA with or without stenting versus medical treatment alone (Jeremias 2009, Katrasis 2005, Ioannidis 2007, Trikalinos 2009) and three subsequent reports of RCTs included in the reviews (Boden 2009, Malek 2009, Mark 2009) were identified in the initial search of trusted sources. There was a large overlap in the RCTs meta-analyzed in the systematic reviews. However, each review combined different RCTs in their analysis and therefore all four reviews are reported on here.

The first review (Katrasis 2005, search date 2004, 11 RCTs, 2950 people with angiographically documented coronary stenosis in non-acute coronary artery disease settings) compared PTCA versus medical treatment. People with an acute coronary syndrome within the past week were excluded. However, in two RCTs all people had an MI within the past 3 months, but not in the past week. Most RCTs mainly included people with single-vessel or two-vessel disease, but one included people with multi-vessel disease only. The use of stents in people receiving PTCA varied among RCTs, and no RCT used drug-eluting stents. The review found no significant difference between PTCA and medical treatment in mortality (11 RCTs; 95/1476 [6%] with PTCA v 101/1474 [7%] with medical management; RR 0.94, 95% CI 0.72 to 1.24), non-fatal MI (11 RCTs; 87/1476 [6%] with PTCA v 65/1474 [4%] with medical management; RR 1.28, 95% CI 0.94 to 1.75), cardiac death or MI (11 RCTs; 126/1476 [8%] with PTCA v 109/1474 [7%] with medical management; RR 1.17, 95% CI 0.88 to 1.57), need for CABG (11 RCTs; 109/1476 [7.4%] with PTCA v 106/1474 [7.2%] with medical management; RR 1.03, 95% CI 0.80 to 1.33), or need for PTCA during follow-up (11 RCTs; 219/1476 [15%] with PTCA v 243/1474 [16%] with medical management; RR 1.23, 95% CI 0.80 to 1.90). However, there was considerable heterogeneity among trials.

Pre-specified subgroup analyses found that there was no significant difference in the end points considered in RCTs whether stents were available or not, and in trials with follow-up exceeding 2 years there was no difference in end points between PTCA and medical treatment. However, in RCTs with a mean follow-up <2 years, PTCA was associated with significantly higher rates of the composite outcome of cardiac mortality or MI compared with medical treatment (RR 1.82, 95% CI 1.10 to 2.99; absolute numbers not reported), although the confidence intervals overlapped with those from longer-term trials in which the difference was not significant (RCTs with follow-up exceeding 2 years, cardiac mortality or MI; RR 0.99, 95% CI 0.68 to 1.46). The review found that, in the two RCTs that exclusively included people with a relatively recent MI (more than one week but less than three months), PTCA significantly reduced mortality (RR 0.40, 95% CI 0.17 to 0.95) and need for PTCA during follow-up (RR 0.42, 95% CI 0.20 to 0.91;

absolute numbers not reported) compared with medical treatment. The largest RCT (Pocock 2000) identified by the review (1018 people) found that, compared with medical treatment, PTCA improved physical functioning ($P < 0.001$), vitality ($P = 0.01$), and general health ($P = 0.008$) at 1 year (proportion of people rating their health "much improved": 33% with PTCA v 22% with medical treatment; $P = 0.008$), but found no significant difference at 3 years. The improvements were related to breathlessness, angina, and treadmill tolerance. High transfer (27%) to PTCA by people initially randomized to medical treatment may partly explain the lack of significant difference between groups at 3 years. The review found no significant difference between groups for death or MI (including procedure-related events) at 5 years (9% with PTCA v 8% with medical treatment; ARR +1.8%, 95% CI -1.7% to +5.2%).

The second review (Ioannidis 2007, search date 2007, 6 RCTs and 1 sub study, 2617 people that were stable and had an occluded coronary artery, 1–45 days from the onset of acute MI symptoms [mean 8 days], most RCTs with a mean ejection fraction between 44% and 53%, 1 RCT with a mean ejection fraction of 36%) compared PTCA versus medical treatment. Three RCTs had long-term follow up (mean: range 34–50 months), while the others were limited to 4 to 12 months. Three RCTs used stents in people receiving PTCA. The review found no significant difference between PTCA and medical treatment in mortality (99/1310 with PTCA v 106/1317 with medical management; RR 0.95, 95% CI 0.73 to 1.23; $P = 0.69$), non-fatal MI (70/1310 with PTCA v 55/1317 with medical management; RR 1.26, 95% CI 0.86 to 1.78; $P = 0.19$), death or MI (161/1310 with PTCA v 141/1317 with medical management; RR 0.99, 95% CI 0.57 to 1.70; $P = 0.96$), or heart failure (51/1310 with PTCA v 67/1317 with medical management; RR 0.67, 95% CI 0.36 to 1.22; $P = 0.19$). The review found no significant heterogeneity among RCTs for any of the summary effects ($P > 0.10$ for all outcomes).

The third review (Jeremias 2009, search date 1997–2008), which included RCTs of coronary revascularization versus medical treatment in people with non-acute coronary artery disease, included a total of 28 RCTs, of which 17 RCTs were confined to PTCA versus medical treatment with a further 2 RCTs randomizing to PTCA, CABG, and medical treatment. In total, 8052 people were included in the trials comparing percutaneous coronary intervention (PCI) versus medical therapy, and the RCTs ranged in follow-up from 1 to 10.2 years. The population in the RCTs included people with stable angina, exercise-induced ischemia, post-thrombolytic therapy for MI, asymptomatic single vessel coronary artery disease, and ischemia post MI, among others. Most RCTs compared balloon angioplasty without stenting versus medical treatment, although in 5 RCTs bare metal stents were implanted in 72% to 100% of cases. The review found that PTCA significantly reduced all-cause mortality compared with medical treatment (OR 0.82, 95% CI 0.68 to 0.99; results presented graphically; absolute numbers not reported).

The fourth review (Trikalinos 2009, search date 2008, people with symptomatic or asymptomatic non-acute coronary artery disease) first compared PTCA without stents versus medical management (7 RCTs, number of people [median] 201, follow-up [median] 60 months, age [mean] 56 years, percentage men [median] 85%, 0% with multivessel disease). The review found no significant difference between PTCA and medical treatment in mortality (7 RCTs, 1991 people; RR 0.82, 95% CI 0.59 to 1.15), non-fatal MI (7 RCTs, 1991 people; RR 1.09, 95% CI 0.59 to 1.99), CABG (5 RCTs, 1646 people; RR 1.10, 95% CI 0.81 to 1.49), and any revascularization (7 RCTs, 1991 people; RR 1.08, 95% CI 0.74 to 1.56; absolute numbers not

reported for any outcome). Significant heterogeneity among RCTs was found for the outcomes of non-fatal MI and any revascularization. The review also compared PTCA with bare metal stents versus medical management (4 RCTs, number of people [median] 1134, follow-up [median] 30 months, age [mean] 60 years, percentage men [median] 83%, 60% with multivessel disease). The review found no significant difference between PTCA with bare metal stents and medical treatment in mortality (3 RCTs, 4518 people; RR 0.96, 95% CI 0.79 to 1.18), non-fatal MI (4 RCTs, 4619 people; RR 1.18, 95% CI 0.97 to 1.43), CABG (2 RCTs, 2267 people; RR 0.97, 95% CI 0.63 to 1.50), and any revascularization (3 RCTs, 4518 people; RR 0.78, 95% CI 0.58 to 1.05; absolute numbers not reported for any outcome). Significant heterogeneity among RCTs was found for the outcome of any revascularization. No RCTs directly compared PTCA with drug-eluting stents versus optimal medical therapy.

The first subsequent report (Boden 2009, 2287 people with initially severe angina [CCS grade 4] stabilized medically and at least 70% stenosis in at least one proximal epicardial coronary artery, and either objective evidence of myocardial ischemia or at least one coronary stenosis of at least 80% and classic angina without provocative testing) reported prespecified tertiary outcomes of one RCT included in a systematic review. The initial report of the RCT (the COURAGE trial) had reported on primary and major secondary end points. This report assessed the impact of PCI when added to optimal medical therapy on major, cause-specific cardiovascular outcomes (i.e., prespecified tertiary end points) during long-term follow-up. PTCA was attempted in 1077 of the 1149 people randomized to PTCA and 94% received at least one stent, the majority being bare metal stents. The RCT found no significant difference between PTCA and medical treatment in cardiac death (39/1149 [3.4%] with PTCA v 44/1138 [3.9%] with medical treatment; HR 0.87, 95% CI 0.56 to 1.33; P = 0.51), the composite outcome of cardiac death and MI (172/1149 [15.0%] with PTCA v 162/1138 [14.2%] with medical treatment; HR 1.07, 95% CI 0.86 to 1.33; P = 0.62), the composite outcome of cardiac death, MI, and acute coronary syndrome (270/1149 [23.5%] with PTCA v 257/1138 [22.6%] with medical treatment; HR 1.07, 95% CI 0.91 to 1.27; P = 0.60), the composite outcome of cardiac death, MI, and stroke (188/1149 [16%] with PTCA v 173/1138 [15%] with medical treatment; HR 1.10, 95% CI 0.89 to 1.35; P = 0.45), and the composite outcome of cardiac death, MI, acute coronary syndrome, and stroke (313/1149 [27.2%] with PTCA v 305/1138 [26.8%] with medical treatment; HR 1.05, 95% CI 0.89 to 1.22; P = 0.51).

The second and third subsequent reports were follow-ups from RCTs included in three systematic reviews (Malek 2009, Mark 2009). Malek 2009 compared PTCA with stenting versus optimal medical therapy in people with total occlusion of the infarct-related artery (793 left anterior descending [LAD group], 1408 left circumflex or right coronary artery [non-LAD group]). On days 3 to 28 (minimum of 24 hours) after MI, people were randomized to PTCA and stenting with optimal medical therapy (1101 people) or to optimal medical therapy alone (1100 people). People with LAD infarct-related artery were significantly older than people with non-LAD infarct-related artery (mean: 59.5 years with LAD v 58.1 years with non-LAD; P = 0.005) and the proportion of men was significantly lower (591/793 [75%] with LAD v 1126/1408 [80%] with non-LAD; P = 0.003). The RCT found that the 5-year cumulative primary composite outcome of first occurrence of MI, admission to hospital for heart failure, or all-cause mortality occurred more frequently in people with LAD infarct-related artery compared with people with non-LAD infarct-

related artery (19.5% with LAD v 16.4% with non-LAD; HR 1.34, 99% CI 1.00 to 1.81; P = 0.01). The RCT found that in people with LAD infarct-related artery, PTCA did not significantly reduce the primary outcome compared with medical treatment (22.7% with PTCA v 16.4% with medical treatment; HR 1.35, 99% CI 0.86 to 2.31; P = 0.09). Similarly, it found that in people with non-LAD infarct-related artery, PTCA did not significantly reduce the primary outcome compared with medical treatment (16.9% with PTCA v 15.8% with medical treatment; HR 1.03, 99% CI 0.70 to 1.52; P = 0.83). It also reported that there was no significant difference between people with LAD infarct-related artery and people with non-LAD infarct related artery for the secondary outcomes of death or non-fatal re-infarction, fatal and non-fatal reinfarction, or admission to hospital for heart failure or stroke. It reported that there was no significant difference for PTCA versus medical treatment for these secondary outcomes in either people with LAD infarct-related artery or in people with non-LAD infarct-related artery.

Mark 2009 (a substudy of 951 of 2166 people in original trial enrolled in the quality-of-life assessment, 3–28 days post MI) compared PTCA versus medical treatment for the outcome of quality of life at 4, 12, and 24 months' follow-up. The RCT found that PTCA significantly improved quality of life as assessed on the Duke Activity Status Index at 4 months' follow up compared with medical treatment (P = 0.008), whereas there was no significant difference between groups at 12 months' (P = 0.36) or 24 months' follow-up (P = 0.29). It found that there was no significant difference for PTCA versus medical treatment in quality of life as assessed by the Mental Health Inventory 5 at any follow-up.

This information is summarized in Table 1.

Table 1. Percutaneous coronary interventions vs. optimal medical therapy

Review or Trial	Outcomes	Sub-group Information
Katrisis 2005 (SR – no DES)	<u>No difference in:</u> <ul style="list-style-type: none"> • Mortality • Non-fatal MI • Composite of cardiac death or MI • Need for CABG • Need for PTCA 	No difference with or without stents Mean F/U < 2 years: higher rates of composite in PTCA Recent (< 3 mos, > 1 week) MI: lower mortality, need for PTCA in PTCA F/U > 5 years: no diff in death or MI
Ioannidis 2007 (SR)	<u>No difference in:</u> <ul style="list-style-type: none"> • Mortality • Non-fatal MI • Composite of cardiac death or MI • Heart failure 	
Jeremias 2009 (SR – no DES)	PTCA reduced all-cause mortality	

Trikalinos 2009 (SR – no DES)	<u>No difference in:</u> <ul style="list-style-type: none"> • Mortality • Non-fatal MI • Any revascularization • CABG 	Same results comparing PTCA without stents and with bare metal stents
Boden 2009 (RCT – most stented, some DES)	<u>No difference in:</u> <ul style="list-style-type: none"> • Cardiac death • Composite of cardiac death or MI • Composite of cardiac death, MI or ACS • Composite of cardiac death, MI or stroke • Composite of cardiac death, MI, ACS or stroke 	
Malek 2009 (RCT – recent MI, most stented)	<u>No difference in:</u> <ul style="list-style-type: none"> • Composite (5 year F/U) of MI, admit to hospital for heart failure, or all-cause mortality • Death or non-fatal reinfarction • Any reinfarction • Admit to hospital for heart failure or stroke 	Same results comparing LAD and non-LAD infarct related arteries
Mark 2009 (RCT – recent MI, most stented)	PTCA improved quality of life at 4 months, but not 12 or 24 months	
TIME Investigators 2001 (RCT)	PTCA reduced all adverse cardiac events and angina severity No difference in deaths or non-fatal MI	Patients > 75
Dolor 2012 (SR)	PCI reduced composite of death, MI or repeat revascularization at 5 year F/U	Women

Subgroups

Age

One systematic review (Jeremias 2009) which included one RCT (TIME investigators 2001) was identified. The RCT (305 people aged >75 years, 44% female, with chronic refractory angina) compared PTCA versus medical treatment alone. It found that PTCA reduced all adverse cardiac events (death, non-fatal MI, hospital admissions for ACS) and decreased anginal severity compared with medical treatment, but had no significant effect on deaths or non-fatal MI after 6 months (adverse cardiac events, AR: 19% with PTCA v 49% with medical treatment; P <0.0001; change in angina class: -2.0 with PTCA v -1.6 with medical treatment; P <0.0001;

deaths, AR: 9% with PTCA v 4% with medical treatment; P = 0.15; non-fatal infarctions, AR: 8% with PTCA v 12% with medical treatment; P = 0.46).

Gender

One SR examined treatment of women with coronary disease (Dolor 2012). For women with stable angina, meta-analysis of three good quality studies (all women less than age 75) showed a reduction in the composite outcome of death/MI/repeat revascularization at 5 years for revascularization with PCI compared to optimal medical therapy (OR 0.64; CI, 0.47 to 0.89; p=0.008, moderate SOE). In one of these trials, patients had multivessel disease.

Evidence from additional sources

Because the initial search of trusted sources may not have identified the most recent and relevant information, staff undertook an additional MEDLINE search through February 2015, duplicating the strategy used in Dolor 2012 but without specifying women. This search identified three relevant reviews. Two of the three are of good quality, and found no benefit to PCI over medical therapy for management of stable angina, but their search dates ended in November 2011 and January 2012, respectively. The most recent review, of fair quality, found a benefit in overall mortality only with new generation drug eluting stents, as well as a reduction in revascularization and a nonsignificant reduction in subsequent MI. Findings are described in detail below.

Thomas and colleagues (2013) performed a systematic review and study-level meta-analysis of randomized controlled trials of patients with stable angina comparing PCI vs medical therapy for each of the following individual outcomes: all-cause mortality, cardiovascular (CV) mortality, myocardial infarction (MI), and angina relief. Staff rated this systematic review as good quality. Authors searched bibliographic databases through November 2011, and included ten prospective randomized controlled trials encompassing a total of 6,752 patients. This review did not detect differences between PCI vs medical therapy for all-cause mortality (663 events; relative risk [RR], 0.97 [confidence interval (CI), 0.84-1.12]; $I^2 = 0\%$), CV mortality (214 events; RR, 0.91 [CI, 0.70-1.17]; $I^2 = 0\%$), MI (472 events; RR, 1.09 [CI, 0.92-1.29]; $I^2 = 0\%$), or angina relief at the end of follow-up (2016 events; RR, 1.10 [CI, 0.97-1.26]; $I^2=85\%$). PCI was not associated with reductions in all-cause or CV mortality, MI, or angina relief. Considering the cost implication and the lack of clear clinical benefit, authors conclude that these findings continue to support existing clinical practice guidelines that medical therapy be considered the most appropriate initial clinical management for patients with stable angina.

A second systematic review and meta-analysis (Pursnani 2012) searched through January 2012 for randomized clinical trials comparing revascularization with PCI to optimal medical therapy (OMT) in patients with stable coronary artery disease. Staff also rated this a good quality review. The primary outcome was all-cause mortality, and secondary outcomes included cardiovascular death, nonfatal myocardial infarction, subsequent revascularization, and freedom from angina. Primary analyses were based on longest available follow-up with secondary analyses stratified by trial duration, with short-term (≤ 1 year), intermediate (1-5 years), and long-term (≥ 5 years) time points. Authors identified 12 randomized clinical trials enrolling 7,182 participants. For the primary analyses, when compared with OMT, PCI was associated with no significant improvement in mortality (risk ratio [RR], 0.85; 95% CI, 0.71-1.01), cardiac death (RR, 0.71;

95% CI, 0.47-1.06), nonfatal myocardial infarction (RR, 0.93; 95% CI, 0.70-1.24), or repeat revascularization (RR, 0.93; 95% CI, 0.76-1.14), with consistent results over all follow-up time points. Sensitivity analysis restricted to studies in which there was >50% stent use showed attenuation in the effect size for all-cause mortality (RR, 0.93; 95% CI, 0.78-1.11) with PCI. However, for freedom from angina, there was a significant improved outcome with PCI, as compared with the OMT group (RR, 1.20; 95% CI, 1.06-1.37), evident at all of the follow-up time points.

A network meta-analysis by Windecker and colleagues (2014) was the most recent and comprehensive review, although it was rated of fair quality by staff due to indirectness of evidence. Randomized controlled trials from 1980 through June 2013 were included if they had a clinical follow-up duration of at least six months and had randomized at least 100 patients per trial arm. Patients had to be randomized to medical treatment, coronary artery bypass grafting, or percutaneous coronary intervention using balloon angioplasty, bare metal stents, early generation stent systems (paclitaxel eluting Taxus stent [Boston Scientific, Natick, MA], sirolimus eluting Cypher stent [Cordis, Miami Lakes, FL], zotarolimus eluting Endeavor stent [Medtronic Cardiovascular, Santa Rosa, CA]) or new generation stent systems (zotarolimus eluting Resolute stent [Medtronic Cardiovascular, Santa Rosa, CA] and everolimus eluting Xience/Promus stent [Abbott Vascular, Santa Clara, CA and Boston Scientific, Natick, MA]) approved by the FDA. The review excluded trials in patients with acute myocardial infarction (ST segment elevation myocardial infarction or non-ST segment elevation myocardial infarction) and symptom onset less than 72 hours, trial arms with polymer or carbon coated bare metal stents, and trial arms with non-FDA approved drug eluting stents. Authors considered studies in general to be of high quality. Ninety five trials including 93,553 randomized patients and 5,346 accumulated events contributed to the analysis of all cause mortality for all interventions including CABG.

Percutaneous coronary intervention with the new generation everolimus eluting stent, but no other percutaneous coronary intervention technology, was associated with reduced mortality compared with medical treatment (0.75, 0.59 to 0.96 17 trials, N = 13,272). There was also a trend toward reduced mortality with the new generation zotarolimus eluting (Resolute) stent (0.65, 0.42 to 1.00 four trials, N = 2,285). The estimated rate ratios for mortality were below 1, but inconclusive for revascularization with balloon angioplasty (0.85, 0.68 to 1.04, 29 trials, N = 7,609), bare metal stents (0.92, 0.79 to 1.05, 50 trials, N = 16,042), and early generation drug eluting stents (paclitaxel eluting: 0.92, 0.75 to 1.12, 27 trials, N = 11,541; sirolimus eluting: 0.91, 0.75 to 1.10, 39 trials, N = 19,781; zotarolimus eluting [Endeavor]: 0.88, 0.69 to 1.10, 8 trials, N = 8,937).

In the analysis of myocardial infarction, 5,796 events were reported during 243,031 patient years. All percutaneous coronary interventions, except bare metal stent (1.04, 0.84 to 1.27) and paclitaxel eluting stent (1.18, 0.88 to 1.54), showed evidence for a relevant but inconclusive reduction of myocardial infarction, with point estimates below 1 for balloon angioplasty (0.88, 0.70 to 1.11), sirolimus eluting stent (0.94, 0.71 to 1.22), zotarolimus eluting (Endeavor) stent (0.80, 0.56 to 1.10), zotarolimus eluting (Resolute) stent (0.82, 0.52 to 1.26), and everolimus eluting stent (0.75, 0.55 to 1.01).

Revascularization using coronary stents was associated with a reduction in subsequent revascularization for bare metal stent (0.44, 0.59 to 0.82), paclitaxel eluting stent (0.44, 0.35 to 0.55), sirolimus eluting stent (0.29, 0.24 to 0.36), zotarolimus eluting (Endeavor) stent (0.38, 0.29 to 0.51), zotarolimus eluting (Resolute) stent (0.26, 0.17 to 0.40), and everolimus eluting stent (0.27, 0.21 to 0.35). Revascularization with balloon angioplasty showed similar risks of subsequent revascularization compared with medical treatment (0.97, 0.82 to 1.16).

