



Health Evidence Review Commission

January 8, 2015

1:30 PM

**Clackamas Community College, Wilsonville Training
Center Room 111-112
29353 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

January 8, 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 (11-13-2014)	Som Saha	X
3	1:40 PM	Director's Report	Darren Coffman	
4	1.50 PM	Value-based Benefits Subcommittee Report on Interim Changes to the Prioritized List	Ariel Smits Cat Livingston	X
5	2:10 PM	Ablation for Atrial Fibrillation a. EbGS coverage guidance recommendation b. VbBS Prioritized List recommended changes	Wiley Chan Cat Livingston Robyn Liu	X
6	2:30 PM	Percutaneous Interventions for Cervical Spine Pain a. HTAS coverage guidance recommendation b. VbBS Prioritized List recommended changes	Wally Shaffer Robyn Liu	X
7	2:50 PM	Advanced Imaging in Staging of Prostate Cancer a. HTAS coverage guidance recommendation b. VbBS Prioritized List recommended changes	Wally Shaffer Robyn Liu	X
8	3:10 PM	Nuclear Cardiac Imaging a. EbGS coverage guidance recommendation b. VbBS Prioritized List recommended changes	Wiley Chan Cat Livingston Robyn Liu	X
9	3:30 PM	Retreat follow-up a. Overall work plan b. Changes to the coverage guidance development process	Jason Gingerich Darren Coffman	X
10	4:20 PM	Next Steps • Schedule next meeting – 3/12/15 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
Meridian Park Hospital
Community Health Education Center Room 117B&C
Tualatin, OR 97062
November 13, 2014

Members Present: Som Saha, MD, MPH, Chair; James Tyack, DMD; Mark Gibson; Leda Garside, RN, MBA; Gerald Ahmann, MD, PhD. Via teleconference: Beth Westbrook, PsyD; Wiley Chan, MD; Vern Saboe, DC.

Members Absent: Susan Williams, MD; Irene Croswell, RPh.

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

Also Attending: Alison Little, MD MPH, OHSU CeBP; Jane Stephen & Deirdra Monroe, Allergan; Carrie Phillipi, MD, OHSU-Doernbecher's; Fiona Clement, University of Californian-SF.

Call to Order

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

Minutes Approval

MOTION: To approve the minutes of the 8/14/2014 meeting as presented. CARRIES 8-0.

Director's Report

Darren Coffman reported he expects an official announcement of governor appointments for two new Commissioners. Senate confirmation is in December and, if all goes well, seating in January.

He offered appreciation for the good discussion we had at the October retreat and noted a survey is forthcoming to gather feedback and address follow-up questions.

Coffman noted some technical corrections to previously approved coverage guidances:

- Add diabetic education codes to Self-Monitoring of Blood Glucose for Type 1 & 2 Diabetes coverage guidance
- Adjust CPT codes for the Prenatal Genetic Testing coverage guidance

Value-based Benefits Subcommittee (VbBS) Report on Prioritized List Changes

[Meeting materials pages 92-107](#)

Ariel Smits and Cat Livingston reported the VbBS met earlier in the day, 11/13/14. Each helped to summarize a number of topics discussed.

Recommended code movement includes:

- Add a number of codes previously found in the DMAP Excluded File to the Prioritized List
- Add recommended placements of the 2015 CPT, CDT, and HCPCS codes
- Add several colonoscopy and sigmoidoscopy codes to several covered lines with gastrointestinal diagnoses
- Remove several procedure codes for arthrocentesis from one or more inappropriate lines, but left on other, covered lines
- Move negative pressure wound therapy procedure codes from the Ancillary File to several covered lines on the Prioritized List
- Move several diagnoses for eye inflammation from one covered line to another
- Delete procedure codes for surgical treatments for atrial fibrillation from one or two covered lines but leave on another covered line
- Add various oral and facial surgery procedures back to the sleep apnea lines for use in patients with craniofacial anomalies only
- Add various straightforward coding changes and corrections

Recommended guideline changes (effective 1/1/15 unless otherwise noted):