In summary, this network meta-analysis (Windecker 2014) found that percutaneous coronary intervention with the new generation everolimus eluting stents reduced mortality compared to medical management. The new generation zotarolimus eluting (Resolute) stent had only four trials contributing data, but also showed a trend toward reduced mortality. No other percutaneous coronary intervention technology was associated with reduced mortality when compared with medical management. All percutaneous coronary interventions, except bare metal stent and paclitaxel eluting stent, showed evidence for a relevant but inconclusive reduction of myocardial infarction. Revascularization using coronary stents was associated with a reduction in subsequent revascularization by 56-74%.

Summary

In summary, based on multiple trusted source and good quality systematic reviews, there is no clear advantage of an initial routine strategy of PTCA with or without stenting compared with medical treatment to reduce mortality and MI in patients with stable coronary disease and no recent MI. The exception, based on one recent fair quality meta-analysis, is a finding of reduced mortality with the new generation everolimus drug-eluting stent. There may be short-term improvement based on two RCTs in quality of life, and for women and older individuals, one systematic review suggests PCI may result in a reduction in angina symptoms and adverse cardiac events. Finally, one meta-analysis found that a strategy of PCI reduced need for subsequent revascularization by 56-74% over medical management.

Coronary artery bypass graft vs. optimal medical therapy

Two systematic reviews comparing CABG versus medical treatment were identified. In the first systematic review (Yusuf 1994, search date not reported, 7 RCTs, 2649 people with CHD, mostly male, aged 41–60 years, 80% with ejection fraction >50%, 60% with prior MI; and 83% with 2–3 vessel disease), people assigned to CABG also received medical treatment, and 37% initially assigned to medical treatment underwent CABG in the following 10 years. It found that, compared with medical treatment, CABG significantly reduced mortality at 5 and 10 years (5 years: RR 0.61, 95% CI 0.48 to 0.77; 10 years: RR 0.83, 95% CI 0.70 to 0.98). Most trials did not collect data on quality of life; neither did they report detailed information about long-term medication use. However, at one year, 66% of the medical treatment group and 20% of the CABG group were treated with beta-blockers, and 19% of the medical treatment group and 26% of the CABG group were treated with antiplatelet agents. The review found that, of the 1240 people who had CABG, 40 (3%) died and 88 (7%) had non-fatal MI within 30 days of the procedure. At 1 year, rates of the combined outcome of mortality or MI were significantly higher with CABG compared with medical treatment (12% with CABG v 8% with medical treatment; RR 1.45, 95% CI 1.18 to 2.03).

The second systematic review (Jeremias 2009, search date 1977–2008) included RCTs of coronary revascularization (CABG/PCI/mixed) versus medical treatment in people with non-acute coronary artery disease. It included 28 RCTs in total, of which 6 RCTs evaluated CABG (largely with saphenous vein grafts) versus medical treatment (all of which were included in the first review) and it included a further two RCTs evaluating PCI or CABG (the majority with internal thoracic artery graft). The 8 RCTs comparing CABG versus medical treatment included 3098 people, who were mostly male, and follow-up in the RCTs was from 1 to 5 years. The 8 RCTs included people with stable angina, disabling angina, mild stable angina, or free of angina post MI, and no symptoms; the year of publication of the RCTs varied from 1977 to 2004. The review found that CABG significantly reduced all-cause mortality compared with medical treatment (8 RCTs; OR 0.62, 95% CI 0.50 to 0.77; results presented graphically; absolute numbers not reported).

No harms were reported in either SR.

The efficacy of revascularization versus medical treatment has been evaluated in people with stable ischemia in one additional RCT (Davies 1997). The RCT (558 people with ischemia identified by exercise test or ambulatory ECG, who were either asymptomatic or whose angina was able to be controlled with medications) compared three interventions: revascularization (90 selected for CABG, 11 later refused and 1 had the procedure outside the specified time window; 102 selected for PTCA, 8 later refused and 2 had the procedure outside the time window), angina-guided medical treatment, and ischemia-guided medical treatment. In the angina-guided treatment group, drug treatment was sufficient to control angina. In the ischemia-guided group, additional drug therapy was added if ischemia was still present on ambulatory ECG recording. At 2 years, the rate of mortality or MI was lower with revascularization (angina-guided treatment: 12%; ischemia-guided treatment: 9%; revascularization: 5%). The difference between angina-guided treatment and revascularization was significant ($P < 0.01$), but the differences between ischemia-guided treatment and revascularization ($P = 0.12$) and angina-guided treatment and ischemia-guided treatment ($P = 0.3$) were not significant. There was a tendency for the benefit of revascularization to be concentrated in those with proximal LAD artery disease, and in those with three-vessel disease compared with one- or two-vessel disease.

Subgroups

Reduced left ventricular function

The Yusuf 1994 systematic review described above found that the relative benefits of CABG were similar in people with normal compared with reduced left ventricular function (death: OR 0.61, 95% CI 0.46 to 0.81, with normal left ventricular function; OR 0.59, 95% CI 0.39 to 0.91, with reduced left ventricular function). The absolute benefit of CABG was greater in people with a reduced left ventricular function because the baseline risk of death was higher.

Multiple vessel disease

Yusuf 1994 found that CABG reduced mortality compared with medical treatment in people with single-vessel, two-vessel, three-vessel, and left main stem disease. Change in mortality was not significant for people with single-vessel and two-vessel disease; however, this may have been because the number of deaths was small. The risk of mortality was 0.54 (95% CI 0.22 to 1.33) with single-vessel disease, 0.84 (95% CI 0.54 to 1.32) with two-vessel disease, 0.58 (95% CI

0.42 to 0.80) with three-vessel disease, and 0.32 (95% CI 0.15 to 0.70) with left main stem disease.

Gender

One SR examined treatment of women with coronary disease (Dolor 2012). For women with stable angina, meta-analysis of two good quality studies showed a reduction in the composite outcome of death/ MI/ repeat revascularization at 5 years for revascularization with CABG compared to OMT (OR 0.56; CI, 0.32 to 0.96; p=0.04; low SOE). However, patients in these two trials either had multivessel disease or left ventricular dysfunction.

Evidence from additional sources

Similar to the process used for PCI v OMT, because the initial search of trusted sources may not have identified the most recent and relevant information, staff undertook an additional MEDLINE search through February 2015, duplicating the strategy used in Dolor 2012 but without specifying women. This search identified one relevant network meta-analysis of CABG versus medical management (Windecker 2014), the details of which are described above. In patients with stable symptomatic or asymptomatic coronary artery disease, compared with a strategy of initial medical treatment, revascularization using coronary artery bypass grafting reduced all cause mortality by 20% (rate ratio 0.80, 95% confidence interval 0.70 to 0.91, 22 trials, N = 8,920). Revascularization using coronary artery bypass grafting compared with medical treatment reduced myocardial infarction during the observational period by 21% (0.79, 0.63 to 0.99). Compared with medical treatment, revascularization with coronary artery bypass grafting was effective in reducing subsequent revascularization by 84% (0.16, 0.13 to 0.20).

Summary

In summary, CABG plus medical treatment may be more effective than medical treatment alone at reducing mortality in the long run in people (mostly male) aged 41 to 60 years, most with previous MI and two to three-vessel disease and also in people with non-acute coronary artery disease (low quality evidence). However, it may increase the estimated incidence of the composite outcome of death or MI at 1 year. Further analysis in people (mostly male) aged 41 to 60 years, most with previous MI and two- to three-vessel disease, found that CABG may reduce mortality compared with medical treatment both in people with normal left ventricular function or with reduced left ventricular function, and may reduce mortality in people with three-vessel and left main stem disease, although the effect of CABG in those with single- or two-vessel disease are unclear, as the number of deaths in these groups was small (low-quality evidence).

A recent fair quality network meta-analysis of patients with symptomatic or asymptomatic stable CAD found a significant reduction in mortality, MI, and need for subsequent revascularization with CABG as compared to medical management.

Limitations of the evidence on coronary artery bypass grafting compared to optimal medical therapy

The results of the systematic reviews may not be easily generalized to current practice. People were generally aged 65 years or younger, but >50% of CABG procedures are now performed on people >65 years of age. In addition, almost all were male, and high-risk people (such as those with severe angina and left main coronary artery stenosis) were under represented. Internal thoracic artery grafts were largely confined to two more recent trials. In the first systematic review lipid lowering agents (particularly statins) and aspirin were used infrequently (aspirin used in 3% of people at enrollment, about 22% at 1 year). Only about 50% of people were taking beta-blockers at baseline. The first systematic review (Yusuf 1994) evaluated the efficacy of an initial strategy of CABG compared with medical treatment, although there was considerable crossover to surgery in those assigned to medical treatment; in the three larger trials, 25% by 5 years, 33% by 7 years, and 41% by 10 years. However, some general observations can be made, and those with more-extensive CHD and impaired left ventricular function are likely to derive the greatest absolute benefit with improved survival from CABG. One RCT (Hueb 2007) included in the second systematic review (Jeremias 2001) in those with preserved left ventricular function and multivessel disease more accurately reflects contemporary clinical practice with the use of more arterial conduits, although the mean age of participants was still only 60 years. The RCT was not powered to detect differences in survival, but CABG reduced the need for additional revascularization procedures and improved angina-free survival at 5 years. People with prior CABG have not been studied in RCTs, although they now represent a growing proportion of those undergoing CABG.

EVIDENCE SUMMARY

Evidence suggests that, compared to optimal medical therapy, PCI does not result in improvement in mortality or most other cardiac outcomes (non-fatal MI, need for revascularization, heart failure, composite outcomes), based on low quality evidence (multiple conflicting SRs). However, most studies utilized only PTCA or bare metal stents, and only a few trials included drug eluting stents. A network meta-analysis incorporating new generation drug-eluting stents found evidence that the everolimus eluting stent, but not other modalities, reduces mortality compared to medical treatment (low quality evidence, based on one fair quality metanalysis). Some subgroups appear to have differential outcomes; PCI may result in short-term benefit in mortality in patients with a recent MI (very low quality evidence, based on three conflicting RCTs), as well as in women (moderate quality evidence, based on one SR). In addition, PCI may improve physical functioning and quality of life in the short-term compared to OMT (very low quality evidence, based on one RCT), and for patients over age 75, may reduce anginal severity (very low quality evidence, based on one RCT).

On the contrary, CABG does appear to result in improved mortality compared to OMT, at least at five years follow up, although short-term risks are higher (low quality evidence). This benefit is present regardless of left ventricular function or gender, but may be limited to patients with three-vessel or left main stem disease.

There are a number of limitations to the evidence base, including the fact that most trials were limited to patients age 65 or younger, few trials included DE stents and OMT in many trials was suboptimal compared to current standards. In addition, for CABG trials, most did not utilize internal thoracic artery grafts. Lastly, there was considerable cross-over to surgery in those assigned to OMT (up to 41% by 10 years).

GRADE-INFORMED FRAMEWORK

The HERC develops recommendations by using the concepts of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are 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. Balance between desirable and undesirable effects, and quality of evidence, are derived from the evidence presented in this document, while estimated relative costs, values and preferences are assessments of the HERC members.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
PCI vs. OMT (patients with non-acute coronary heart disease)	No difference in mortality (except with 1 out of 2 new generation drug-eluting stents), MI, MACE. PCI caused reduction in subsequent revascularization by 56-74%	Low based on multiple conflicting SRs*	Moderate	LOW most patients would not want a semi-invasive intervention without some assurance of proven significant benefit	Recommended for coverage in patients with stable angina whose symptoms are not controlled with optimal medical therapy ¹ or who cannot tolerate such therapy (<i>weak recommendation</i>)	While the evidence is weak, it would be appropriate to cover PCI for symptomatic relief if optimal medical therapy has been tried and is ineffective at controlling symptoms, and coronary anatomy is appropriate. PCI cannot be recommended for coverage for improvement in MACE or mortality given the lack of consistent evidence of benefit for these critical outcomes.
	Possible short-term improvement in physical functioning, QOL, angina	Low based on 2 RCTs [#]				

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
CABG vs. OMT	Short-term worse mortality, long-term benefit in mortality (benefit possibly limited to three vessel or left main stem disease) 21% reduction in MI and 84% reduction in subsequent revascularization compared with OMT in patients with stable disease	Low based on multiple SRs*	High	MODERATE Long term benefit is appealing but this is a major cardiac surgery and increased short-term mortality is concerning	Recommended for coverage in those with three vessel or left main stem disease (<i>strong recommendation</i>) Recommended for coverage in patients with stable angina whose symptoms are not controlled with optimal medical therapy ¹ or who cannot tolerate such therapy (<i>weak recommendation</i>)	There is low quality evidence but with significant improvements in long-term mortality. CABG is recommended for coverage for those who have failed optimal medical therapy and for those with stable CHD but with appropriate anatomy, regardless of failure of OMT.

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

Note: GRADE framework elements are described in Appendix A

POLICY LANDSCAPE

Quality measures

Nine potentially relevant quality measures were identified when searching the [National Quality Measures Clearinghouse](#). Six were measures developed by the Agency for Healthcare Research and Quality, and three were developed by the Canadian Institute for Health Information. Seven of the measures quantified utilization of either PCI or CABG (area rate, volume), while there was one measure for each PCI and CABG documenting the mortality rate associated with the procedure.

Professional society guidelines

The 2012 ACC/AHA/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients With Stable Ischemic Heart Disease addresses diagnosis, risk assessment, treatment and follow up of patients with known or suspected SIHD. While the guideline developers have been meticulous in maintaining and documenting editorial independence, the guideline overall receives a poor rating, primarily because study selection criteria are not specified, and no assessment of study quality is taken into account when developing recommendations.

Treatment is the section of the guideline that pertains to this coverage guidance document. Selected background and recommendations that are pertinent to stable disease from this section are presented below.

Factors That Should Not Influence Treatment Decisions

The 2 medical indications for revascularization are to prevent death and cardiovascular complications and to improve symptoms and quality of life. Nonetheless, the use of revascularization has risen dramatically in the past 3 decades. Much of this increase appears to be for indications for which benefits in survival or symptoms in comparison with noninvasive therapies are unlikely. National data suggest that about 12% of PCIs could be inappropriate because they lack evident potential to improve either survival or symptoms. Several reasons influence patients and physicians to prefer revascularization when the likelihood of benefit is less than the potential risk of the procedure. An ingrained preference for action (i.e., revascularization) over perceived inaction (i.e., medical therapy alone) likely often influences the decision making of both patients and physicians. Moreover, some healthcare professionals are unduly pessimistic about survival with conservative medical therapy and inaccurately optimistic about the survival benefits of revascularization procedures. As indicated earlier, patients often believe mistakenly that PCI has the potential to prevent AMI and prolong survival. In addition, the attendant expense and risk of combined antiplatelet therapy for an uncertain period of time might not be fully considered. Physicians are professionally obligated to provide accurate estimates of the risks, benefits, and costs of various therapeutic options that are based on the best available scientific data. Other factors can induce physicians to recommend revascularization. These include medicolegal concerns (often exaggerated) and feeling compelled to satisfy the expectations of patients and referring physicians (which are sometimes misinformed or unrealistic). Additionally, there are well-

documented regional variations in the use and appropriateness of cardiac procedures that appear to reflect local practice styles. This might partly reflect a mistaken belief by some physicians that “more care is better care”.

Although successful procedures can be psychologically satisfying to the physician and the patient, this does not justify the attendant economic costs and risk of complications of procedures that offer minimal, if any, genuine benefit. Although rarely discussed explicitly, financial incentives seem to affect the willingness of a minority of physicians and institutions to recommend certain procedures or drug therapies. Strong incentives created by the payment system encourage overutilization. Also, a small number of physicians might have financial relationships with the manufacturers of devices or drugs that might represent apparent conflicts that ought to be disclosed to patients. At a higher level, those responsible for the payment system, the manufacturers of devices and drugs, and physicians making clinical decisions must commit to supporting guideline based interventions. Any and all conflicts of interest must be revealed to patients in the process of informed consent before any invasive or noninvasive procedure.

Revascularization to Improve Survival: Recommendations

Left Main CAD Revascularization

CLASS I Recommendations

1. CABG to improve survival is recommended for patients with significant ($\geq 50\%$ diameter stenosis) left main coronary artery stenosis. (Level of Evidence: B)

CLASS IIa Recommendations

1. PCI to improve survival is reasonable as an alternative to CABG in selected stable patients with significant ($\geq 50\%$ diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (e.g., a low SYNTAX score [≤ 22], ostial or trunk left main CAD); and 2) clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (e.g., STS-predicted risk of operative mortality $\geq 5\%$). (Level of Evidence: B)

CLASS IIb Recommendations

1. PCI to improve survival may be reasonable as an alternative to CABG in selected stable patients with significant ($\geq 50\%$ diameter stenosis) unprotected left main CAD with: a) anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (e.g., low–intermediate SYNTAX score of < 33 , bifurcation left main CAD); and b) clinical characteristics that predict an increased risk of adverse surgical outcomes (e.g., moderate–severe chronic obstructive pulmonary disease, disability from previous stroke, or previous cardiac surgery; STS-predicted risk of operative mortality $> 2\%$). (Level of Evidence: B)

CLASS III Recommendations: Harm

1. PCI to improve survival should not be performed in stable patients with significant ($\geq 50\%$ diameter stenosis) unprotected left main CAD who have unfavorable anatomy for PCI and who are good candidates for CABG. (Level of Evidence: B)

Non-Left Main CAD Revascularization

CLASS I Recommendations

1. CABG to improve survival is beneficial in patients with significant ($\geq 70\%$ diameter) stenoses in 3 major coronary arteries (with or without involvement of the proximal LAD artery) or in the proximal LAD artery plus 1 other major coronary artery. (Level of Evidence: B)

2. CABG or PCI to improve survival is beneficial in survivors of sudden cardiac death with presumed ischemia-mediated ventricular tachycardia caused by significant ($\geq 70\%$ diameter) stenosis in a major coronary artery. (CABG Level of Evidence: B ; PCI Level of Evidence: C)

CLASS IIa Recommendations

1. CABG to improve survival is reasonable in patients with significant ($\geq 70\%$ diameter) stenoses in 2 major coronary arteries with severe or extensive myocardial ischemia (e.g., high-risk criteria on stress testing, abnormal intracoronary hemodynamic evaluation, or $>20\%$ perfusion defect by myocardial perfusion stress imaging) or target vessels supplying a large area of viable myocardium. (Level of Evidence: B)

2. CABG to improve survival is reasonable in patients with mild–moderate LV systolic dysfunction (EF 35% to 50%) and significant ($\geq 70\%$ diameter stenosis) multi-vessel CAD or proximal LAD coronary artery stenosis, when viable myocardium is present in the region of intended revascularization. (Level of Evidence: B)

3. CABG with a left internal mammary artery (LIMA) graft to improve survival is reasonable in patients with significant ($\geq 70\%$ diameter) stenosis in the proximal LAD artery and evidence of extensive ischemia. (Level of Evidence: B)

4. It is reasonable to choose CABG over PCI to improve survival in patients with complex 3-vessel CAD (e.g., SYNTAX score >22), with or without involvement of the proximal LAD artery who are good candidates for CABG. (Level of Evidence: B)

5. CABG is probably recommended in preference to PCI to improve survival in patients with multivessel CAD and diabetes mellitus, particularly if a LIMA graft can be anastomosed to the LAD artery. (Level of Evidence: B)

CLASS IIb Recommendations

1. The usefulness of CABG to improve survival is uncertain in patients with significant (70%) diameter stenoses in 2 major coronary arteries not involving the proximal LAD artery and without extensive ischemia. (Level of Evidence: C)
2. The usefulness of PCI to improve survival is uncertain in patients with 2- or 3-vessel CAD (with or without involvement of the proximal LAD artery) or 1-vessel proximal LAD disease. (Level of Evidence: B)
3. CABG might be considered with the primary or sole intent of improving survival in patients with SIHD with severe LV systolic dysfunction (EF<35%) whether or not viable myocardium is present. (Level of Evidence: B)
4. The usefulness of CABG or PCI to improve survival is uncertain in patients with previous CABG and extensive anterior wall ischemia on noninvasive testing. (Level of Evidence: B)

CLASS III Recommendations: Harm

1. CABG or PCI should not be performed with the primary or sole intent to improve survival in patients with SIHD with 1 or more coronary stenoses that are not anatomically or functionally significant (e.g., <70% diameter non-left main coronary artery stenosis, FFR >0.80, no or only mild ischemia on noninvasive testing), involve only the left circumflex or right coronary artery, or subtend only a small area of viable myocardium. (Level of Evidence: B)

Revascularization to Improve Symptoms: Recommendations

CLASS I Recommendations

1. CABG or PCI to improve symptoms is beneficial in patients with 1 or more significant ($\geq 70\%$ diameter) coronary artery stenoses amenable to revascularization and unacceptable angina despite guideline directed medical therapy (GDMT). (Level of Evidence: A)

CLASS IIa Recommendations

1. CABG or PCI to improve symptoms is reasonable in patients with 1 or more significant ($\geq 70\%$ diameter) coronary artery stenoses and unacceptable angina for whom GDMT cannot be implemented because of medication contraindications, adverse effects, or patient preferences. (Level of Evidence: C)
2. PCI to improve symptoms is reasonable in patients with previous CABG, 1 or more significant ($\geq 70\%$ diameter) coronary artery stenoses associated with ischemia, and unacceptable angina despite GDMT. (Level of Evidence: C)
3. It is reasonable to choose CABG over PCI to improve symptoms in patients with complex 3-vessel CAD (e.g., SYNTAX score >22), with or without involvement of the proximal LAD artery, who are good candidates for CABG. (Level of Evidence: B)

CLASS IIb Recommendations

1. CABG to improve symptoms might be reasonable for patients with previous CABG, 1 or more significant ($\geq 70\%$ diameter) coronary artery stenoses not amenable to PCI, and unacceptable angina despite GDMT. (Level of Evidence: C)
2. Transmyocardial revascularization (TMR) performed as an adjunct to CABG to improve symptoms may be reasonable in patients with viable ischemic myocardium that is perfused by arteries that are not amenable to grafting. (Level of Evidence: B)

CLASS III Recommendations: Harm

1. CABG or PCI to improve symptoms should not be performed in patients who do not meet anatomic ($\geq 50\%$ diameter left main or $\geq 70\%$ non-left main stenosis diameter) or physiological (e.g., abnormal FFR) criteria for revascularization. (Level of Evidence: C)

The 2014 ACC/AHA/AATS/PCNA/SCAI/STS Focused Update of the Guideline for the Diagnosis and Management of Patients With Stable Ischemic Heart Disease updates the 2012 guideline described above. The areas addressed, where new evidence was found or recommendations were revised, were the following:

- Diagnosis of SIHD
- Treatment: Chelation therapy
- Treatment: Enhanced external counterpulsation
- CAD Revascularization: Revascularization to improve survival

Only the last area pertains to this guidance document, and will be discussed further. The 2012 recommendation was as follows:

Class IIa

CABG is probably recommended in preference to PCI to improve survival in patients with multivessel CAD and diabetes mellitus, particularly if a LIMA graft can be anastomosed to the left anterior descending (LAD) artery. (Level of Evidence: B)

The 2014 focused update makes the following new recommendation:

Class I

1. A Heart Team approach to revascularization is recommended in patients with diabetes mellitus and complex multivessel CAD. (Level of Evidence: C)
2. CABG is generally recommended in preference to PCI to improve survival in patients with diabetes mellitus and multivessel CAD for which revascularization is likely to improve survival (3-vessel CAD or complex 2-vessel CAD involving the proximal LAD), particularly if a LIMA graft can be anastomosed to the LAD artery, provided the patient is a good candidate for surgery. (Level of Evidence: B)

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.

APPENDIX A. GRADE ELEMENT DESCRIPTIONS

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
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, considering the quality of evidence, cost and resource allocation, and values and preferences.

Against: The subcommittee is confident that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

Quality or strength of evidence rating across studies for the treatment/outcome¹

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

Moderate: The subcommittee is moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical sets of studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

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

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

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

APPENDIX B. APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
413.0	Angina decubitus
413.1	Prinzmetal angina
413.9	Other and unspecified angina pectoris
414.0	Coronary atherosclerosis
414.2	Chronic total occlusion of coronary artery
414.8-9	Other specified and unspecified forms of chronic ischemic heart disease
ICD-10 Diagnosis Codes	
I20.1	Angina pectoris with documented spasm
I20.8	Other forms of angina pectoris
I20.9	Angina pectoris, unspecified
I20.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
I25.82	Chronic total occlusion of coronary artery
I25.89	Other forms of chronic ischemic heart disease
I25.9	Chronic ischemic heart disease, unspecified
ICD-9 Volume 3 (Procedure Codes)	
36.0	Removal of coronary obstruction and insertion of stent(s)
36.1	Bypass anastomosis for heart revascularization
CPT Codes	
33510-33516	Coronary artery bypass – venous grafting only
33517-33530	Combined arterial-venous grafting for coronary bypass
33533-33548	Arterial grafting for coronary artery bypass
92920-92944	Percutaneous revascularization procedures
HCPCS Level II Codes	
	None

Note: Inclusion on this list does not guarantee coverage

APPENDIX C. HERC GUIDANCE DEVELOPMENT FRAMEWORK

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 judgment. 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;
- Expected values and preferences of patients.

PCI for chronic stable angina vs. OMT – Based on mortality, MI



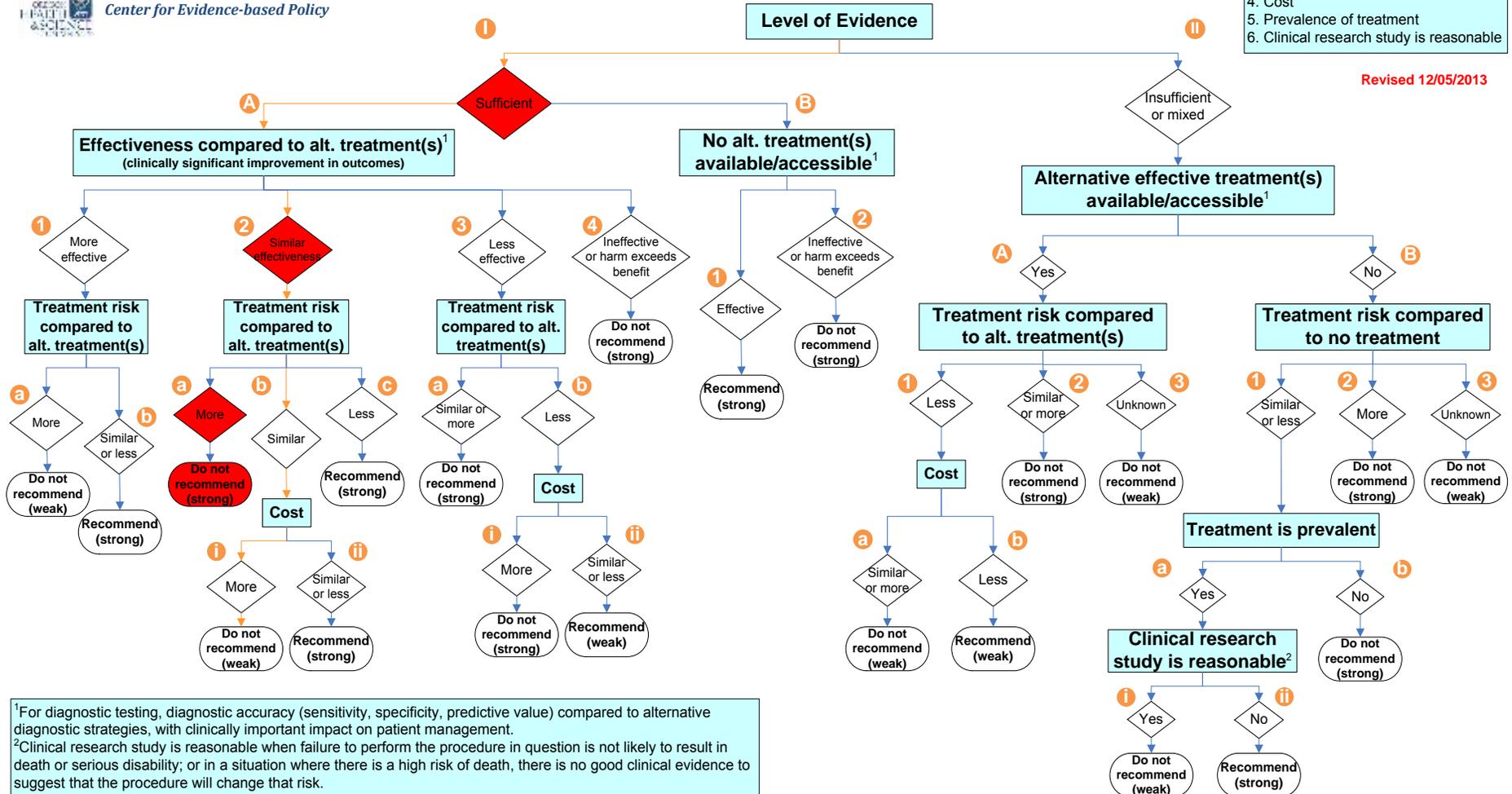
Oregon Health & Science Center for Evidence-based Policy

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

Revised 12/05/2013



PCI for chronic stable angina vs. OMT based on quality of life



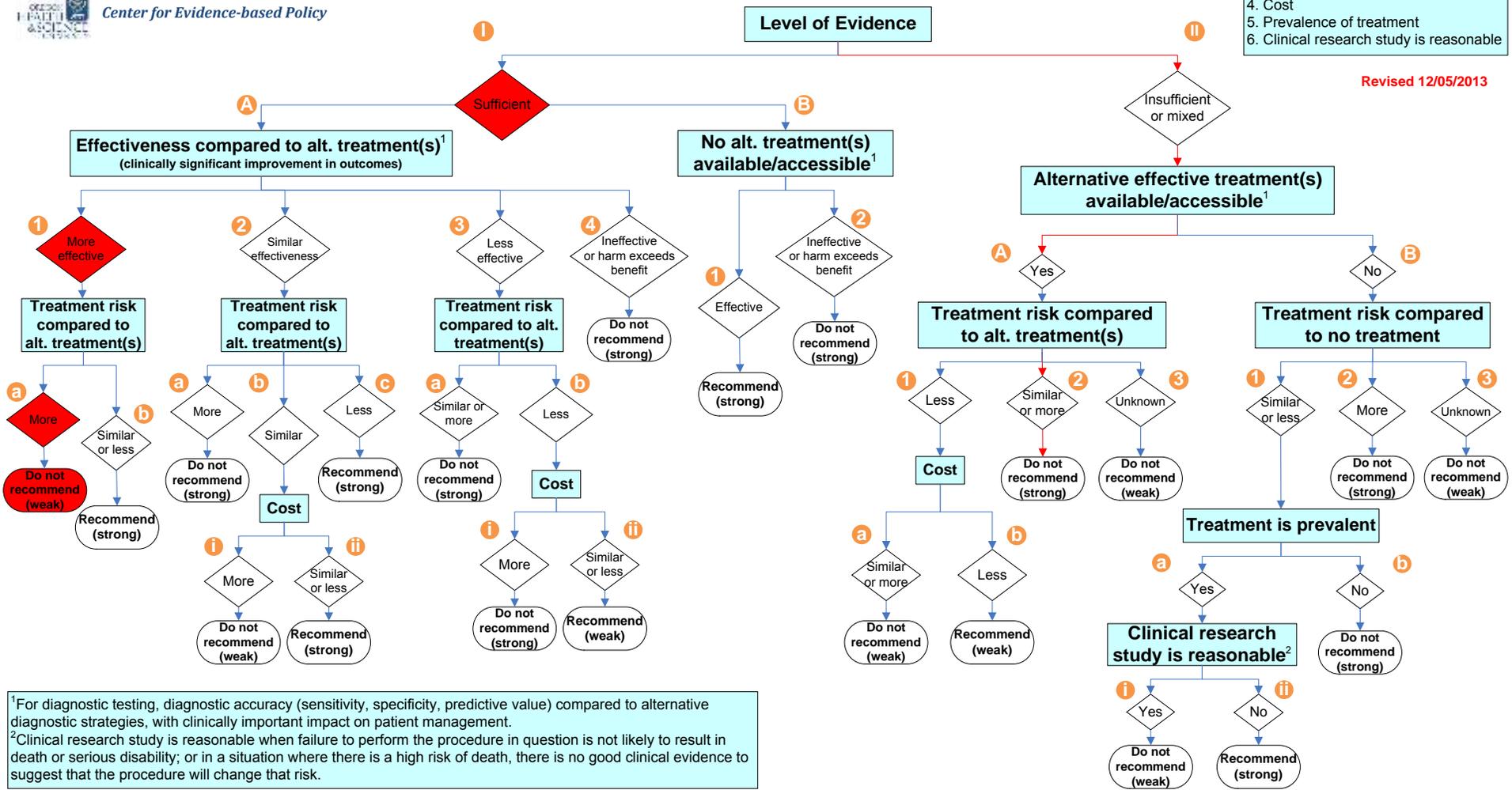
Center for Evidence-based Policy

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

Revised 12/05/2013



¹For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
²Clinical 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.

CABG for chronic stable angina vs. OMT in 3-vessel and left main disease, based on mortality, MI, MACE



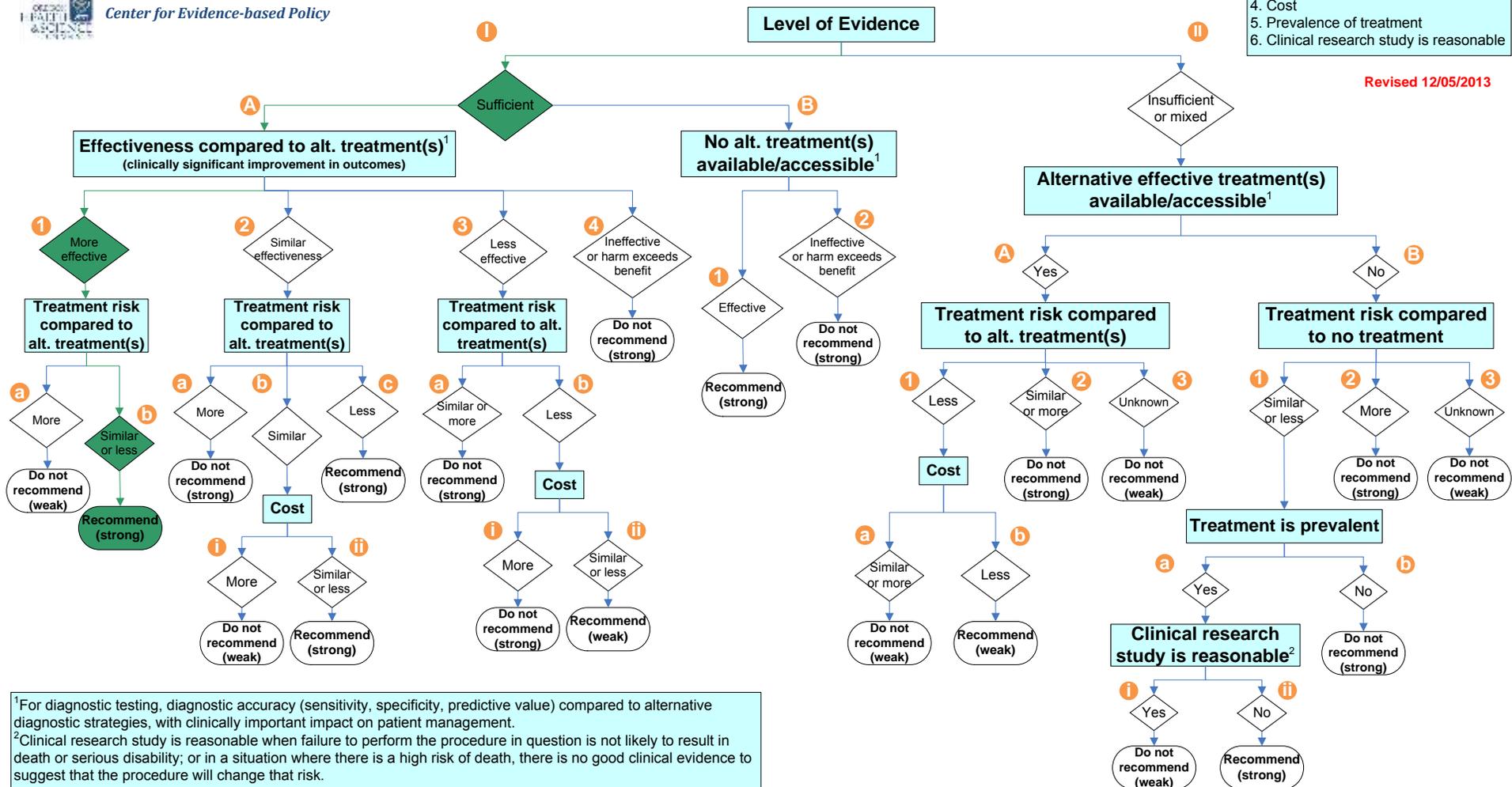
Center for Evidence-based Policy

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

Revised 12/05/2013



CABG for chronic stable angina vs. OMT in 1- or 2-vessel, not left main, based on mortality, MI, MACE



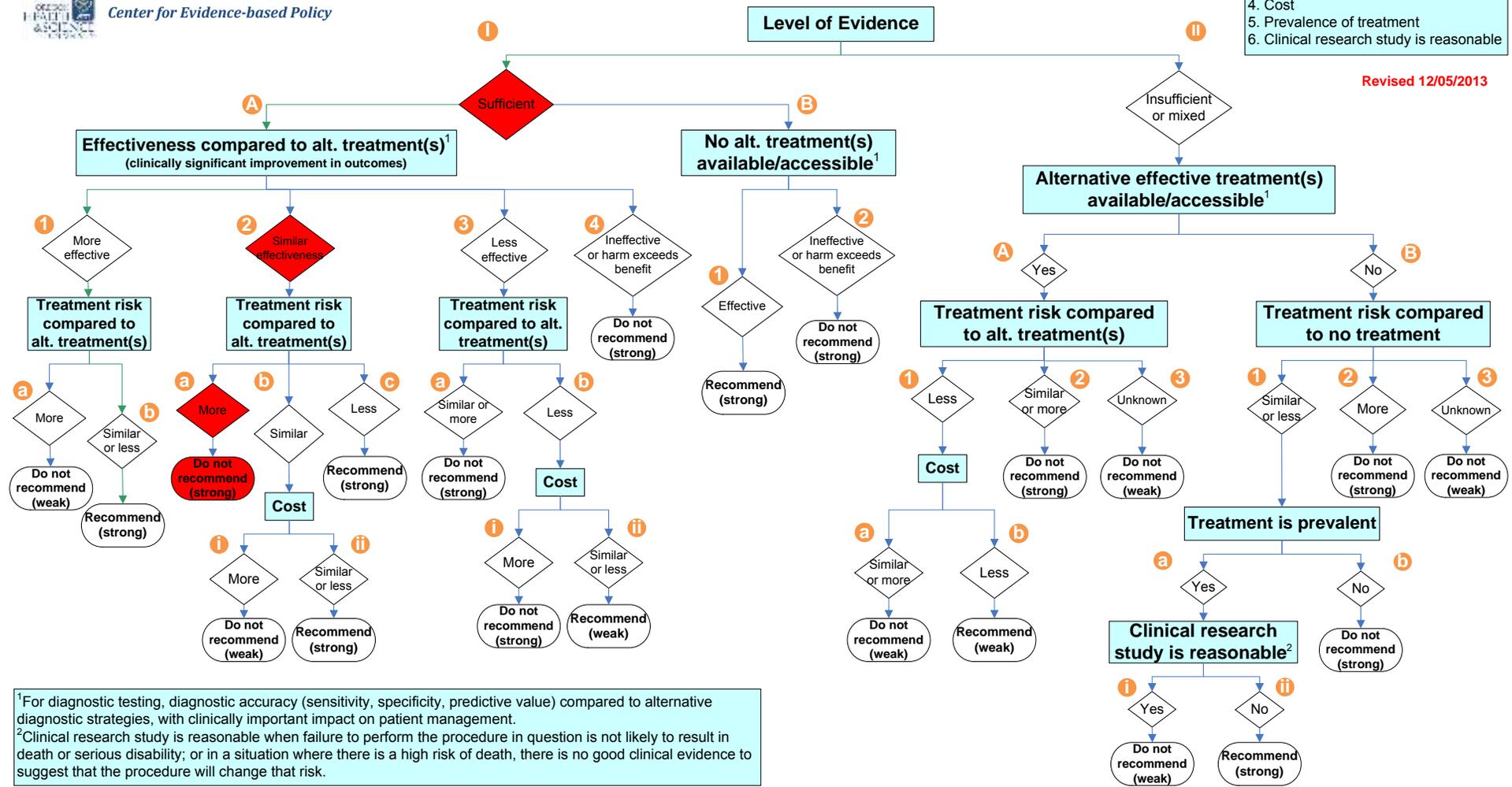
Center for Evidence-based Policy

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

Revised 12/05/2013



¹For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
²Clinical 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.

Coronary Artery Revascularization for Stable Angina – Prioritized List Changes

Current Prioritized List status

ICD-9 Code	Code Description	Current Line(s) / Lists
413.x	Angina	193 CHRONIC ISCHEMIC HEART DISEASE
414.0x	Coronary atherosclerosis	193 CHRONIC ISCHEMIC HEART DISEASE
414.8-414.9	Chronic ischemic heart disease	193 CHRONIC ISCHEMIC HEART DISEASE
ICD-10 Code		
I20.x	Angina pectoris	193 CHRONIC ISCHEMIC HEART DISEASE
I25.111-I25.118	Atherosclerotic heart disease of native coronary artery with angina pectoris	193 CHRONIC ISCHEMIC HEART DISEASE
I25.119	Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris	Services Recommended for Non-Coverage Table
I25.701, I25.708, I25.711, I25.721, I25.731, I25.738, I25.751, I25.758, I25.761, I25.768, I25.791, I25.798	Atherosclerosis of autologous/non-autologous vein/artery coronary artery bypass graft(s) with angina pectoris	193 CHRONIC ISCHEMIC HEART DISEASE
I25.709	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris	Services Recommended for Non-Coverage Table
I25.719	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unspecified angina pectoris	Services Recommended for Non-Coverage Table
I25.729	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unspecified angina pectoris	Services Recommended for Non-Coverage Table
I25.739	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unspecified angina pectoris	Services Recommended for Non-Coverage Table
I25.759	Atherosclerosis of native coronary artery of transplanted heart with unspecified angina pectoris	Services Recommended for Non-Coverage Table
I25.769	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unspecified angina pectoris	Services Recommended for Non-Coverage Table
I25.799	Atherosclerosis of other coronary artery bypass graft(s) with unspecified angina pectoris	Services Recommended for Non-Coverage Table
I25.89	Other forms of chronic ischemic heart disease	193 CHRONIC ISCHEMIC HEART DISEASE
I25.9	Chronic ischemic heart disease, unspecified	193 CHRONIC ISCHEMIC HEART DISEASE

Coronary Artery Revascularization for Stable Angina –
Prioritized List Changes

CPT codes		
33510-33516	Coronary artery bypass – venous grafting only	73 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 103 CARDIOMYOPATHY 193 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
33517-33530	Combined arterial-venous grafting for coronary bypass	73,103,193,290
33533-33536	Arterial grafting for coronary artery bypass	73,193,290
92920-92944	Percutaneous revascularization procedures	49,73,102,193

Coronary Artery Revascularization for Stable Angina – Prioritized List Changes

HERC Staff recommendations:

- 1) Add ICD-10 I25.119, I25.709, I25.719, I25.729, I25.739, I25.759, I25.769, I25.799 (Atherosclerosis with unspecified angina) to line 193
 - a. Remove from the Recommended for Non-Coverage Table
- 2) Adopt the following new guideline for line 193

GUIDELINE NOTE XXX REVASCULARIZATION FOR CHRONIC STABLE ANGINA

Line 193

Coronary revascularization with percutaneous coronary intervention (PCI; CPT 92920-92944) or coronary artery bypass surgery (CABG; CPT 33510-33516, 33517-33530, 33533-33536) is included on this line for patients with stable angina (ICD-9 413.x, 414.0x, 414.8, 414.9/ICD-10 I20.x, I25.111-119, I25.701-9, I25.711-9, I25.721-9, I25.731-9, I25.751-9, I25.761-9, I25.791-9, I25.89, I25.9) whose symptoms are not controlled with optimal medical therapy for angina or who cannot tolerate such therapy.