- Edit the non-prenatal genetic testing guideline to reflect the new genetic testing CPT placements (noting non-covered codes and placing restrictions on use of some codes). Update the references to expert documents.
- Edit the negative pressure wound therapy guideline, changing it from an ancillary guideline to be a standard guideline as the CPT codes involved were moved from the Ancillary File to the Prioritized List
- Edit the high risk for breast cancer guideline to require women without a history of breast cancer to have services determined based on NCCN requirements and to specify that contralateral mastectomy is a covered service for women with breast cancer
- Delete the denture guideline. DMAP rules will be used to determine eligibility for dentures in the future.
- Edit the intraocular steroid for chronic non-infectious uveitis guideline to allow treatment for intermediate and pan-uveitis as well as posterior uveitis
- Edit the intraocular steroid implants for central retinal vein occlusion to allow treatment for macular edema resulting from branch retinal vein occlusion in certain circumstances
- Edit the sinus surgery guideline to clarify when adenoidectomy is appropriate
- Edit the sleep apnea guideline to clarify when adenoidectomy is appropriate and to specify that oral/facial surgery codes are included on the line only for patients with craniofacial anomalies
- Add a new guideline regarding surgical treatments for atrial fibrillation (effective date pending HERC approval along with related coverage guidance)
- Add a new diagnostic guideline for SPECT imaging (effective date pending HERC approval along with related coverage guidance)

Liver elastoplasty/Fibroscan

Wally Shaffer, MAP Medical Director, commented about the proposed placement of liver elastoplasty (CPT code 91200) on the Non-Covered Table. He explained Fibroscan, a test to see how fibrotic or stiff a liver is to help determine the level of cirrhosis, is part of the hepatitis C drug protocol for OHP recommended by the hepatology group in Portland advising CareOregon. Non-coverage presents a problem, as the hepatologists who informed CareOregon's process see this scan as a way of avoiding a liver biopsy to categorize patient treatment needs. If the clinical picture and the scan are concordant then you can avoid biopsies. Previously, there was no code to bill. OHP is currently set up to accept this protocol, as it accepts the results of the test. Now that there is a code, perhaps it should not be excluded for payment.

Previously this year, the Commission tabled discussion of use of the expensive new hepatitis C drugs. Coffman discussed how the condition falls in the funded region and CCOs have developed their own treatment protocols but the fee-for-service side may need direction. Gibson asserted that CCOs can and should pay for services considered cost-savings; it is in their purview to do so.

After much discussion, the members decided to have further discussion about the technology at their January meeting for potential placement on the October 1, 2015 Prioritized List. Fee-for-service and CCOs may use the code as they see fit until then.

Breast Pumps:

Livingston outlined a new guideline recommended by VbBS covering breast pumps and supplies for postpartum women when a pump is necessary to establish or maintain milk production in order to maximize availability of breast milk to the baby and that lactation support services are covered for pregnant and postpartum women for 6 months postpartum

- The proposed language changed from the VbBS meeting materials.
- Livingston expressed concern that the CCO medical directors might not be in support of the new language, but Holly Jo Hodges expressed full support of the proposal.
- Carrie Phillipi, MD, general pediatrician and lactation consultant, testified about the disparity between private insurance and OHP clients for access to high quality electric breast pumps. She supported the new proposed language.
- Discussion centered on providing tools necessary to support breast-feeding.

The guideline recommended by VbBS was amended to read as follows:

GUIDELINE NOTE 140, BREASTFEEDING PUMPS AND SUPPLIES

Line 3

Breast pumps and supplies are covered for postpartum women when a pump is necessary to establish or maintain milk production in order to maximize availability of breast milk to the baby.

For cases in which there is a medical indication for breast pumps, the pumps should be supplied whenever possible within 24 hours to allow for continued milk production.

Lactation support services (including education and counseling by trained providers) are covered for pregnant and postpartum women (for six months postpartum).

MOTION: To approve the breast feeding guideline as amended: Carries: 8-0.

MOTION: To accept the all other VbBS recommendations on *Prioritized List changes* as stated other than those related to coverage guidances or liver elastography. See the VbBS minutes of 11/13/14 for a full description. Carries: 8-0.