Optimal medical therapy for angina symptom control prior to PCI is defined as two or more antianginals (beta-blocker, nitrate, calcium channel blocker, or ranolazine) in addition to standard treatment for coronary artery disease.

For those with left main coronary artery stenosis or three-vessel coronary artery stenosis, CABG is included on this line with or without a trial of optimal medical therapy.

HERC Coverage Guidance

Coronary Artery Revascularization for Stable Angina

Oregon Health Evidence Review Commission

May 7, 2015



Center For Evidence-based Policy

Revascularization

Primary evidence sources

Dolor, R.J., Melloni, C., Chatterjee, R., Allen LaPointe, N.M., Williams, J.B., Coeytaux, R.R., et al. (2012). *Treatment strategies for women with coronary artery disease*. Rockville, MD: AHRQ. Accessed on October 2, 2014, from

http://effectivehealthcare.ahrq.gov/ehc/products/218/1227/CER66_Treatment-Coronary-Artery-Disease_FinalReport_20120816.pdf

Greenhalgh, J., Hockenhull, J., Rao, N., Dundar, Y., Dickson, R. C., & Bagust, A. (2010). Drug-eluting stents versus bare metal stents for angina or acute coronary syndromes. *The Cochrane Database of Systematic Reviews*, Issue 5. Accessed on March 6, 2015, from DOI:10.1002/14651858.CD004587.pub2.

Skinner, J.S., & Cooper, A. (2011). Secondary prevention of ischemic cardiac events. *BMJ Clinical Evidence*, 8 (206), 1-66. Accessed on March 6, 2015, from <http://www.ncbi.nlm.nih.gov/pubmed/21875445>

Revascularization

Additional evidence sources

Windecker, S., Stortecky, S., Stefanini, G.G., da Costa, B.R., Rutjes, A.W., Di Nisio, M., et. al. (2014). Revascularization versus medical treatment in patients with stable coronary artery disease: network meta-analysis. *British Medical Journal (Clinical Research Edition)*, 23(348), g3859. Accessed on March 6, 2015, from DOI: 10.1136/bmj.g3859. *Fair quality*

Purnani, S., Korley, F., Gopaul, R., Kanade, P., Chandra, N., Shaw, R.E., et. al. (2012). Percutaneous coronary intervention versus optimal medical therapy in stable coronary artery disease: A systematic review and meta-analysis of randomized clinical trials. *Circulation Cardiovascular Interventions*, 5(4), 476-490. *Good quality*

Thomas, S., Gokhal, R., Boden, W.E., & Devereaux, P.J. (2012). A meta-analysis of randomized control trials comparing percutaneous coronary interventions with medical therapy in stable angina pectoris. *The Canadian Journal of Cardiology*, 29(4), 472-482. Accessed on March 6, 2015, from DOI: 10.1016/j.cjca.2012.07.010. *Good quality*

Revascularization Clinical Background

Chronic stable angina

- Commonly caused by coronary artery disease
- Discomfort in the chest, jaw, shoulder, back, or arm
- Aggravated by moderate to severe exertion or emotional stress
- Relieved with rest or sublingual nitroglycerin

Revascularization Clinical Background

Treatments for angina

Percutaneous coronary intervention (PCI)

- Non-surgical treatment to treat narrowing coronary arteries
- Includes balloon angioplasty, bare metal stents, and drug-eluting stents

Coronary artery bypass grafting (CABG)

- Bypass surgery that creates new routes around narrowed and blocked coronary arteries

Revascularization Clinical Background

Treatments for angina

Optimal medical therapy

- Two or more antianginals (in addition to standard treatment for coronary artery disease)
 - beta-blocker, nitrate, calcium channel blocker, or ranolazine

Revascularization Evidence Summary

PCI vs. OMT

- No improvement in mortality or most other cardiac outcomes with PCI
 - Low quality evidence (multiple conflicting SRs)
- Some new generation drug-eluting stents may reduce mortality
 - Low quality evidence, based on one fair quality meta analysis
- Short-term improvement in quality of life with PCI
 - Low quality evidence, based on 1 RCT

Revascularization Evidence Summary

CABG vs. OMT

- Improved mortality at five years follow up, short-term risks are higher with CABG
 - low quality evidence, based on multiple SRs
- Benefit present regardless of left ventricular function or gender
- Mortality benefit of CABG may be limited to patients with three-vessel or left main stem disease

Revascularization Evidence Summary

PCI vs. OMT – All-cause mortality

Study (year)	Number of studies (N)	Effect size (95% CI)
Katrisis (2005)	SR, 11 RCTs (N=2,950)	RR 0.94 (0.72 to 1.24)
Ioannidas (2007)	SR, 6 RCTs (N=2,617)	RR 0.95 (0.73 to 1.23)
Trikalios (2009)	SR, 7 RCTs (N=1,991)	RR 0.82 (0.59 to 1.15)
Jeremias (2009)	SR, 17 RCTs (N=8,052)	OR 0.82 (0.68 to 0.99)

No significant differences in PCI vs. OMT in 3 SRs, significant reduction in 1 SR

Revascularization Evidence Summary

New drug-eluting stents vs. OMT – All-cause mortality

Windecker 2014 - network MA **fair quality**

Eluting stent type	# studies (N)	Rate Ratio (95% CI)
Everolimus	17 RCTs (N=13,272)	0.75 (0.59 to 0.96)
Zotarolimus (Resolute)	4 RCTs (N=2,285)	0.65 (0.42 to 1.00)
Paclitaxel	27 RCTs (N=11,541)	0.92 (0.75 to 1.12)
Sirolimus	39 RCTs (N=19,781)	0.91 (0.75 to 1.10)
Zotarolimus (Endeavor)	8 RCTs (N=8,937)	0.88 (0.69 to 1.10)

Trend toward reduced mortality with new generation drug-eluting stents. No difference in all-cause mortality with early generation drug-eluting stents.

Revascularization Evidence Summary

PCI vs. OMT – major adverse cardiac events (MACE)

- 3 SRs
 - 11 RCTs, N=2,950 (Katrisis 2005)
 - 6 RCTs, N=2,617 (Ionnidis 2007)
 - 7 RCTs, N=1,991 (Trikalinos 2009)
- No significant difference in non-fatal MI, cardiac death or MI, *need for subsequent revascularization*, or heart failure

Revascularization Evidence Summary

PCI vs. OMT – Quality of Life

Mark 2009

- 1 RCT (N=951)
- Duke Activity Status Index
 - Significant improvement at 4-months, disappears at 12 and 24-months
- Mental Health Inventory-5
 - No significant differences at any follow-up

Revascularization Evidence Summary

CABG vs. OMT – All-cause mortality

Yusuf 1994

- SR (7 RCTs, N=2,649)
 - Significant short-term increase and long-term reduction in mortality
- 1-year (mortality or MI): RR 1.45 (95% CI 1.18 to 2.03)
- 5 years: RR 0.61 (95% CI 0.48 to 0.77)
- 10 years: RR 0.83 (95% CI 0.70 to 0.98)

Revascularization Evidence Summary

CABG vs. OMT – All-cause mortality

Jeremias 2009

- SR (8 RCTs, N=3,098)
 - Significant reduction
 - Relative benefits similar in people with normal compared with reduced left ventricular function
 - OR 0.62 (95% CI 0.50 to 0.77)

Revascularization Evidence Summary

CABG vs. OMT – Mortality (sub-groups)

Yusuf 1994

- SR (7 RCTs, N=2649)
- Non-significant reduction
 - Single-vessel disease: 0.54 (95% CI 0.22 to 1.33)
 - Two-vessel disease: 0.84 (95% CI 0.54 to 1.32)
- Significant reduction
 - Three-vessel disease: 0.58 (95% CI 0.42 to 0.80)
 - Left-main stem disease: 0.32 (95% CI 0.15 to 0.70)

HERC Coverage Guidance – Coronary artery revascularization for stable angina Disposition of Public Comments

Stakeholder	#	Comment	Disposition
	1	No public comments were received for this topic.	

DRAFT

Section 3.0

VbBS Report

Straightforward Issues—May, 2015

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
V10.79	Personal history of other lymphatic and hematopoietic neoplasms	162 NON-HODGKIN'S LYMPHOMAS 167 NON-HODGKIN'S LYMPHOMAS Treatment: BONE MARROW TRANSPLANT	V10.79 was on 3 lymphoma and leukemia lines from 2013 through 2014, then was moved to the Non-Covered List for the January 1, 2015 List. Similar V codes are on appropriate leukemia or lymphoma lines. All listed subdiagnoses in ICD-9 are lymphoma related.	Add V10.79 to lines 162 and 167. Remove V10.79 from the Services Recommended for Non-Coverage Table
V07.4 Z79.890	Hormone replacement therapy (postmenopausal)	474 GONADAL DYSFUNCTION, MENOPAUSAL MANAGEMENT	ICD-9 V07.4 and ICD-10 Z79.890 are currently on the Services Recommended for Non-Coverage Table. Both codes can be used for a visit in which a woman is given a prescription for hormone replacement therapy.	Add V07.4 and Z79.890 to line 474 Remove V07.4 and Z79.890 from the Services Recommended for Non-Coverage Table
31561 31588	Laryngoscopy, direct, operative, with arytenoidectomy; with operating microscope or telescope Laryngoplasty, not otherwise specified (eg, for burns, reconstruction after partial laryngectomy)	70 LARYNGEAL STENOSIS OR PARALYSIS WITH AIRWAY COMPLICATIONS	DMAP requested that 31561 and 31588 be paired with 478.74 (Stenosis of larynx). 478.74 is located on line 71 for surgical treatment and on line 364 DYSTONIA (UNCONTROLLABLE); LARYNGEAL SPASM AND STENOSIS for medical treatments.	Add 31561 and 31588 to line 70

Straightforward Issues—May, 2015

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
27570	Manipulation of knee joint under general anesthesia	435 INTERNAL DERANGEMENT OF KNEE AND LIGAMENOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT	DMAP requested that 27570 pair with 718.56 (Ankylosis of joint, lower leg). 718.56 is currently on lines 435 and 616 SPRAINS AND STRAINS OF ADJACENT MUSCLES AND JOINTS, MINOR. 27570 is currently located on lines 362,391,427.	Add 27570 to line 435
743.65	Specified congenital anomalies of lacrimal passages	398 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN 516 DYSFUNCTION OF NASOLACRIMAL SYSTEM IN ADULTS; LACRIMAL SYSTEM LACERATION	DMAP requested that 743.65 be added to line 398. Currently, 743.65 only appears on line 516. Similar codes such as 743.64 (Specified congenital anomalies of lacrimal gland) appear on both lines.	Add 743.65 to line 398
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)	291 CANCER OF VAGINA, VULVA, AND OTHER FEMALE GENITAL ORGANS	DMAP requested that 58661 pair with 183.2 (Malignant neoplasm of fallopian tube). 58661 is the laparoscopic alternative to the open removal of adnexal structures (CPT 58943). 58661 is currently on 12 lines.	Add 58661 to line 291

Straightforward Issues—May, 2015

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
377.00	Papilledema, unspecified	659 INTRACRANIAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	ICD-9 377.00 is on line 659. This is basically a symptom which needs further evaluation. The ICD-10 equivalent, H47.10, is on the Diagnostic File.	Remove 377.00 from line 659 Advise DMAP to add 377.00 to the Diagnostic Workup file

VbBS Summary Documents from 5/7/15 meeting

Revised DMAP List Codes Requiring HERC Action

Question: should certain non-prioritized ICD-10 codes currently on DMAP lists (Diagnostic Workup File, Undefined, Informational, or Services Recommended for Non-coverage) be moved to lines on the Prioritized List?

Question source: HERC staff

Issue: MAP has revised the files that include the diagnosis codes that are not included on the Prioritized List. The current MAP “Exempt” and “Excluded” Lists will no longer exist.

HERC staff have been working with MAP to review and align placement of non-prioritized ICD-10 codes on the MAP lists. As part of this review, several codes have been identified that are better placed on lines of the Prioritized List.

HERC staff recommendation:

- 1) Make the List changes shown in the table below

ICD-10 Code	Code Description	Current Placement	Recommended Placement	Comments
G89.3	Neoplasm related pain (acute) (chronic)	Exempt	Cancer lines (any line with radiation therapy and/or chemotherapy in the treatment description)	
G89.4	Chronic pain syndrome	Services Recommended for Non Coverage	<i>For October 1 2015</i> 612 DISORDERS OF SOFT TISSUE <i>For January 1, 2016</i> 533 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, AND RELATED DISORDERS	Will match fibromyalgia placement
H32	Chorioretinal disorders in diseases classified elsewhere	Services Recommended for Non Coverage	363 CHORIORETINAL INFLAMMATION	
Z44.8	Encounter for fitting and adjustment of other external prosthetic devices	Ancillary	381 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	

Guideline Note Errata

Issues:

- 1) Changes to Guideline Notes 29 and 51 were made at the January, 2015 VBBS meeting which did not include earlier edits made to these guideline notes. The changes made at the January meeting did not affect the previously changed sections of these guidelines. HERC staff realizes that it was the intent of the Commission to include all the changes adopted at various meetings, but needs to affirm the final approved wording with the Commission. The corrected guideline notes with all intended changes are shown below.
- 2) Guideline note 25 has errors of omission and typos

HERC staff recommendation:

- 1) Affirm that the guideline notes shown below are the correct versions to appear in the October 1, 2015 Prioritized List

GUIDELINE NOTE 29, TYMPANOSTOMY TUBES IN ACUTE OTITIS MEDIA

Line 394

Tympanostomy tubes ([CPT 69436](#)) are only included on this line as treatment for

- 1) recurrent acute otitis media (three or more [well-documented and separate](#) episodes in six months or four or more [well-documented and separate](#) episodes in ~~one year~~ [the past 12 months with at least 1 episode in the past 6 months](#)) ~~that fail appropriate medical management in patients who have unilateral or bilateral middle ear effusion at the time of assessment for tube candidacy, or~~
- ~~2) for patients who fail medical treatment secondary to multiple drug allergies or who fail two or more consecutive courses of antibiotics, or~~
- 3) [2\) patients with](#) complicating conditions (immunocompromised host, meningitis by lumbar puncture, acute mastoiditis, sigmoid sinus/jugular vein thrombosis by CT/MRI/MRA, cranial nerve paralysis, sudden onset dizziness/vertigo, need for middle ear culture, labyrinthitis, or brain abscess).

Patients with craniofacial anomalies, Down's syndrome, cleft palate, [permanent hearing loss of 25dB or greater independent of otitis media with effusion](#), and patients with speech and language delay may be considered for tympanostomy if unresponsive to appropriate medical treatment or having recurring infections (without needing to meet the strict "recurrent" definition above).

[Removal of retained tympanostomy tubes requiring anesthesia \(CPT code 69424\) or as an office visit, is included on line 427 as a complication, pairing with 385.83/ H74.8xX](#)

Guideline Note Errata

GUIDELINE NOTE 51, CHRONIC OTITIS MEDIA WITH EFFUSION

Line 383, 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](#)).

Patients with specific higher risk conditions (including 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 be included on Line 383. Otherwise hearing loss associated with chronic otitis media with effusion (without those specific higher risk conditions) is only included on Line 502.

For coverage to be considered on either Line 383 or 502, 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 children with chronic OME present for 3 months or longer. Children with language delay, learning problems, or significant hearing loss 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 children over 3 years who are having their second set of tubes.

Removal of retained tympanostomy tubes requiring anesthesia (CPT code 69424) or as an office visit, is included on line 427 as a complication, pairing with 385.83/ H74.8xX.

The development of this guideline note was informed by a HERC coverage guidance. See <http://www.oregon.gov/oha/herc/Pages/blog-management-chronic-otitis.aspx>

GUIDELINE NOTE 25, MENTAL HEALTH PROBLEMS IN CHILDREN AGE FIVE AND UNDER RELATED TO NEGLECT OR ABUSE

Line 177

ICD-10-CM T76.02xA and T76.02xD (Child neglect or abandonment, suspected), (ICD-10-CM T74.02xA and T74.02xD (Child neglect or abandonment, confirmed), T74.22xA and T74.22xD (Child sexual abuse, confirmed), T76.22xA and T76.22xD (Child sexual abuse, suspected), [T76.12xA and T76.12xD](#) (Child physical abuse, suspected, ~~subsequent encounter~~) or T74.12xA and T74.12xD (Child physical abuse, confirmed) and corresponding ICD-9-CM codes 995.52, 995.53, 995.54 and —995.59, may be used in any children when there is evidence or suspicion of abuse or neglect. These codes are to be used when the focus of treatment is on the alleged child victim. This can include findings by child welfare of abuse or neglect; or statements of

Guideline Note Errata

abuse or neglect by the child, the perpetrator, or a caregiver or collateral report. Although these diagnoses can be used preventively, i.e. for children who are not yet showing symptoms, presence of symptoms should be demonstrated for interventions beyond evaluation or a short-term child or family intervention.

The codes T74.02xA, T74.02xD, T764.02XA, T764.02XD, T74.22xA, T74.22xD, T76.22xA, T76.22xD, T76.12xA, T76.12xD, T74.12xA or T74.12xD and corresponding ICD-9-CM codes 995.52, 995.53, 995.54 and —995.59 may be used in children age five and younger and, in these instances only, is limited to pairings with the following procedure codes:

- Assessment and Screening: 90791, 90792, H0002, H0031, H0032, T1023
- Family interventions and supports: 90832-90838, 90846, 90847, 90849, 90887, H0038, H0045, H2021, H2022, H2027, S5151, S9125, T1005
- Individual counseling and therapy: 90785, 90832-90838, 99201-99215
- Group therapy: 90832-90838, 90853, 90857, H2032
- Case Management: 90882, T1016
- Interpreter Service: T1013
- Medication management is not indicated for these conditions in children age 5 and under.

Gender Dysphoria Guideline Correction

Issue: The current gender dysphoria guideline has a sentence which was from an older version and makes coverage of cross sex hormone therapy unclear. The suggested wording simply clarifies the intent of the Commission.

HERC staff recommendation:

- 1) Modify GN127 as shown below

GUIDELINE NOTE 127, GENDER DYSPHORIA

Line 413

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

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

1. have persistent, well-documented gender dysphoria
2. have the capacity to make a fully informed decision and to give consent for treatment
3. have any significant medical or mental health concerns reasonably well controlled
4. have a thorough psychosocial assessment by a qualified mental health professional with experience in working with patients with gender dysphoria

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

1. have persistent, well documented gender dysphoria
2. have completed twelve months of continuous hormone therapy as appropriate to the member's gender goals unless hormones are not clinically indicated for the individual
3. have completed twelve months of living in a gender role that is congruent with their gender identity unless a medical and a mental health professional both determine that this requirement is not safe for the patient
4. have the capacity to make a fully informed decision and to give consent for treatment
5. have any significant medical or mental health concerns reasonably well controlled
6. have two referrals from qualified mental health professionals with experience in working with patients with gender dysphoria who have independently assessed the patient. Such an assessment should include the clinical rationale supporting the patient's request for surgery, as well as the rationale for the procedure(s)

Prenatal Genetic Testing Guideline Revisions

Questions:

- 1) Should Diagnostic Guideline D17, PRENATAL GENETIC TESTING be modified to clarify the CPT codes available for amniocentesis or chorionic villus sampling?
- 2) Should an additional CPT code be added to D17 for microarray testing?
- 3) Should various CPT codes used for prenatal testing be moved from the Diagnostic List to Line 1 PREGNANCY?
- 4) Should Diagnostic Guideline D17, PRENATAL GENETIC TESTING be modified to reflect updated recommendations for chromosomal microarray testing?

Question sources:

- 1) Holly Jo Hodges, MD, OHP Medical Director
- 2) Shelly Bosworth, certified genetic counselor from the Center for Genetics and Maternal Fetal Medicine in Eugene

Issues:

Amniocentesis CPT code issue

The CPT codes included in item #8 in the guideline are not an inclusive list of codes used for amniocentesis or chorionic villus sampling (CVS). The current 2 codes only code for the procedure itself, not the subsequent laboratory analysis. These CPT laboratory codes are all either on line 1 or the DMAP Diagnostic List. The medical director request was to clarify which CPT codes should be covered for either amniocentesis or CVS.

From Cori Feist:

- CVS ultrasound and procedure CPT: 59015 (Chorionic villus sampling, any method), 76945 (Ultrasonic guidance for chorionic villus sampling)
- CVS/amniocentesis karyotype CPT: 88235 (Tissue culture for non-neoplastic disorders; amniotic fluid or chorionic villus cells), 88267 (Chromosome analysis, amniotic fluid or chorionic villus, count 15 cells, 1 karyotype, with banding), 88280 (Chromosome analysis; additional karyotypes, each study)
- Amniocentesis ultrasound and procedure CPT: 59000 (Amniocentesis; diagnostic), 76946 (Ultrasonic guidance for amniocentesis, imaging supervision and interpretation)
- Interphase FISH for aneuploidy (either CVS or amniocentesis): 88271, 88275
- Chromosomal microarray (either CVS or amniocentesis): 81228 (Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants); some labs use 81229 (Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities) instead

Suggested by other clinicians:

- 88291 Cytogenetics and molecular cytogenetics, interpretation and report

Coding issue

Multiple CPT codes which are only used for amniocentesis or CVS are included in the DMAP Diagnostic List, but they are not visible to providers or medical directors. These codes are more appropriately placed on line 1 PREGNANCY.

CPT codes on Diagnostic List which only apply in pregnancy

Prenatal Genetic Testing Guideline Revisions

76945 Ultrasonic guidance for chorionic villus sampling, imaging supervision and interpretation

76946 Ultrasonic guidance for amniocentesis, imaging supervision and interpretation

88235 Tissue culture for non-neoplastic disorders; amniotic fluid or chorionic villus cells

88267 Chromosome analysis, amniotic fluid or chorionic villus, count 15 cells, 1 karyotype, with banding

88269 Chromosome analysis, in situ for amniotic fluid cells, count cells from 6-12 colonies, 1 karyotype, with banding

Microarray testing

Several genetic counselors have noted that the microarray testing section of D17 does not agree with current practice. The question is whether to allow microarray testing before karyotype—this test is faster and provides more information than karyotype. The question is based on the practical question of allowing a faster, more complete test. Shelly Bosworth recommended that item #9 in the guideline be changed to read: "...apparent on imaging, and karyotype is not required normal." She felt that this would allow more timely and efficient testing and eliminate what might be an unnecessary test and expense.

In December, 2013, ACOG published an updated committee opinion regarding when fetal chromosomal microarray testing should be performed. This new committee opinion does not agree with the current prenatal genetic testing guideline. The current guideline states that "Array CGH (CPT 81228) when major fetal congenital anomalies apparent on imaging, and karyotype is normal." The ACOG opinion recommends chromosomal microarray analysis 1) in patients with a fetus with one or more major structural abnormalities identified on ultrasonographic examination and who are undergoing invasive prenatal diagnosis, chromosomal microarray analysis is recommended. This test replaces the need for fetal karyotype; 2) in patients with a structurally normal fetus undergoing invasive prenatal diagnostic testing, either fetal karyotyping or a chromosomal microarray analysis can be performed.

The only CPT code for microarray testing in D17 is 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)), however, 81229 (Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities) is also commonly used for this procedure.

Prenatal Genetic Testing Guideline Revisions

Expert Input

Cori Feist, certified genetic counselor at OHSU

The current ACOG & SMFM recommendations state array CGH can be used instead of karyotype for anyone having an invasive procedure because of the increased detection of significant abnormalities that would be missed by standard karyotyping. This is especially true when there are fetal structural anomalies.

I agree whole-heartedly with Shelly. But in my opinion, aCGH should be available for anyone who wants it regardless of whether or not there is an anomaly (but ESPECIALLY if there is a birth defect). At OHSU, we offer array to anyone having an invasive procedure and recommend it to anyone with a fetal anomaly. However, karyotype is still useful when Down syndrome/T18/T13 is strongly suspected. It should really be at the discretion of the physician/genetic counselor. I think providers educated about genetics can use their expertise to devise strategies on the most cost-effective, yet appropriate, testing for patients. I fully expect array to replace standard karyotype as a first-tier test. In the future, I expect karyotype to be used only to confirm or further explain array findings.

I expect this to become standard of care within the next 2-3 years. The reason we offer array to anyone is that 1/1,000 live births is affected with a microdeletion or microduplication syndrome that would have been missed by standard karyotype. Most of these syndromes do not have ultrasound findings but have significant morbidity and mortality. These syndromes are only slightly less common than Down syndrome (1/700 live births), which we spend a considerable amount of time and money screening/testing for in pregnancy.

It's also hard to tell a woman having amniocentesis that she can only have karyotype, which will detect about 90-95% of all known chromosome abnormalities, but not an array which will detect >99% of all known chromosome abnormalities. It's like telling her she can only have some of the information about her baby's health, but not all.

Standard karyotype generally costs about \$1,000-1,500. The results take about 14 days, so many physicians recommend FISH for rapid results. FISH costs another \$1,000-1,500. Prenatal microarray generally costs about \$1,500-2,000. Results take 7-10 days because cultured cells are not required.

Prenatal Genetic Testing Guideline Revisions

HERC staff recommendation:

- 1) Modify Diagnostic Guideline D17 as shown below
 - a. CPT code changes
 - i. Add CPT 81229 (Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities) to #9, as this CPT code is commonly used for chromosomal array testing.
 - ii. Add CPT 76945, 76946, 88235, 88267, 88280, 88291 to #8 to specify the ultrasound and laboratory testing portion of the amniocentesis/ CVS
 - iii. Alternative: remove all CPT codes from the guideline note. These codes are difficult to ensure complete inclusion.
 - b. Simple wording clarification regarding the definition of CVS
 - c. Modify the entry for microarray testing
 - i. CGH testing provides more information for about the same cost as karyotyping. CGH results are available more quickly and may result in less FISH testing for an overall cost savings. The change also helps to prevent unnecessary duplicative testing
- 2) Add the following CPT codes to line 1 PREGNANCY and advise DMAP to remove from the Diagnostic List. These codes are only used during pregnancy.
 - a. 76945 Ultrasonic guidance for chorionic villus sampling, imaging supervision and interpretation
 - b. 76946 Ultrasonic guidance for amniocentesis, imaging supervision and interpretation
 - c. 88235 Tissue culture for non-neoplastic disorders; amniotic fluid or chorionic villus cells
 - d. 88267 Chromosome analysis, amniotic fluid or chorionic villus, count 15 cells, 1 karyotype, with banding
 - e. 88269 Chromosome analysis, in situ for amniotic fluid cells, count cells from 6-12 colonies, 1 karyotype, with banding

DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING

The following types of prenatal genetic testing and genetic counseling are covered for pregnant women:

1. Genetic counseling (CPT 96040, HPCPS S0265) for high risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, or elevated risk of neural tube defect.
2. Genetic counseling (CPT 96040, HPCPS S0265) prior to consideration of [chorionic villus sampling \(CVS\)](#), amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening
3. Validated questionnaire to assess genetic risk in all pregnant women
4. Screening high risk ethnic groups for hemoglobinopathies (CPT 83020, 83021)
5. Screening for aneuploidy with any of five screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, and contingency] (CPT 76813, 76814, 81508-81511)
6. Cell free fetal DNA testing (CPT 81507) for evaluation of aneuploidy in women who have an elevated risk of a fetus with aneuploidy (maternal age >34, family history or elevated risk based on screening).
7. Ultrasound for structural anomalies between 18 and 20 weeks gestation (CPT 76811, 76812)

Prenatal Genetic Testing Guideline Revisions

8. CVS or amniocentesis (CPT 59000, 59015, [76945](#), [76946](#), [88235](#), [88267](#), [88280](#), [88291](#)) for a positive aneuploidy screen, maternal age >34, fetal structural anomalies, family history of inheritable chromosomal disorder or elevated risk of neural tube defect.
9. Array CGH (CPT 81228, [81229](#)) when major fetal congenital anomalies are apparent on imaging, or with normal imaging when array CGH would replace karyotyping ~~and karyotype is normal~~
10. FISH testing (CPT 88271, 88275) only if karyotyping is not possible due a need for rapid turnaround for reasons of reproductive decision-making (i.e. at 22w4d gestation or beyond)
11. Screening for Tay-Sachs carrier status (CPT 81255) in high risk populations. First step is hex A, and then additional DNA analysis in individuals with ambiguous Hex A test results, suspected variant form of TSD or suspected pseudodeficiency of Hex A
12. Screening for cystic fibrosis carrier status once in a lifetime (CPT 81220-81224)
13. Screening for fragile X status (CPT 81243, 81244) in patients with a personal or family history of
 - a. fragile X tremor/ataxia syndrome
 - b. premature ovarian failure
 - c. unexplained early onset intellectual disability
 - d. fragile X intellectual disability
 - e. unexplained autism through the pregnant woman's maternal line
14. Screening for spinal muscular atrophy (CPT 81401) once in a lifetime
15. Screening those with Ashkenazi Jewish heritage for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255)
16. Expanded carrier screening only for those genetic conditions identified above

The following genetic screening tests are not covered:

1. Serum triple screen
2. Screening for thrombophilia in the general population or for recurrent pregnancy loss
3. Expanded carrier screening which includes results for conditions not explicitly recommended for coverage

The development of this guideline note was informed by a HERC coverage guidance. See <http://www.oregon.gov/oha/herc/CoverageGuidances/Prenatal%20Genetic%20Testing.pdf>

Open Wound of Ear Drum

Question: should we merge lines containing open wound of ear drum diagnoses?

Question source: HERC staff

Issue: Up to and including the present Prioritized list, there have been two lines for open wound of ear drum, a surgical line (currently line 436) which contains only two diagnosis codes (ICD-9 872.61, 872.71 open wound of ear drum complicated and uncomplicated) and a medical line (currently line 563) which contained a range of diagnosis codes, including open wound of ear drum and perforation of ear drum. The chronic otitis media line (currently line 481) contains a range of diagnosis codes for perforations of the ear drum as well as the surgical treatment codes.

In October, 2013, the surgical line for open wound of ear drum was merged with the chronic otitis media line. The surgical open wound of the ear drum was a covered line at the time, and merged into the chronic otitis media line, which was uncovered. This merge was done because there was only one diagnosis code on the open wound of the ear drum line that was not duplicated on the chronic otitis media line and all the appropriate treatment CPT codes were on the chronic otitis media line. There was concern that the covered wound line would start to be used for treatment of what were actually perforations and belonged on the chronic otitis media line. There was also a thought that open wounds of the ear drum due to trauma/injury are not treated significantly differently in practice from spontaneous ruptures of the ear drum and therefore should not be on different priority lines.

During the 2013 line merge discussion, it was not recognized or discussed that there was also a medical line for open wound of the ear drum. This line has a lower priority than the chronic otitis media line. This medical line contains only one ICD-9 diagnosis (872.71 Open wound of ear drum, complicated) which is not also found on the chronic otitis media line.

During the ICD-10 ENT review, the ENT experts advised moving all the ear drum perforation codes (H72.xx) off of the chronic otitis media line and onto the two open wound of ear drum lines. However, the equivalent ICD-9 codes were not moved from the chronic otitis media line during the conversion back to the "bilingual list."

The usual treatment for a perforation or wound of the ear drum is observation. Most heal on their own, or require antibiotic ear drops. Those openings that do not spontaneously close and that cause hearing loss are normally closed with a surgical tympanoplasty.

HERC staff summary

- 1) The ICD-10 reviewers and VBBS/HERC have previously indicated that wounds of the eardrum should be prioritized similarly to spontaneous perforations of the ear drum.
- 2) Currently, perforations of the ear drum are prioritized with chronic otitis media.

Open Wound of Ear Drum

January 1, 2015 Prioritized List

Line: 436

Condition: OPEN WOUND OF EAR DRUM

Treatment: TYMPANOPLASTY

ICD-9: 872.61,872.71

ICD-10: H72.00-H72.13,H72.2x1-H72.93,S09.20xA-S09.20xD,S09.21xA-S09.21xD,
S09.22xA-S09.22xD

CPT: 64505-64530,69450,69610-69643,96127,98966-98969,99051,99060,99070,99078,
99184,99201-99239,99281-99285,99291-99404,99408-99412,99429-99449,
99468-99480,99487-99498,99605-99607

HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467

Line: 481

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

ICD-10: H65.20-H65.33,H65.411-H65.93,H66.10-H66.23,H66.3x1-H66.3x9,H68.001-
H68.009,H68.021-H68.139,H69.00-H69.03,H70.10-H70.13,H70.90-H70.93,H73.10-
H73.13,H73.811-H73.93,H74.01-H74.09,H74.40-H74.43,H74.8x1-H74.93,H95.111-
H95.119,H95.131-H95.199

CPT: 42830-42836,64505-64530,69210-69222,69310,69420-69511,69601-69650,69700,
69801,69905,69910,69979,92562-92565,92571-92577,92590,92591,96127,98966-
98969,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,
99408-99412,99429-99449,99468-99480,99487-99498,99605-99607

HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467

Line: 563

Condition: OPEN WOUND OF EAR DRUM (See Guideline Notes 64,65)

Treatment: MEDICAL THERAPY

ICD-9: 384.20,384.21,384.22,384.23,384.24,384.25,872.61,872.71

ICD-10: H72.00-H72.13,H72.2x1-H72.93,S09.20xA-S09.20xD,S09.21xA-S09.21xD,
S09.22xA-S09.22xD

CPT: 96127,98966-98969,99051,99060,99070,99078,99184,99201-99239,99281-99285,
99291-99404,99408-99412,99429-99449,99468-99480,99487-99498,99605-99607

HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467

January 1, 2016 Prioritized List

479 CHRONIC OTITIS MEDIA; OPEN WOUND OF EAR DRUM

561 OPEN WOUND OF EAR DRUM Treatment: MEDICAL THERAPY

Open Wound of Ear Drum

HERC staff recommendation:

- 1) Merge line 561 OPEN WOUND OF EAR DRUM Treatment: MEDICAL THERAPY with line 479 CHRONIC OTITIS MEDIA, OPEN WOUND OF EAR DRUM Treatment: PE TUBES/ ADENOIDECTOMY/ TYMPANOPLASTY, MEDICAL THERAPY and keep at line 479 for the January 1, 2016 Biennial Review Prioritized List
 - a. ICD-9 (872.71 Open wound of ear drum, complicated) would be added to line 479
 - b. All ICD-10 codes for perforation of ear drum (H72.xx and S02.2xx) would be added to line 479
 - c. Follows previous VBBS/HERC intent to merge the open wound of ear drum line with the chronic otitis media line
- 2) **Other options (not preferred):**
 - a. Keep line 561 as a medical treatment only line. This is highly problematic as line 479 already contains medical therapy procedure codes.
 - b. Put all wound/perforation diagnosis codes on line 561, remove from line 479. Add all tympanoplasty CPT codes to line 561. Rename line 561 OPEN WOUND AND PERFORATIONS OF EAR DRUM, Treatment MEDICAL AND SURGICAL TREATMENT. This is problematic as it prioritizes repair of ear drum perforations/wounds lower than treatment of chronic otitis media, which is not the previous prioritization intent
 - c. Return to the previous line structure, with two separate lines for surgical and medical treatment of open wounds of the eardrum. These lines would contain both open wound and perforation diagnoses per the ICD-10 reviewers. This is problematic as it allows treatment for ear drum perforations/wounds which is not available currently.

Yttrium Internal Radiation Therapy for Liver Cancer

Question: should yttrium internal radiation therapy (CPT 79445) be covered for liver cancers or isolated colon cancer metastases to the liver?

Question source: Alison Little, MD, MPH, OHP medical director

Issue: Yttrium-90 is a radioactive element that can be injected into the arterial system of the liver to treat non-surgically resectable liver cancer or liver metastases from colon cancer. This treatment was removed from the Prioritized List in 2006. Dr. Little requested a re-review of this topic, as she found a Hayes report giving limited support to this therapy.

From Dr. Little:

from Hayes (TACE is the arterial embolization, TARE is the yttrium):
Per Hayes, TACE is accepted treatment (Grade B), and one RCT found prolonged survival. For TARE for treatment of primary liver cancer, they give it a C rating, and state the following: "Transarterial radioembolization (TARE) with yttrium-90 (90Y) appears to have comparable clinical outcomes to other intra-arterial therapies (IATs), specifically transarterial chemoembolization (TACE), as well as sorafenib." The majority of the studies for TARE versus TACE report comparable results for survival and tumor response, with limited inconsistent evidence suggesting that TARE may result in better survival. Limited inconsistent evidence suggests that TARE may have more favorable time to progression compared with TACE. TARE with 90Y has consistently fewer overall hospitalization days versus TACE, but inconsistent results for rehospitalization. The evidence for TARE with 90Y suggests comparable safety, with more hepatic dysfunction, postembolization syndrome, and lymphopenia, but less hematologic complications, abdominal pain, and fever than TACE."

From the April, 2006 HOSC minutes (line 489 was liver cancer):

Treatment of Liver Cancer: Little explained that the Commission previously considered embolization for tumor destruction using yttrium and elected not to place it on the list; however, the code for embolization remains. A case at OMAP resulted in her questioning whether appropriate treatments were listed on this line. Olson explained the different treatments, as follows: Radiofrequency ablation is insertion of a an ultrasound catheter with use of heat to kill tissue, cryotherapy is the same thing except using a liquid nitrogen probe, chemoembolization is when a catheter is inserted into an artery that feeds the tumor, chemotherapy is infused then the artery is embolized with gel foam. The yttrium procedure does not involve embolization. All of these are used to treat both primary liver cancer and metastatic colon cancer. Saha asked if any of these treatments were controversial except the yttrium. Olson stated that for colon cancer metastatic only to the liver, resection can result in 25% long-term survival. Hepatic artery infusion with 5-FU improved outcomes as well. The data on RFA and cryotherapy is weaker.

Chemoembolization results in shrinkage of tumor, but causes severe side-effects. RFA and yttrium have fewer side effects. Hepatic artery infusion is also effective, but systemic chemotherapy has improved to the point that it is rarely done anymore. Saha clarified that the task today is to determine if any of these treatments should be removed from the List. Olson stated that there are some cases where an isolated metastasis is too close to the bile duct to operate, and in those cases it makes sense to use RFA or cryo. He also said that yttrium treatment costs approximately \$70,000.

Decision: Line 489: Delete 79445 – Radiopharmaceutical therapy, by intra-arterial particulate

Yttrium Internal Radiation Therapy for Liver Cancer

Current Prioritized List status:

79445 (Radiopharmaceutical therapy, by intra-arterial particulate administration) is on lines 129,130,160,161,162,165,195,204,214,238,242,262,265,274,279,291,292,299,319,321,333,346,376,439,465,533,600,611

Line 320 CANCER OF LIVER

Evidence

- 1) **NICE 2013**, guidance for use of yttrium 90 SIRT for primary hepatocellular carcinoma
 - a. Current evidence on the efficacy and safety of selective internal radiation therapy (SIRT) for primary hepatocellular carcinoma is adequate for use with normal arrangements for clinical governance, consent and audit. Uncertainties remain about its comparative effectiveness, and clinicians are encouraged to enter eligible patients into trials comparing the procedure against other forms of treatment.
 - i. 2 non-randomized comparative studies (n=331 patients)
 1. SIRT vs transarterial chemoembolization (TACE)
 2. Both found improved response rates for SIRT
 3. One study found improved survival for SIRT (42 months vs 19 months)
 4. One study found increased length of time to progression for SIRT
 - ii. 1 non-randomized comparative study (N=26 patients)
 1. SIRT vs cisplatin
 2. Found no significant differences in quality of life or functional assessment between treatment groups
 - iii. 2 case series (N=326 patients), SIRT treatment
 - iv. Death, radiation pneumonitis, post-embolization syndrome (fatigue, flu-like symptoms) and local ulceration were listed as complications
 1. Death and post-embolization syndrome rates no different from TACE
 - v. Other comments: The Committee noted wide variation in the published evidence about prior and adjunctive treatments that patients received. This made interpretation of the effect of SIRT difficult.
- 2) **NICE 2013**, guidance on SIRT for primary intrahepatic cholangiocarcinoma
 - a. Current evidence on the safety and efficacy of selective internal radiation therapy (SIRT) for primary intrahepatic cholangiocarcinoma is limited in both quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 3) **CTAF 2010**, SIRT for inoperable colorectal metastases to the liver

Yttrium Internal Radiation Therapy for Liver Cancer

- a. Twenty-two case series with data on patients with metastatic colorectal cancer have demonstrated that it is feasible to deliver radiation therapy to liver tumors and achieve at least partial remission in a substantial proportion of patients with relatively few serious adverse events. Procedure specific adverse events such as radiation pneumonitis, GI ulceration and radiation induced liver disease have been characterized and pretreatment planning strategies have been developed to limit their frequency and severity. The results of the two randomized trials described above are encouraging, but not definitive. Both demonstrated improvements in disease-free survival and a trend towards longer overall survival. However, the trials were very small (less than 100 patients in total) and the response rates in the control groups were lower than expected. Furthermore, the control groups did not use the standard first-line therapy for colorectal cancer metastatic only to the liver. Ongoing clinical trials that are randomizing over 800 newly diagnosed patients to first line chemotherapy with or without RE should define the efficacy of combined therapy and the associated additional toxicity. Similarly, the data on the utility of RE as salvage therapy for patients who have failed multiple rounds of chemotherapy is limited and immature.
 - b. It is recommended that radioembolization for the treatment of inoperable liver metastases from colorectal cancer does not meet CTAF TA Criterion 2 through 5 for improvement in health outcomes.
- 4) **Townsend 2009**, Cochrane review of yttrium selective internal radiation therapy (SIRT) for liver metastases
- a. N=1 study (21 patients) comparing SIRT + systemic chemotherapy with systemic chemotherapy alone
 - i. There was a significant improvement in progression free survival and median survival associated with SIRT, both for the total studied population and for those disease limited to the liver. There was an increase in toxicity with the use of SIRT.
 - b. N=1 study (63 patients) comparing SIRT and regional chemotherapy with regional chemotherapy alone.
 - i. There was no significant difference in progression free survival and median survival seen with SIRT, in either the total patient group or in the 22 patients with disease limited to the liver. There was no significant increase in toxicity with the addition of SIRT to regional chemotherapy.
 - c. There were no randomised studies comparing SIRT with best supportive care in patients with refractory disease, and no randomised studies assessing the effect of SIRT in patients with resectable liver metastases.
 - d. **Authors' conclusions** There is a need for well designed, adequately powered phase III trials assessing the effect of SIRT when used with modern combination chemotherapy regimens. Further studies are also needed for patients with refractory disease with a particular focus on the impact on quality of life.
- 5) **Vente 2009**, meta-analysis of yttrium-90 radioembolization for liver malignancies
- e. For colorectal liver metastases (mCRC), in a salvage setting, response was 79% for 90Y-RE combined with 5-fluorouracil/ leucovorin (5-FU/LV), and 79% when combined with 5-FU/LV/oxaliplatin or 5-FU/LV/irinotecan, and in a first-line setting 91% and 91%, respectively.
 - f. For hepatocellular carcinoma (HCC), response was 89% for resin microspheres and 78% for glass microspheres.
 - g. No statistical method is available to assess median survival based on data presented in the literature.

Yttrium Internal Radiation Therapy for Liver Cancer

- h. Conclusion: In mCRC, 90Y-RE delivers high response rates, especially if used neoadjuvant to chemotherapy. In HCC, 90Y-RE with resin microspheres is significantly more effective than 90Y-RE with glass microspheres. The impact on survival will become known only when the results of phase III studies are published.

Other guidelines

- 1) **NCCN 2015**, hepatocellular carcinoma
 - a. Locoregional therapy should be considered in patients who are not candidates for surgical curative treatments, or as part of a strategy to bridge patients to other curative therapies.
 - b. Radioembolization (RE) with yttrium-90 is listed as a locoregional therapy
 - c. Listed as category 2B
 - d. Sorefenib is recommended as first line, with locoregional therapy second line in the majority of these cases
 - e. Evidence reviewed that yttrium-90 RE has been found to be safe and effective in the treatment of non-resectable cholangiocarcinoma
 - f. For HCC, ablation therapy should be first line, and locoregional therapy, including yttrium RE should only be considered when ablation is not feasible

Other policies

- 1) **Aetna 2014**
 - a. Covers yttrium SIRT for non-resectable primary HCC and for select, rare metastatic liver disease. Does not cover for most metastases to the liver, including colorectal carcinoma.
- 2) **Cigna 2006**
 - a. Covers yttrium SIRT for non-resectable primary HCC and for colorectal cancer metastatic to the liver

Summary: Based on limited data, yttrium-90 appears to have comparable impact on liver cancer and liver metastases as transarterial embolization. Trusted sources recommend utilization, in limited circumstances.

Utilization:

FFS reports 2 requests in the past year. Most CCOs report 0-1 request for yttrium-90 therapy in the past year.

HERC staff recommendation:

- 1) Add yttrium-90 radioembolization (CPT 79445) as a treatment to Line 320 CANCER OF LIVER

Left Ventricular Assist Devices as Destination Therapy

Question: should destination therapy be added as an indication for left ventricular assist devices (LVADs) on the Prioritized List?

Question source: HERC staff

Issue: LVADs are currently covered on the Prioritized List as a bridge to heart transplantation and as a bridge to recovery for severe heart failure. LVADs can also be used as destination therapy—treatment for severe heart failure when transplant is not an option for a patient. This indication for LVADs was discussed at two HOSC/HSC meetings in 2010, and destination therapy was not added as an indication due to concerns about the increased cost to the health plans from both increased patient demand/eligible patients and longer utilization. DMAP estimated that addition of LVADs as destination therapy would increase costs more than 1%.

Testimony was heard from Dr. Howard Song, cardiothoracic surgeon at OHSU, that LVADs are placed for patients with serious heart failure, and then the decision regarding heart transplant is addressed. At times, the patients with LVADs are not eligible for transplant and therefore the LVAD is used for destination therapy regardless of the OHP guidelines. He also felt that there was strong evidence that LVADs were much superior to optimal medical management of Class IV heart failure in terms of reducing mortality. Dr. Song argued that LVADs were more cost effective than indicated in the studies, as the newer generation models were more effective and the cost savings from avoiding hospitalization and other care for end stage heart failure patients on medical management is substantial.

In 2010, the HSC determined that more experience with LVADs should be obtained and better cost-effectiveness data should be published prior to adoption of LVADs as destination therapy on the Prioritized List.

In March, 2015, NICE published a new coverage guidance based on a December 2014 evidence review which recommended coverage of LVADs as destination therapy. This change in NICE policy was driven mainly by the substantive decreased in mortality seen in end stage heart failure patients with LVADs as compared to medical management.

Left Ventricular Assist Devices as Destination Therapy

Current Prioritized List status:

CPT code	Code description	Current Line(s)
33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle	86 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS 102 HEART FAILURE 267 ARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL HEART DISEASE Treatment: CARDIAC TRANSPLANT
33980	Removal of ventricular assist device, implantable intracorporeal, single ventricle	86,102,267
33981-33983	Replacement of ventricular assist device pump(s), implantable intracorporeal,	86,102,267
93750	Interrogation of ventricular assist device (VAD), in person, with physician or other qualified health care professional analysis of device parameters	86,102,267

GUIDELINE NOTE 18, VENTRICULAR ASSIST DEVICES

Lines 102,267

Ventricular assist devices are covered only in the following circumstances:

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

Ventricular assist devices are not covered for destination therapy.

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

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

Left Ventricular Assist Devices as Destination Therapy

HOSC minutes October, 2010

LVAD as destination therapy

Dr. Howard Song from OHSU Heart Transplantation Program gave a presentation on left ventricular assist devices (LVAD) as destination therapy. A patient, Jean Knospe from Salem, spoke on her experiences with long term LVAD therapy. The discussion centered around cost savings from the device. Saha was concerned about the newness of the technology. There is currently only 1 certified VAD program in Oregon (OHSU). Dodson was concerned about access for rural patients. Song and McKelvey reported that there are rural patients receiving VADs and that the rural physicians are able to care for this device. The device costs the same as a heart transplant. Olson pointed out that our current coverage is twice as expensive (payment for VAD and transplant).

Olson suggested having only CMS certified centers provide this treatment for OHP patients. Song stated that CMS has criteria for when patients should be given a VAD.

Saha suggested having the HRC look at this technology and bring a report to the HSC. Shaffer reported that the MED project reviewed VADs recently. Only one study has been done to date on the new generation of VAD devices with 120 patients. No children or adolescents were included in that trial. No cost-effectiveness data was found. McKelvey felt that the HSC already pays for this technology and therefore further research does not need to be done. There is not a huge group of patients who will demand this therapy if it becomes covered. Song indicated that there will be some newer studies published soon.

The decision was to have HSC staff review CMS criteria and the MED report and cost info and possible cost savings from rehospitalizations, etc. and come up with criteria/guideline to discuss in December.

Action:

HSC staff to review CMS coverage criteria and the MED report and any additional information found on cost information/possible cost savings. Staff to develop criteria/guideline for LVAD as destination therapy to discuss at the December meeting

HOSC minutes December, 2010

LVADs as destination therapy

Smits introduced the summary document reviewing the possible expansion of left ventricular assist devices (LVADs) for use as destination therapy. Dr. Howard Song from OHSU provided testimony.

Dr. Song noted that not covering LVADs for destination therapy created problems when patients are unable to receive a heart transplant due to donor shortages or when patients decide to simply keep the LVAD rather than pursue transplant.

There was discussion about whether LVADs as destination therapy was new technology. Coffman noted that CMS has covered LVADs for this indication since 2003, which included older LVAD technology which was less effective.

Concern was expressed on the part of the OHP health plans and DMAP that expanding the indications for LVAD use to destination therapy would greatly increase the number of patients receiving this expensive technology and therefore increase costs considerably.

Left Ventricular Assist Devices as Destination Therapy

Song stated that including Joint Commission certification as a qualification in the guideline would restrict the number of centers that would be available to place LVADs in the future. He did not think that this would lead to a "growth industry." Concern was raised that such restricted access could be problematic for rural patients. Song replied that the OHSU program (currently the only accredited program in Oregon) tries to ensure outreach to rural areas to train local providers/make sure support is there to allow access. Olson wondered which patients would not qualify for LVAD. Song replied that patients with right ventricular failure or other major organ failure or lack of social support would not qualify. Olson also wondered how many patients would access LVAD technology through Medicaid, given that many would end up on disability (Medicare). Song noted that many younger patients with LVADs are not disabled, and in fact are able to return to work. McKelvey stated that she felt that LVAD use would not increase much with allowing destination therapy, as OHP already covers LVADs for bridge to transplant, which frequently turns into destination therapy. She noted that the population that qualifies for LVADs given the proposed guideline would be quite small. Olson pointed out that the patients who would become eligible for LVADs as destination therapy are already costing the health plans a considerable amount of money in other health care costs.

Song was asked whether his program has any projected numbers for OHP patients who would receive LVADs if destination therapy was allowed. Song would anticipate possibly a 50% increase (7-8 total patients per year).

Price reported that 5 OHP patients a year have received LVADs as bridge to transplant in the past 2 years. Of the 5 patients given LVADs in 2010, 1 has elected to not be transplanted, 2 have not been listed for transplant yet, 1 is listed for transplant, and 1 died before transplant. In 2009, 5 patients received LVADs, and all were transplanted.

Shaffer expressed DMAPs concern with how much expansion there would be with destination therapy, the cost associated with this technology, and the limited evidence of effectiveness in current published literature for destination therapy. Dodson also indicated concern about lack of cost effectiveness data.

DMAP indicated that adding LVADs as destination therapy would lead to cost increases in the current contracts with the health plans. These rate increase estimates would not be ready until January, 2012. Therefore, DMAP could not implement coverage of LVADs as destination therapy until that time.

In terms of current knowledge of costs, Song indicated that after the initial hospitalization and procedure, the patient has costs for dressing changes (\$100/mo out of pocket), medications, and Coumadin monitoring. Price indicated that DMAP has paid for LVAD placement/hospital stay, as well as \$11,000 to set up at home. She did not have information on ongoing costs.

The group felt that there was not enough data on cost effectiveness, possible cost increases for OHP and anticipated numbers of patients who would use this technology.

The group felt that waiting until the August meeting to readdress this issue would not affect the implementation date of this technology if the decision was for coverage, given that DMAP cannot cover until January, 2012. Song will try to obtain cost data on patients who would qualify who do not receive LVADs (hospital costs, medications, etc.) to help the

Left Ventricular Assist Devices as Destination Therapy

HSC look at overall cost. He will also try to obtain overall health care costs after LVAD placement

Action:

Dr. Song and DMAP will try to obtain better cost figures for coverage of LVADs for destination therapy as well as medical care of patients who would qualify but do not receive LVADs. The HOSC will reconsider LVADs as destination therapy at their August, 2011 meeting.

Evidence review

- 1) **NICE 2014**, evidence review for LVADs for destination therapy (Available at <http://www.nice.org.uk/guidance/ipg516/evidence/ipg516-implantation-of-a-left-ventricular-assist-device-for-destination-therapy-in-people-ineligible-for-heart-transplantation-overview2>)
 - a. N=9 studies
 - i. 2795 patients from 1 registry, 2 randomised controlled trials, 1 non-randomised comparative study and 3 case series.
 - ii. Some possible overlap of patients between studies
 - iii. Longest follow up period was 4 yrs
 - b. Survival
 - i. RCT of 129 patients (68 LVAD, 61 medical management), survival rates were 23% and 8% respectively at 2-year follow-up (p=0.09). In a longer follow-up of the same study, survival rates were 16% in the pulsatile-flow LVAD group and 8% in the optimal medical management group at 4-year follow-up (no p value reported).
 - ii. In a registry of 1287 patients treated by continuous-flow (n=1160) or pulsatile-flow (n=127) LVADs survival rates were 76% and 68% respectively at 1-year follow-up (p<0.0001). At 2-year follow-up, survival rates were 67% in the continuous-flow group and 45% in the pulsatile-flow group (p<0.0001). In the same study, survival to device exchange or death secondary to device malfunction was 96% in the continuous-flow group and 83% in the pulsatile-flow group at 1-year follow-up (no p value reported).
 - c. Quality of life
 - i. RCT of 200 patients, mean MLWHF scores (scores range from 0 to 105 with lower scores indicating better quality of life) improved from 75.4 to 34.1 (p<0.001) and 76.1 to 44.4 (p<0.001) respectively at 1-year follow-up (p value between groups=0.03). In the same study, mean overall KCCQ scores (scores range from 0 to 100 with higher scores indicating better quality of life) improved from 27.4 to 65.9 (p<0.001) in the continuous-flow group and from 46.5 to 59.1 (p<0.001) in the pulsatile-flow group at 1-year follow-up (p value between groups=0.06).
 - ii. RCT of 129 patients treated by pulsatile-flow LVAD destination therapy or optimal medical management, mean MLWHF scores (scores range from 0 to 105 with lower scores indicating better quality of life) improved from 75 to 41 and 75 to 58 respectively at 1-year follow-up (p value between groups=0.11).

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- d. Adverse events
 - i. Death due to device failure or malfunction: ranged from less than 1% to 2% of patients
 - ii. LVAD related infection: reported in 28-36% of patients
 - iii. Local infection: reported in 46-49% of patients
 - iv. Pump replacement: reported in 9-34% of patients at 2 yrs
 - v. Pump thrombosis: reported in 4-5% of patients
 - vi. Bleeding that needed blood transfusion: reported in 23-76% of patients at 2 years
 - vii. Neurologic events: Stroke was reported in 7-12% of patients with up to 2 yrs of follow up
 - viii. Right heart failure: reported in 20-27% of patients with LVADs
 - ix. Respiratory failure: Reported in 38-41% of patients
 - x. Renal failure: reported in 16-24 % of patients
 - xi. Cardiac arrhythmia: reported in 56-59% of patients
 - xii. Sepsis: reported in 36-44% of patients
- 2) **Rector 2012**, VA meta-analysis of LVADs for destination therapy
 - a. Found moderate strength evidence that the newer generation LVAD devices provided better patient outcomes than older devices
 - b. Insufficient evidence was found to refine patient or site criteria for best outcomes from LVAD devices
 - c. Based on a single industry funded analysis, the cost effectiveness of the current generation LVAD as destination therapy was found to be approximately \$200,000 per QALY, with strength of evidence for this estimate found to be low
- 3) **MED 2010, review of VADs**
 - a. Results based mainly on one RCT (N=129) and two registry based studies (N=377, 100)
 - b. Moderate quality evidence that LVAD improves survival when used as destination therapy (DT). A statistically significant reduction in the risk of death attributable to the use of LVAD in patients who are ineligible for transplantation was found in the one good quality RCT. Median survival was 408 days in the LVAD arm and 150 days in the OMM arm, a difference of 258 days. A poor-quality nonrandomized trial and analysis of two registries reported survival results consistent with the RCT.
 - c. Moderate-quality evidence has shown LVAD to substantially improve disease-specific and generic functional status and suggests small improvements in other QOL measures.
 - d. Serious adverse events, both medical events and device failure, are common in patients undergoing chronic support with LVAD and are at least partially attributable to the device according to moderate-quality evidence from the randomized controlled trial (RCT). Device failure or malfunction is also common, but reported experiences suggest that it does not contribute substantially to mortality. According to the best available evidence, patients experience on average approximately six serious adverse events per year.
 - e. Evidence of cost-effectiveness is of low quality and included two disparate ICERs.
 - i. According to two U.S. cost-consequence studies, the cost for initial hospital care associated with LVAD implantation for DT is \$137,000 to \$164,000, and lifetime hospital costs for readmission, according to one of the studies, is \$126,000 (2009 values).
 - ii. A cost-effectiveness study from the British payer perspective, comparing LVAD with OMM, reported an ICER of £170,161/QALY over a five-year time horizon.

Left Ventricular Assist Devices as Destination Therapy

- iii. An older Canadian study reported ICERs of \$46,000/QALY to \$55,000/QALY (2006 U.S. values) for a 12-year time horizon.
- f. There was no evidence pertaining to LVAD as DT in children or adolescents. 80-92% of patients in the included studies were men

Cost effectiveness studies

1) Long 2014

- a. model for life expectancy and cost effectiveness of medical management vs heart transplant vs LVAD as bridge to transplant vs LVAD as destination therapy
 - i. Medical management: life expectancy: 1.1 yrs (39% survival to 1 yr)
 - ii. Heart transplant after medical therapy: life expectancy 8.5 yrs, cost \$97,000/QALY
 - iii. LVAD followed by heart transplant: life expectancy 12.3 years, cost \$226,000/QALY (authors note cost/QALY much reduced with longer anticipated wait times prior to transplant)
 - iv. LVAD as destination therapy: life expectancy 4.4 yrs, \$202,000/QALY
 - v. LVAD intended for heart transplant but converted to destination therapy: \$175,000/QALY (no survival mentioned)
 - vi. Projected 5 yr survival is essentially the same for heart transplant vs LVAD as destination therapy (see figure 2)
 - i. **Conclusions**—Under most scenarios, orthotopic heart transplantation (OHT) prolongs life and is cost effective in eligible patients. Bridge to transplant-LVAD is estimated to offer >3.8 additional life-years for patients waiting ≥ 6 months, but does not meet conventional cost-effectiveness thresholds. Destination therapy-LVAD significantly improves life expectancy in OHT-ineligible patients. However, further reductions in adverse events or improved quality of life are needed for destination therapy-LVAD to be cost effective.

2) Rogers 2012

- a. Modeling study for continuous flow LVAD vs optimal medical management
- b. Compared with medically managed patients, continuous-flow LVAD patients had higher 5-year costs (\$360,407 versus \$62,856), quality-adjusted life years (1.87 versus 0.37), and life years (2.42 versus 0.64). The incremental cost-effectiveness ratio of the continuous-flow device was \$198 184 per quality-adjusted life year and \$167 208 per life year. This equates to a 75% reduction in incremental cost-effectiveness ratio compared with the \$802 700 per quality-adjusted life year for the pulsatile-flow device.
- c. **Conclusions**—The cost-effectiveness associated with continuous-flow LVADs for destination therapy has improved significantly relative to the pulsatile flow devices. This change is explained by significant improvements in survival and functional status and reduction in implantation costs.

Coverage guidances

1) NICE 2015, LVADs for destination therapy

- a. Current evidence on the efficacy and safety of the implantation of a left ventricular assist device for destination therapy in people ineligible for heart transplantation is adequate to support the use of this procedure

Left Ventricular Assist Devices as Destination Therapy

Other policies

- 1) **CMS 2010:** The evidence is adequate to conclude that VAD implantation as destination therapy improves health outcomes and is reasonable and necessary when the device has received FDA approval for a destination therapy indication and only for patients with New York Heart Association (NYHA) Class IV end-stage ventricular heart failure who are not candidates for heart transplant and who meet all of the following conditions:
 - a. Have failed to respond to optimal medical management (including beta-blockers, and ACE inhibitors if tolerated) for at least 45 of the last 60 days, or have been balloon pump dependent for 7 days, or IV inotrope dependent for 14 days; and,
 - b. Have a left ventricular ejection fraction (LVEF) < 25%; and,
 - c. Have demonstrated functional limitation with a peak oxygen consumption of ≤ 14 ml/kg/min unless balloon pump or inotrope dependent or physically unable to perform the test.
- 2) Aetna and Regence and Anthem BCBS cover LVAD as destination therapy with Medicare criteria

HERC staff summary:

LVAD as destination therapy prolongs survival for patients with end stage heart failure compared to optimal medical management by a factor of approximately 4 (0.64 to 1.1 yr \rightarrow 2.4 to 4.4 yr). Quality of life measures are significantly better with LVAD as destination therapy compared to optimal medical management for end stage heart failure. Heart transplantation is significantly better than LVAD for both survival length and quality of life; however, the supply of donor hearts is limited.

The cost/QALY of LVAD as destination therapy is approximately \$200,000. However, the anticipated cost/QALY of LVAD followed by heart transplant is actually higher, explained by the cost/complications of two major surgical procedures vs one. The cost/QALY of LVAD as a destination therapy has been significantly reduced with newer versions of the technology.

Left Ventricular Assist Devices as Destination Therapy

HERC Staff Recommendations:

- 1) Adopt LVADs for destination therapy
 - a. Modify GN1 as shown below

GUIDELINE NOTE 18, VENTRICULAR ASSIST DEVICES

Lines [86](#), [102](#), [267](#)

Ventricular assist devices are covered ~~only in the following circumstances: 1) as a bridge to cardiac transplant; 2) as treatment for pulmonary hypertension when pulmonary hypertension is the only contraindication to cardiac transplant and the anticipated outcome is cardiac transplant; or, 3) as a bridge to recovery.~~ and as destination therapy.

~~Ventricular assist devices are not covered for destination therapy.~~

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

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

When used as destination therapy, patients must

- 1) have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure), AND
- 2) not be candidates for heart transplantation, AND
- 3) meet all of the following conditions:
 - a. Have failed to respond to optimal medical management, including beta-blockers and ACE inhibitors (if tolerated) for at least 45 of the last 60 days, or have been balloon pump dependent for 7 days, or IV inotrope dependent for 14 days; and
 - b. Have a left ventricular ejection fraction (LVEF) <25%; and
 - c. Have demonstrated functional limitation with a peak oxygen consumption of <14 ml/kg/min unless balloon pump or inotrope dependent or physically unable to perform the test.

Varicose Veins

Question: should additional treatments for varicose veins be added to the covered line with these diagnoses?

Question source: Senator Winters

Issue: Currently, only varicose veins with ulceration or infection/inflammation are on covered lines on the Prioritized List, on lines 383 CHRONIC ULCER OF SKIN and 209 SUPERFICIAL ABSCESSSES AND CELLULITIS. These lines do not contain most (383) or any (209) of the minimally invasive therapies for varicose veins, which can be done in the less expensive outpatient setting. The more expensive therapies, such as vein stripping, are covered on 383, but not 209. Senator Winters expressed concern about the limited coverage of outpatient treatments for varicose veins.

Conservative therapy includes leg elevation and compression garments.

Minimally invasive treatments for varicose veins which can be done in the office setting:
sclerotherapy (CPT 36470, 36471)
endovenous ablation therapy (CPT 36475, 36476), includes laser therapy and radiofrequency ablation
stab phlebectomy (CPT 37765, 37766)
Echosclerotherapy (HCPCS S2202)

On review of the current coding on the Prioritized List for varicose veins, HERC staff identified several additional issues:

- 1) ICD-9 454.1 (Varicose veins of lower extremities with inflammation) is not used for varicose veins causing infection. This code is considered synonymous with stasis dermatitis, a benign skin change caused by chronic vein insufficiency in the legs. It does not belong on a covered line (209)
 - a. Line 209 does not have any treatment codes for varicose veins and therefore ICD-9 454.1 has no appropriate treatment pairings currently
- 2) Line 1 Pregnancy has a series of varicose vein diagnosis codes, but no treatment codes for pairing
- 3) Some treatment codes are missing from line 649 (varicose veins without complication)

Varicose Veins

ICD-9 code	Code Description	Location	Procedures
454.0	Varicose veins of lower extremities with ulcer	383 CHRONIC ULCER OF SKIN	Compression dressings, stab phlebectomy, ligation, division, and/or excision of varicose vein
454.1	Varicose veins of lower extremities with inflammation	209 SUPERFICIAL ABSCESSSES AND CELLULITIS	None
454.2	Varicose veins of lower extremities with ulcer and inflammation	383	See 454.0
454.8	Varicose veins of lower extremities with other complications	648 VARICOSE VEINS OF LOWER EXTREMITIES WITHOUT ULCER OR INFLAMMATION	All but stab phlebectomy
454.9	Asymptomatic varicose veins	648	See above
671.0x	Varicose veins of legs complicating pregnancy and the puerperium	1 PREGNANCY	None
671.1x	Varicose veins of vulva and perineum complicating pregnancy and the puerperium	1 PREGNANCY	None

ICD-10 Code	Code Description	Location	Treatments
I83.0xx	Varicose vein with ulcer	383	See 454.0
I83.1x	Varicose veins with inflammation	522 PHLEBITIS AND THROMBOPHLEBITIS, SUPERFICIAL	None
I83.2xx	Varicose vein with both ulcer and inflammation	383	See 454.0
I83.81x	Varicose veins with pain	648	See 454.8
I83.89x	Varicose veins with other complications	648	See 454.8
I83.9x	Asymptomatic varicose veins	648	See 454.8
O22.0x	Varicose veins of lower extremity in pregnancy	1 PREGNANCY	None

Varicose Veins

CPT code	Code Description	Location
29582-29584	Application of multi-layer compression system, lower and upper extremities	383 427 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT 525 POSTTHROMBOTIC SYNDROME 579 LYMPHEDEMA 648
36470	Injection of sclerosing solution; single vein	525 553 SUBLINGUAL, SCROTAL, AND PELVIC VARICES 648
36471	multiple veins, same leg	525, 648
36475-36479	Endovenous ablation therapy of incompetent vein, extremity	525, 648
37500	Vascular endoscopy, surgical, with ligation of perforator veins, subfascial (SEPS)	83 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
37700	Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions	383,525,648
37718	Ligation, division, and stripping, short saphenous vein	383,525,648
37722	Ligation, division, and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below	383,525,648
37735	Ligation and division and complete stripping of long or short saphenous veins with radical excision of ulcer and skin graft	83, 383,525,648
37760	Ligation of perforator veins, subfascial, radical (Linton type), including skin graft, when performed, open, 1 leg	83,383,525,648
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg	83,383,525,648
37765	Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions	383
37766	more than 20 incisions	383, 525, 648

Varicose Veins

37785	Ligation, division, and/or excision of varicose vein cluster(s), 1 leg	83,383,525,648
37780	Ligation and division of short saphenous vein at saphenopopliteal junction	383, 525, 648
S2202	Echosclerotherapy	Services Recommended for Non-Coverage Table

Varicose Veins

Background:

From the December 2003 HOSC minutes:

Regarding code 37765, stab phlebotomy, Dr. Glass explained that this procedure is used only for small veins, which usually are only problematic cosmetically. Therefore, it was agreed to add this code only to the lower varicose vein line, 688.

From the September 23, 2004 HOSC minutes:

Varicose Veins

Dr. Little stated that this issue was raised by the medical directors, who expressed concern that varicose veins were covered on Line 354, Chronic ulcer of skin, unless they are asymptomatic. She recommends moving 454.8, varicose veins of lower extremities with other complications (edema, pain, swelling), and possibly 454.1, varicose veins of lower extremities with inflammation, from Line 354 to 688, Asymptomatic varicose veins. Dr. Walsh noted that the title of Line 688 would need to be changed, to eliminate the word asymptomatic. Dr. Saha stated that patients with severe venous stasis dermatitis without an ulcer should have access to medical therapy to prevent ulceration. Dr. Mangum asked if this situation would be covered as a co morbid condition, and Dr. Turek thought not. Dr. Saha suggested that these codes be moved to a medical therapy line, but not one that included vein-stripping codes. After discussion, it was agreed to move 454.1 to Line 355, Abscess and Cellulitis, and move 454.8 to line 688. Dr. Little asked the Subcommittee to reconsider the prior actions of the morning concerning post-phlebotic syndrome. For consistency, the Subcommittee agreed to move those codes with inflammation to the cellulitis line, keep those codes with ulcer on Line 354 and leave those codes with "other" complications on Line 688.

MOTION: Move ICD-9-CM codes 454.1, 459.12 and 459.32 to Cellulitis Line; move 454.8 to Line 688; delete 459.11, 459.13, 459.31 and 459.33 from Line 688; delete 459.19 and 459.39 from Line 354. Motion carries 4-0.

From the June 2009 HOSC minutes

Varicose veins

Smits reviewed a suggestion to change the treatment codes associated with varicose vein diagnoses, as well as previous deliberations on these treatments from HOSC minutes.

The

HOSC did not change any treatments associated with varicose veins.

From the June 2010 HOSC minutes

Keep 459.2 on Line 655 Varicose Veins Of Lower Extremities Without Ulcer Or Inflammation.

Varicose Veins

Evidence

- 1) **Cochrane 2009**, sclerotherapy vs surgery for varicose veins
 - a. N=9 RCTs
 - b. the trend was for sclerotherapy to be evaluated as significantly better than surgery at one year; after one year (sclerotherapy resulted in worse outcomes) the benefits with sclerotherapy were less, and by three to five years surgery had better outcomes. The data on cost-effectiveness was not adequately reported.
 - c. **Authors' conclusions** There was insufficient evidence to preferentially recommend the use of sclerotherapy or surgery. There needs to be more research that specifically examines both costs and outcomes for surgery and sclerotherapy
- 2) **Hamdan 2012**, JAMA review of treatments for varicose veins
 - a. Surgical therapy was compared with compression in a randomized controlled trial in patients with uncomplicated varicose veins. The REACTIV trial randomized 246 patients to lifestyle changes and compression therapy vs surgical stripping and phlebectomy. Surgery resulted in significant increase in quality of life and anatomical and symptom relief.
 - b. A number of trials have looked at surgery vs endovenous therapies and have shown an early postoperative advantage with endovenous therapy, often balanced out over the course of the next several months. Local anesthesia, office-based practice, and rapid recovery without incisions account for patient preference strongly favoring endovenous techniques over surgery

Trusted sources:

1) **NICE 2013**

- a. Consider treatment of varicose veins if
 - i. Symptomatic (typically pain, aching, discomfort, swelling, heaviness and itching).
 - ii. Cause skin changes such as pigmentation or eczema
 - iii. Cause venous insufficiency
 - iv. Cause superficial vein thrombosis
 - v. Cause ulceration
- b. Treatments to consider
 - i. Offer endothermal ablation
 - ii. Endovenous laser treatment of the long saphenous vein
 - iii. If endothermal ablation is unsuitable, offer ultrasound-guided foam sclerotherapy (this is included in the procedure called endovenous ablation therapy)
 - iv. If ultrasound-guided foam sclerotherapy is unsuitable, offer surgery.
 - v. Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable.

Clinical Practice Guidelines:

- 1) **Gloviczki 2011**, Society for Vascular Surgery clinical practice guidelines for varicose veins
 - a. We suggest compression therapy for patients with symptomatic varicose veins (GRADE 2C) but recommend against compression therapy as the primary treatment if the patient is a candidate for saphenous vein ablation (GRADE 1B)

Varicose Veins

- b. We recommend compression therapy as the primary treatment to aid healing of venous ulceration (GRADE 1B). To decrease the recurrence of venous ulcers, we recommend ablation of the incompetent superficial veins in addition to compression therapy (GRADE 1A).
- c. For treatment of the incompetent great saphenous vein (GSV), we recommend endovenous thermal ablation (radiofrequency or laser) rather than high ligation and inversion stripping of the saphenous vein to the level of the knee (GRADE 1B).
- d. We recommend phlebectomy or sclerotherapy to treat varicose tributaries (GRADE 1B) and suggest foam sclerotherapy as an option for the treatment of the incompetent saphenous vein (GRADE 2C).
- e. We recommend against selective treatment of perforating vein incompetence in patients with simple varicose veins (CEAP class C2; GRADE 1B), but we suggest treatment of pathologic perforating veins (outward flow duration >500 ms, vein diameter >3.5 mm) located underneath healed or active ulcers (CEAP class C5-C6; GRADE 2B).

Indications for treatment of varicose veins by major insurers

1) Aetna 2015

- a. Intractable ulceration
- b. Recurrent hemorrhage or hemorrhage requiring blood transfusion
- c. The following if symptoms persist following 3 months of prescription compression garments and analgesic therapy:
 - i. Recurrent superficial thrombophlebitis; *or*
 - ii. Severe and persistent pain and swelling interfering with activities of daily living and requiring chronic analgesic medication

2) Anthem BCBS 2015

- a. Symptoms of venous insufficiency or recurrent thrombophlebitis (including but not limited to: aching, burning, itching, cramping, or swelling during activity or after prolonged sitting) which:
 - i. are interfering with activities of daily living; **and**
 - ii. persist despite appropriate non-surgical management, for no less than 6 weeks, such as leg elevation, exercise and medication; **and**
 - iii. persist despite a trial of properly fitted gradient compression stockings for at least 6 weeks**or**
- b. There is ulceration secondary to stasis dermatitis;
- c. There is hemorrhage from a superficial varicosity

3) Medicare 2014

- a. Medicare will consider interventional treatment of varicose veins (sclerotherapy, ligation with or without stripping, and endovenous radiofrequency or laser ablation) medically necessary if the patient remains symptomatic after a six-week trial of conservative therapy. The components of the conservative therapy include, but are not limited to:
 - i. weight reduction,
 - ii. a daily exercise plan,
 - iii. periodic leg elevation, and
 - iv. the use of graduated compression stockings.

Varicose Veins

- b. The conservative therapy must be documented in the medical record. Inability to tolerate compressive bandages or stockings and the reason for such intolerance must be documented in the medical record.
- c. The patient is considered symptomatic if any of the following signs and symptoms of significantly diseased vessels of the lower extremities are documented in the medical record:
 - i. stasis ulcer of the lower leg, as above,
 - ii. significant pain and significant edema that interferes with activities of daily living,
 - iii. bleeding associated with the diseased vessels of the lower extremities,
 - iv. recurrent episodes of superficial phlebitis,
 - v. stasis dermatitis, or
 - vi. refractory dependent edema.

HERC Staff Summary:

Minimally invasive therapies for varicose veins appear to be as effective as surgical vein stripping, but at lower cost due to requiring only local anesthesia and occurring in the outpatient treatment settings. Most insurers and trusted evidence sources (NICE) cover varicose veins for more indications that currently included on the Prioritized List.

Varicose Veins

HERC Staff Recommendations:

- 1) Move ICD-9 454.1 (Varicose veins of lower extremities with inflammation) from line 209 SUPERFICIAL ABSCESSSES AND CELLULITIS to line 522 PHLEBITIS AND THROMBOPHLEBITIS, SUPERFICIAL
 - a. No appropriate CPT codes appear on line 209
 - b. This ICD-9 code does not code for infection, as was previously thought in its placement
 - c. Matches placement of ICD-10 I83.1x (Varicose veins with inflammation)
- 2) Add CPT 29582-29584, 36470-36479, 37500, 37700-37761, 37765, 37766, 37785, 37780 to line 522 PHLEBITIS AND THROMBOPHLEBITIS, SUPERFICIAL
 - a. No therapies there currently to pair with varicose vein with inflammation diagnoses
- 3) Do not add treatment codes to line 1 PREGNANCY
 - a. Generally treated only with non-prescription support hose; usually resolves after pregnancy
- 4) Add CPT 37765 (Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions) to line 648 VARICOSE VEINS OF LOWER EXTREMITIES WITHOUT ULCER OR INFLAMMATION
- 5) Add CPT 36470 and 36471 (Injection of sclerosing solution) and 36475-36479 (Endovenous ablation therapy of incompetent vein, extremity) to line 383 CHRONIC ULCER OF SKIN
 - a. Minimally invasive therapies are as effective as the surgical treatments included on this line at lower cost
- 6) Change the title of line 648 to VARICOSE VEINS OF LOWER EXTREMITIES WITHOUT ULCER OR ~~INFLAMMATION~~ OTHER MAJOR COMPLICATION
- 7) Discuss adding prophylactic treatment for varicose veins prior to development of complications and/or adding additional indications for treatment such as hemorrhage or chronic pain

Developmental Coordination Disorder

Question: Should developmental coordination disorder be removed from the Prioritized List?

Question source: Alison Little, MD, MPH, OHP Medical Director

Issue: Developmental co-ordination disorder (ICD-9 315.4) is also known as clumsiness syndrome, dyspraxia syndrome, or specific motor development disorder. This condition has been reviewed several times by the HSC/HERC. The last review of this code was part of a large scale review of codes on the Excluded List by DMAP and HERC staff, at which time it was moved from the Excluded List to two dysfunction lines. This review was not in-depth and did not include a review of the evidence or effectiveness of treatment. The medical plans are asking that it be replaced on the Non-Covered List.

Currently, 315.4 is currently on lines 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS and 381 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION. The equivalent ICD-10 code, F82 (Specific developmental disorder of motor function) is also on these lines. ICD-10 F82 has the same sub-diagnoses (clumsy child syndrome, developmental coordination disorder, developmental dyspraxia) as ICD-9 315.4.

HSC/HERC history

HOSC Minutes August 24, 1995

Deatherage presented the recommendation of the Task Force on Developmental Delay. She explained the process that had been followed and how consensus had been reached. The Task Force's recommendation was that 315.4X be added to the Posture and Movement line with criteria specifying that for age 3 and under it is an appropriate diagnosis and for ages greater than 3, the use is diagnostic and should be time limited. The Task Force also recommended a prior authorization protocol be adopted requiring documentation of expected outcomes after a specific period of treatment for 3 and under and for those over three, that authorization be for no more than 120 days. These recommendations were adopted by the Subcommittee.

September 23, 2004 HOSC Minutes

VII. Coordination Disorder Guideline - Alison Little

Dr. Little explained that the guideline for Line 336 (in packet), had been attached to that line for many years, and that she queried Dr. Kitchen about its origin, who did not recall. The diagnosis, 315.4, is also known as developmental coordination disorder, clumsiness syndrome, dyspraxia syndrome and specific motor development disorder. The current guideline for physical therapy is in conflict with this guideline.

MOTION: Delete the Coordination Disorder guideline from Line 336. Motion carries 4-0.

HOSC Minutes August 12, 2010

Dyspraxia

Smits introduced a summary document regarding dyspraxia. The discussion centered around whether there were effective treatments for dyspraxia syndrome (315.4), and the decision was there were not, and that the diagnosis was hard to define. However, the group felt that dyspraxia (781.3) should be kept on the Signs and Symptoms list to allow work up for a cause. There are no treatments included for diagnoses on the signs and symptoms list.

Developmental Coordination Disorder

- 1) Advise DMAP to keep dyspraxia (781.3) on the Signs and Symptoms List.
- 2) Remove dyspraxia syndrome (315.4) from line 317 Neurological Dysfunction In Posture And Movement Caused By Chronic Conditions. Advise DMAP to place dyspraxia syndrome (315.4) on the Never Covered List.

November 2014 VBBS Minutes DMAP/HSC Code Clean Up

Smits introduced an Excel spreadsheet with recommendations for placement of CPT codes which currently are duplicated on several lists or are otherwise in need of revision. The supplemental issues Word document was also reviewed. There was no discussion; the subcommittee accepted the recommendations as presented.

HERC Staff Recommendation

- 1) Remove ICD-9 315.4 (developmental coordination disorder, clumsiness syndrome, dyspraxia syndrome, or specific motor development disorder) and ICD-10 F82 (Specific developmental disorder of motor function) from lines 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS and 381 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
Place ICD-9 315.4 and ICD-10 F82 on the DMAP "Undefined Conditions File"

Unspecified Developmental Diagnoses

Question:

- 1) Should ICD-9 315.9 (Unspecified delay in development) continue to be on the Prioritized List?
- 2) Should ICD-9 348.9 (Unspecified condition of brain) continue to be on the Prioritized list?

Question source: Alison Little, MD, OHP medical director

Issue: ICD-9 315.9 is currently on 2 dysfunction lines. The ICD-10 equivalents are on the Recommended for Non-Coverage Table: F89 (Unspecified disorder of psychological development) and F81.9 (Developmental disorder of scholastic skills, unspecified). The other codes in the 315 series specify various learning disorders.

ICD-9 348.9 is currently on all 4 dysfunction lines. The ICD-10 equivalent, G93.9 (Disorder of brain, unspecified) is on the Recommended for Non-Coverage Table. ICD-9 348.9 has many subdiagnoses, including cerebellar deficiency syndrome, lesion of brain, and mass lesion of brain. However, most of conditions can be coded with other, more specific ICD-9 codes. The other subdiagnoses include disorder of brain or non-specific brain syndrome.

There is no mention of these codes in the HOSC minutes.

From Dr. Little:

One [code] that is being used is 315.9, unspecified delay in development. Any toddler who is below the median in developmental tasks is qualifying for 30 visits of OT.

I am seeing lots of sensory integration disorder, and because it doesn't have a code (that I have been able to find), it comes in with 348.9, unspecified condition of the brain, as do many vague, mild developmental delays. It is currently on all the dysfunction lines.

From Dr. John Kolsbun, Allcare

We discussed this situation within AllCare. We have found that these two codes are being utilized for payment for a wide range of conditions, many of which are clearly not intended to be paid for. Our feeling at AllCare is that these two codes could be eliminated, and that if a member is truly in need of supplies or services, that more appropriate coding can be utilized to get payment for these services.

HERC staff recommendations:

- 1) Remove ICD-9 315.9 (Unspecified delay in development) from lines 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS and 381 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
 - a. Place ICD-9 315.9 on the DMAP "Undefined" List
- 2) Remove ICD-9 348.9 (Unspecified condition of brain) from lines 75 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES, 297, 349 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS and 318

Place ICD-9 348.9 on the DMAP "Undefined" List

Ventral Hernia Guideline Issue Summary

Question: How should the complicated hernia guideline be modified with regard to ventral hernias with obstruction?

Question source: Gael Martin, Government Program Supervisor for Health Care Services, Moda Health

Issue:

Guideline note 24, which defines complicated hernias, is confusing about the intent with regard to ventral hernias. The goal of excluding ventral hernias from the language was because many of them are incarcerated (irreducible) by definition. For ventral hernias, incarceration is common and is not dangerous; in contrast, for many other types of hernias, incarceration is a predisposing step toward obstruction and gangrene. If a ventral hernia were to somehow cause obstruction or gangrene, this would, of course, be intended for coverage.

Current Prioritized List Status

Line: 172

Condition: COMPLICATED HERNIAS; UNCOMPLICATED INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER;

PERSISTENT HYDROCELE (See Guideline Notes 24,63,64,65)

Treatment: REPAIR

ICD-9: 550.00-550.93,551.00-551.29,551.8-551.9,552.00-552.29,552.8-552.9,603.0,603.8-603.9

CPT: 44050,44120,49491-49572,49582,49587,49590,49650-49659,55040-55060,64505-

64530,96127,98966-98969,

99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99412,99429-99449,99468-

99480,99487-99498,99605-99607

HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467

Line: 530

Condition: UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN INGUINAL HERNIA IN CHILDREN AGE 18

AND UNDER OR DIAPHRAGMATIC HERNIA) (See Guideline Notes 64,65)

Treatment: REPAIR

ICD-9: 550.90-550.93,553.00-553.29,553.8-553.9

CPT: 44050,49250,49505,49520,49525-

49550,49555,49560,49565,49568,49570,49580,49585,49590,49650-49659,

55540,96127,98966-98969,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-

99412,99429-99449,99468-99480,99487-99498,99605-99607

HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467

GUIDELINE NOTE 24, COMPLICATED HERNIAS

Line 172

Complicated hernias (excluding ventral hernias) are included on this line if they are incarcerated (defined as non-reducible by physical manipulation) or have symptoms of obstruction and/or strangulation. Chronic incarceration that does not place the patient at risk for impending strangulation (e.g. such as a large ventral hernia with loss of domain), is included on Line 530

Ventral Hernia Guideline Issue Summary

UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER OR DIAPHRAGMATIC HERNIA).

Line 172 ventral hernia ICD 10 codes

Code	Code description
K43.6	Other and unspecified ventral hernia with obstruction, without gangrene
K43.7	Other and unspecified ventral hernia with gangrene

Line 530 ventral hernia ICD 10 code

Code	Code Description
K43.9	Ventral hernia without obstruction or gangrene

Recommendations:

1) **Modify Guideline Note 24 as follows:**

GUIDELINE NOTE 24, COMPLICATED HERNIAS

Line 172, [530](#)

Complicated hernias (~~excluding ventral hernias~~) are included on ~~this line~~ [Line 172](#) if they ~~are incarcerated (defined as non-reducible by physical manipulation) or have~~ [cause](#) symptoms of obstruction and/or strangulation. ~~Chronic incarceration that does not place the patient at risk for impending strangulation (e.g. such as a large ventral hernia with loss of domain), is included on Line 530 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER OR DIAPHRAGMATIC HERNIA).~~ [Incarcerated hernias \(defined as non-reducible by physical manipulation\) are also included on Line 172, excluding ventral hernias. Incarcerated ventral hernias are included on Line 530, because the chronic incarceration of large ventral hernias does not place the patient at risk for impending strangulation.](#)

2) Rename Line 530 UNCOMPLICATED HERNIA (OTHER THAN INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER OR DIAPHRAGMATIC HERNIA); ~~AND~~ [INCARCERATED](#) VENTRAL HERNIA

Other Penile Anomalies

Question: What conditions coded by ICD-9 752.69 (Other penile anomalies) should be covered and what restrictions on any of these diagnoses should be made?

Question source: Allison Little, MD MPH, OHP medical director

Issue: ICD-9 752.69 as many subdiagnoses, some of which are medically important and some are not. This code is currently found on line 438 HYPOSPADIAS AND EPISPADIAS. The ICD-10 equivalent is Q55.69 (Other congenital malformation of penis) which is also found on line 438. Other congenital or acquired conditions of the penis, such as congenital chordee and hidden penis, are found on line 438 and have guidelines which specify when repair is covered.

Many of the subdiagnoses under ICD-9 752.69 have unique codes in ICD-10. These codes were generally placed on line 438 HYPOSPADIAS AND EPISPADIAS and line 667 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY. There is currently no guideline note delineating when these codes should be included on the upper or lower line.

Subdiagnoses of ICD-9 752.69

Diagnosis	ICD-10 Code	ICD-10 code Placement
Aplasia of penis	Q55.5 Congenital absence and aplasia of penis	438 HYPOSPADIAS AND EPISPADIAS
Congenital absence of penis	Q55.5	438
Congenital anomaly of penis	Q55.69 Other congenital malformation of penis	438
Congenital familial idiopathic priapism		
Congenital hypoplasia of penis	Q55.62 Hypoplasia of penis	667 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
Congenital lateral curvature of penis	Q55.61 Curvature of penis (lateral)	438 667
Congenital penile adhesion		
Congenital penile torsion	Q55.63 Congenital torsion of penis	438 667
Diphallus		
Finding of appearance of penis		
Hooded penis		
Paraspadias	Q54.9 Hypospadias, unspecified	438 667
Rotated penis		
Short preputial frenulum		
Webbed penis		

The specific medical director question which resulted in this review regarded congenital penile torsion. In this anomaly, the penile shaft is rotated. In one review, repair of this anomaly was only recommended if accompanied by congenital chordee or hypospadias. Otherwise, repair

Other Penile Anomalies

was felt to be cosmetic and appeared to have no relation to penile function. Congenital penile torsion has its own code in ICD-10 (Q55.63).

Priapism (ICD-9 607.3) is located on line 331 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION.

Utilization:

During CY 2013 there were 3792 units of service billed for CCO/MCO vs 123 for FFS, representing 317 unique individuals. \$1.1 million was billed, with about \$325,000 allowed.

Current guidelines for conditions on line 483

GUIDELINE NOTE 73, CONGENITAL CHORDEE

Line 438

Congenital chordee (ICD-10-CM Q54.4/ICD-9-CM 752.63) is included on Line 438 only for severe cases (35 degrees of curvature or greater) and for all cases associated with hypospadias.

GUIDELINE NOTE 89, REPAIR OF HIDDEN PENIS

Line 438

Repair of hidden penis (ICD-10-CM Q55.64/ICD-9-CM 752.65) is only covered if the patient has documented urinary retention, repeated urinary tract infections, meatitis, or balanitis.

Expert Input: Dr. Steven Skoog, OHSU Pediatric Urology

Aplasia of the penis requires repair, but occurs very rarely. Hypoplasia should be covered if associated with hypospadias. Priapism is a surgical emergency, regardless of the cause, and must be treated. The diagnoses that results in curvature can result in voiding problems. Lateral curvature diagnoses should be covered if more than 35 degrees of curvature or if the child has voiding issues. Ventral curvature is chordee and should have the requirements in the current guideline. Torsion should be covered if more than 60 degree or if associated with chordee or hypospadias. Penile adhesions are related to the foreskin. The congenital type is normal and self-resolves. Acquired adhesions are related to circumcisions, dense adhesions results in curvature and can lead to infection. Treat adhesions with topical steroids, rarely a surgical issue. Hooded penis/concealed penis/hidden penis/webbed penis—all the same issue. Recommends using the current guideline restrictions for hidden penis.

Other Penile Anomalies

HERC staff recommendation

- 1) Add ICD-9 752.69 (Other penile anomalies) to line 667 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
- 2) Adopt a new guideline regarding repair of anomalies of penis
 - a. Delete current GN73 and GN89

GUIDELINE NOTE XXX, PENILE ANOMALIES

Lines 438, 667

Anomalies of the penis (ICD-9 752.63, 752.65, 752.69/ICD-10 Q54.4, Q55.5, Q55.6x) are included on line 438 only when they

- 1) Are associated with hypospadias, OR
- 2) Result in documented urinary retention, OR
- 3) Result in repeated urinary tract infections, OR
- 4) Result in recurrent infections such as meatitis or balanitis, OR
- 5) Involve 35 degrees of curvature or greater for conditions resulting in lateral or ventral curvature, OR
- 6) Involve 60 degrees of rotation or greater for conditions resulting in penile torsion, OR
- 7) Involve aplasia/congenital absence of the penis.

Otherwise, these diagnoses are included on line 667.

~~GUIDELINE NOTE 73, CONGENITAL CHORDEE~~

~~*Line 438*~~

~~Congenital chordee (ICD-10-CM Q54.4/ICD-9-CM 752.63) is included on Line 438 only for severe cases (35 degrees of curvature or greater) and for all cases associated with hypospadias.~~

~~GUIDELINE NOTE 89, REPAIR OF HIDDEN PENIS~~

~~*Line 438*~~

~~Repair of hidden penis (ICD-10-CM Q55.64/ICD-9-CM 752.65) is only covered if the patient has documented urinary retention, repeated urinary tract infections, meatitis, or balanitis.~~

Back Line Reorganization Outstanding Issues

Issue: The back line reorganization plan was approved at the March, 2015 VBBS/HERC meetings. However, several issues remain incompletely resolved or not addressed or have arisen since the last meeting.

Outstanding Back Issues:

- 1) The non-urgent surgical line title requires clarification. This will clarify how this line differs from line 351 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS
 - a. Recommendation: Rename the lower surgical line Line 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
- 2) Placement of CPT 62310 (Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; cervical or thoracic)
 - a. Currently Ancillary
 - b. Back line review moved to Services Recommended for Non-Coverage Table
 - c. Recommendation: Add CPT 62310 to lines 75 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES and 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
 - i. Matches other placements of 62311 (the lumbar equivalent)
- 3) Intrathecal/epidural medication pumps
 - a. CPT 62360-62362 (Implantation or replacement of device for intrathecal or epidural drug infusion) were added to all three surgical lines (351,366 and 532). These codes are currently not on any back lines and it has been the intent of the HSC/HERC to not cover this treatment for back pain. These codes are also on various chemotherapy and dysfunction lines.
 - i. Remove CPT 62360-62362 from lines 351, 366 and 532
 - b. CPT 62355 (Removal of previously implanted intrathecal or epidural catheter) and 62365 (Removal of subcutaneous reservoir or pump, previously implanted for intrathecal or epidural infusion) are currently on lines 351, 366 and 532
 - i. Remove CPT 62355 and 62365 and keep on their current placement on a complications line
 - c. Guideline note 72 was not reviewed as part of the back lines reorganization
 - i. CPT 62367-62368 were added to lines 351, 366 and 532. CPT 62369-62370 also refer to electronic analysis of intrathecal pumps and are on these back surgical lines
 - ii. Recommendation is modify GN72 as shown below

GUIDELINE NOTE 72, ELECTRONIC ANALYSIS OF INTRATHECAL PUMPS

Lines ~~374,545,~~ 351, 366, 532, 612

Electronic analysis of intrathecal pumps, with or without programming (CPT codes 62367-~~62368~~62370), is included on these lines only for pumps implanted prior to April 1, 2009.

- 4) Epidural steroid injection guideline
 - a. Clarify the definition of radiculopathy
 - b. Consider adding active therapy modalities as a requirement for injections

Back Line Reorganization Outstanding Issues

- c. See staff recommendations after following review
- 5) Diagnostic Guideline D4
 - a. Errors in asterisks
 - b. Changes to footnotes

VbBS Summary Documents from 5/7/15 meeting

Back Line Reorganization Outstanding Issues

Epidural steroid injections

There were several outstanding questions regarding the epidural steroid injection guideline.

- 1) Whether to include radicular pain as an indication for epidural steroid injections.
- 2) Whether to require some type of active therapy, i.e. use the injection to allow patients to be more active/involved with PT, etc. rather than just passively relying on the injection for pain relief

Evidence

- 1) **AHRQ 2015**, meta-analysis of percutaneous interventions for low back pain
 - a. N=78 RCTs for epidural injections
 - b. Definition of radicular pain differed among studies. The review authors defined radiculopathy as presence of leg pain (typically worse than back pain), with or without sensory deficits or weakness, in a nerve root distribution. A number of studies used the term “sciatica,” which was classified as radiculopathy.
 - c. For epidural corticosteroid injections versus placebo interventions for radiculopathy, the only statistically significant effects were on mean improvement in pain at immediate-term follow-up (weighted mean difference [WMD] -7.55 on a 0 to 100 scale, 95% CI -11.4 to -3.74) (strength of evidence [SOE]: moderate), mean improvement in function at immediate-term follow-up when an outlier trial was excluded (standardized mean difference [SMD] -0.33 , 95% CI -0.56 to -0.09) (SOE: low), and risk of surgery at short-term follow-up (relative risk [RR] 0.62 , 95% CI 0.41 to 0.92) (SOE: low). The magnitude of effects on pain and function was small, did not meet predefined thresholds for minimum clinically important differences, and there were no differences on outcomes at longer-term follow-up. Trials of epidural corticosteroid injections for radiculopathy versus nonplacebo interventions did not clearly demonstrate effectiveness (SOE: insufficient to low).
 - d. Evidence was limited for epidural corticosteroid injections versus placebo interventions for spinal stenosis (SOE: low to moderate) or nonradicular back pain (SOE: low), but showed no differences in pain, function, or likelihood of surgery.
 - e. **Conclusions:** Epidural corticosteroid injections for radiculopathy were associated with immediate improvements in pain and might be associated with immediate improvements in function, but benefits were small and not sustained, and there was no effect on long-term risk of surgery. Evidence did not suggest that effectiveness varies based on injection technique, corticosteroid, dose, or comparator. Limited evidence suggested that epidural corticosteroid injections are not effective for spinal stenosis or nonradicular back pain.
- 2) Summary of evidence from the CEBP table presented at the March 2015 meeting
 - a. Epidural steroid injections for non-radicular back pain had insufficient evidence of effectiveness and was not recommended for coverage
 - b. Epidural steroid injections for radicular low back pain due to herniated lumbar disc had moderate evidence of effectiveness for short term benefit and was recommended for coverage with a weak recommendations
- 3) Coverage guidance “box language” on epidural steroid injections for low back pain
 - a. For radicular low back pain, epidural steroid injections are recommended for coverage for patients with persistent radiculopathy due to herniated lumbar disc; it is recommended that shared decision-making regarding epidural steroid

Back Line Reorganization Outstanding Issues

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 are not recommended for coverage.

- b. Epidural steroid injections are not recommended for coverage for central spinal canal stenosis.

HERC staff summary:

The evidence base for epidural steroid injections defines radiculopathy as radicular pain with or without weakness or sensory deficits. The current guideline wording includes only weakness and sensory deficits as covered indications, which does not match the evidence base. There is no requirement for participation in physical therapy or other active treatment modality along with the injection in the current guideline. It was the intent of the Back Lines Reorganization Taskforce that epidural steroid injections only be included for coverage if such injections allowed more active participation in rehabilitation activities.

HERC staff recommendations

- 1) Modify GN105 as shown below
 - a. Modify the definition of radiculopathy to correspond with the definition used in the studies used for determining the effectiveness of this therapy
 - b. Require participation in physical therapy or similar active treatment modality

GUIDELINE NOTE 105, EPIDURAL STEROID INJECTIONS FOR LOW BACK PAIN

Line MMM

Epidural lumbar steroid injections (CPT 62311, 64483, 64484) are included on this line for patients with persistent radiculopathy due to herniated lumbar disc, where radiculopathy is defined as pain, weakness, or sensory deficits in a nerve root distribution. ~~showing objective evidence of one or more of the following:~~

- A) ~~Markedly abnormal reflexes~~
- B) ~~Segmental muscle weakness~~
- C) ~~Segmental sensory loss~~
- D) ~~EMG or NCV evidence of nerve root impingement~~

One epidural steroid injection is included on ~~these lines~~ this line; a second epidural steroid injection may be provided after 3-6 months only if objective evidence of 3 months of sustained pain relief was provided by the first injection. 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. Epidural lumbar steroid injections are not included on ~~these lines~~ this line for spinal stenosis or for patients with low back pain without radiculopathy. Epidural steroid injections are only included on this line when the patient is also participating in an active therapy such as physical therapy or home exercise therapy.

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

Back Line Reorganization Outstanding Issues

Diagnostic Guideline D4 Corrections

- 1) HERC staff recommendations:
 - a. Modify D4 as shown below
 - i. Asterisks in the 6th entry are in an incorrect position
 - ii. Asterisks in the last entry are incorrect
 - iii. Definition of radiculopathy should be changed to match the definition adopted for GN105
 - iv. The 3rd footnote should be modified to remove inference that epidural steroid injections are appropriate for spinal stenosis

DIAGNOSTIC GUIDELINE D4, ADVANCED IMAGING FOR LOW BACK PAIN

In patients with non-specific low back pain and no “red flag” conditions [see Table D4], 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.

Table D4
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"> • History of cancer with new onset of LBP 	MRI	ESR
	<ul style="list-style-type: none"> • Unexplained weight loss • Failure to improve after 1 month • Age >50 years • Symptoms such as painless neurologic deficit, night pain or pain increased in supine position 	Lumbosacral plain radiography	
	<ul style="list-style-type: none"> • Multiple risk factors for cancer present 	Plain radiography or MRI	
Spinal column infection	<ul style="list-style-type: none"> • Fever • Intravenous drug use • Recent infection 	MRI	ESR and/or CRP
Cauda equina syndrome	<ul style="list-style-type: none"> • Urinary retention • Motor deficits at multiple levels • Fecal incontinence • Saddle anesthesia 	MRI	None
Vertebral compression fracture	<ul style="list-style-type: none"> • History of osteoporosis • Use of corticosteroids • Older age 	Lumbosacral plain radiography	None
Ankylosing spondylitis	<ul style="list-style-type: none"> • Morning stiffness • Improvement with exercise • Alternating buttock pain • Awakening due to back pain during the second part of the night • Younger age 	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"> • Back pain with leg pain in an L4, L5, or S1 nerve root distribution present < 1 month • Positive straight-leg-raise test or crossed straight-leg-raise test 	None	None
	<ul style="list-style-type: none"> • Radiculopathic** signs** present >1 month • Severe/progressive neurologic deficits (such as foot drop), progressive motor weakness 	MRI***	Consider EMG/NCV
Spinal stenosis	<ul style="list-style-type: none"> • Radiating leg pain • Older age • Pain usually relieved with sitting (Pseudoclaudication a weak predictor) 	None	None

Back Line Reorganization Outstanding Issues

Possible cause	Key features on history or physical examination	Imaging*	Additional studies*
	<ul style="list-style-type: none"> Spinal stenosis symptoms present >1 month 	MRI**	Consider EMG/NCV

* Level of evidence for diagnostic evaluation is variable

** Radiculopathic signs are defined for the purposes of this guideline is defined as the presence of as in Guideline Note 37 with any of the following: pain, weakness, or sensory deficits in a nerve root distribution

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

*** Only if patient is a potential candidate for surgery or, if indicated, lumbar 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.

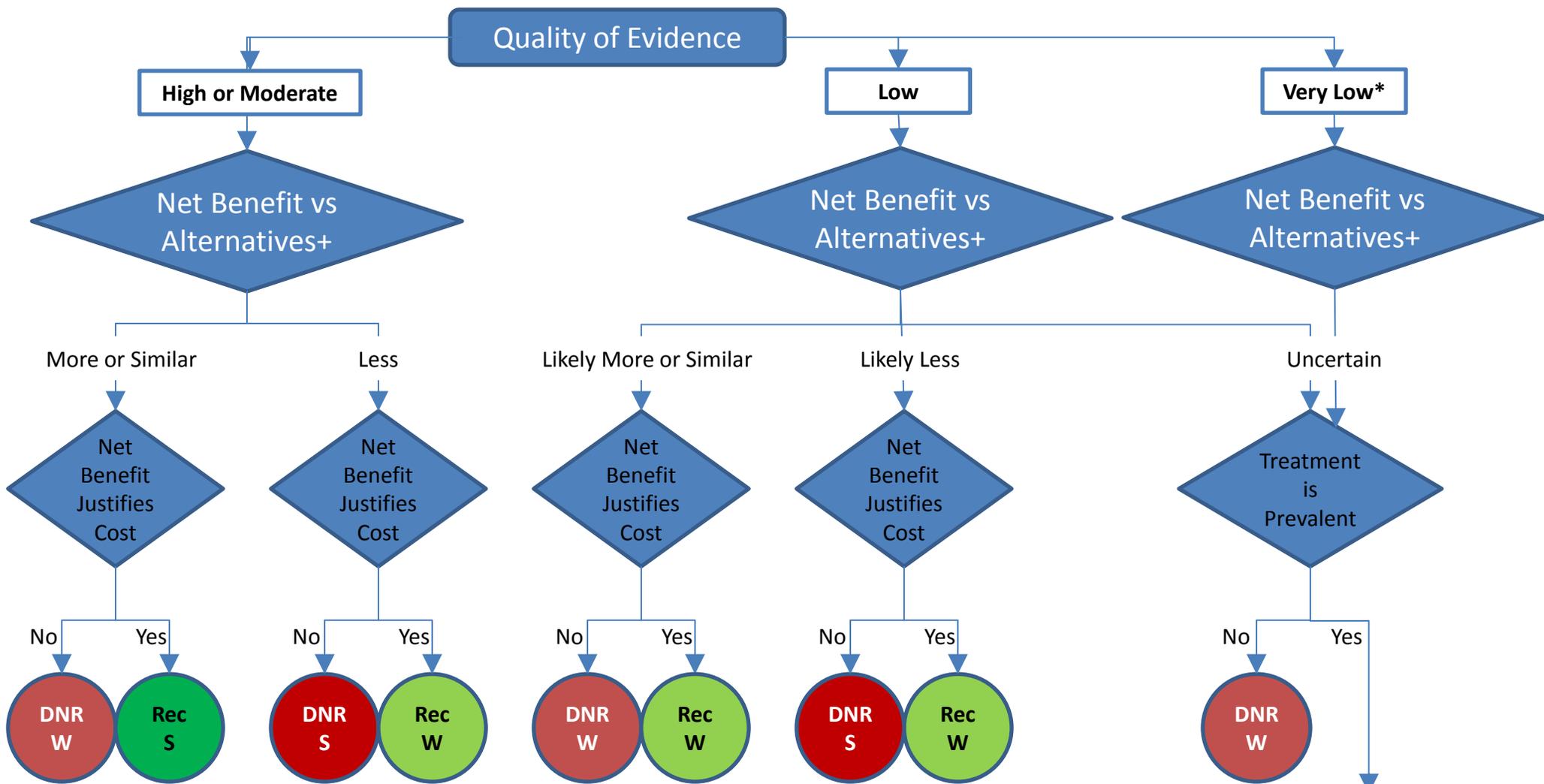
The development of this guideline note was informed by a HERC coverage guidance. See <http://www.oregon.gov/oha/herc/Pages/blog-adv-imaging-low-back.aspx>

Section 4.0
Coverage Guidance
Development Process and
algorithm revisions

Proposed Revised HERC Methods and Processes for Coverage Guidance Development

One of the recommendations to the OHA in the 2014 assessment of HERC processes, products, outreach and dissemination efforts was to establish continuous improvement processes for report development, including those that would address delays and inefficiencies in report and guidance development. Over the past months it has become clear that the complexity of topics undertaken by the HERC has increased since HERC guidance development methods were established in 2011. The initial evidence search methods involved a selected set of core “trusted sources.” While these sources generally identified important evidence for early HERC topics they have performed less well with more complicated, recent topics. Public input has frequently been identifying newer and additional sources of evidence on several topics over the past year and the HERC has had several topics delayed because of the large number of comments and the need to do additional searches. In order to identify a more complete and relevant set of evidence sources for the initial guidance draft, HERC staff are proposing the following methodologic and process revisions for guidance development. If approved, HERC staff will work with leadership between meetings to assure that the integration of these changes accomplish the intended goals. Staff will report back to HERC on progress and receive approval on continued implementation.

1. Identify critical and important outcomes for each topic under consideration at the initiation of the guidance when the population, intervention, comparator and outcomes (PICO) and key questions are developed. This will facilitate development of GRADE tables for these critical and important outcomes.
2. Adopt a “best evidence” approach for evidence searches. This involves searches for high quality systematic reviews, health technology assessments and meta-analyses as is the current practice for the HERC, but also adds a thorough search (i.e. Medline) to identify any more recent studies.
3. Continue to search for high-quality, evidence-based clinical practice guidelines that may inform the guidance and coverage decisions.
4. Implement the internationally accepted GRADE system more fully into development of strength of evidence assessments and strength of recommendation ratings for use by the HERC.
5. Replace our existing GRADE table, working with HERC leadership to develop a format that is easier to follow and better integrates the factors which lead to our decisions.
6. Pilot test the GRADE/DECIDE “Evidence to Decision” framework to assist in development of transparent coverage decision development. Assess whether this framework is useful for HERC guidance development.
7. Assess the time to development and HERC satisfaction with guidances that are developed using these revisions over the upcoming cycle of topics (beginning September 2015.)



+Values & preferences are integral in the assessment of net benefit. Alternative interventions usually have proven net benefit and cost-effectiveness, but if none exist, can include placebo or no treatment.

*In most cases of very low quality evidence, assessment of net benefit will be uncertain.

The algorithm is designed to give a general sense of the decision-making process for recommendations. However, the ultimate strength and direction of recommendation is determined by assessing quality of evidence, values & preferences, magnitude of net benefit, and magnitude of cost & resource differential compared to alternative interventions. None of these assessments is categorical or dichotomous. Therefore, the algorithm cannot always accurately reflect the judgments or ultimate decisions behind recommendations.