Coverage Guidance Topic: Indications for Hyperbaric Oxygen Therapy (HBOT)
[Meeting materials](#), pages 208-277

Wally Shaffer presented the proposed coverage guidance from HTAS:

- Systemic administration of 100% oxygen in treatment chamber under pressures > 1 atmosphere
- No standard protocol (frequency, duration, dose)
- Considered established treatment for
 - Decompression illness
 - Air or gas embolism
 - Acute CO poisoning
 - Cyanide poisoning
- Primary evidence source was Washington State Health Care Authority Health Technology Assessment Program 2013 report (retrieved from http://www.hca.wa.gov/hta/documents/021513_hbot_final_report.pdf)
 - Supplemented by 9 additional reviews from core sources and two documents provided by expert including Underwater and Hyperbaric Medical Society (UHMS) guideline

Evidence Review

Diabetic non-healing wounds, including foot ulcers

- HBOT effective in improved wound healing and limb salvage (moderate quality of evidence (QOE))
- NICE guideline recommends against provision of HBOT, despite concluding that HBOT results in:
 - Fewer surgical interventions (moderate QOE)
 - Fewer major amputations (low QOE)
 - No difference in minor amputations or improved wound healing up to 6 weeks (moderate QOE)
 - No difference in reduction in ulcer surface area (low QOE)
 - Cost effectiveness analysis ~ £ 25,000

Venous ulcers

- Short-term reductions in wound area; no evidence for complete wound healing or superior results after 30 days (low QOE)
- UHMS does not recommend HBOT

Surgical reconstruction (without grafts and flaps)

- Limited evidence for improvements in wound healing, lower risk of infection for HBOT group (very low QOE)
- UHMS does not address this indication

Compromised grafts and flaps

- Mixed results – Improved healing/graft survival (low QOE)
- UHMS recommends HBOT

Crush injuries

- No difference in healing time, amputations, length of hospital stay; improved complete healing (low QOE)
- UHMS recommends HBOT

Thermal burns

- Mixed results – no difference in length of hospital stay, additional surgeries, mortality; improvement in healing time (very low QOE)
- UHMS does not address this indication

Refractory osteomyelitis

- No RCTs – mixed results regarding relapse rate, cure (very low QOE)
- UHMS recommends HBOT

Late radiation tissue injury

- Improved outcomes in bone and soft tissue damage; decreased risk of developing osteoradionecrosis following tooth extraction (moderate QOE)
- UHMS does not address this indication

Traumatic Brain injury

- Possible improved outcomes at 1 month, but unclear clinical significance (moderate QOE)
- UHMS does not address this indication

Cerebral palsy

- Mixed results regarding motor function (low QOE)
- UHMS does not address this indication

Multiple sclerosis

- No benefit on MS-related outcomes (moderate QOE)
- UHMS does not address this indication

Migraine and cluster headaches

- HBOT relieves acute migraine attacks; does not prevent attacks, reduce nausea/vomiting or need for rescue meds (low QOE)
- Insufficient evidence for cluster headaches
- UHMS does not address this indication

Sensorineural hearing loss

- Acute: Mixed results - possible benefit if treated within 2 weeks but clinical significance uncertain (low QOE)
- Chronic: No benefit (very low to moderate QOE)
- UHMS does not address this indication

Delayed/non-healing fractures, Bell's Palsy, Malignant Otitis Externa

- No evidence available
- UHMS does not address these indications

Vascular dementia

- HBOT plus donepezil – possible improvement in cognitive function (very low QOE)
- UHMS does not address this indication

Acute coronary syndrome

- Possible decreased mortality, heart muscle damage, MACE, time to relief of pain – high risk of bias (low QOE)
- UHMS does not address this indication

Gas gangrene

- Possible improved survival rates; fewer amputations (low QOE)
- UHMS does not address this indication

Frequency, Duration, or Dose

- Insufficient evidence to determine optimal frequency, duration, or dose for HBOT
 - No studies reported on duration
 - Mixed results from a subgroup analysis on frequency
 - Significant heterogeneity between studies addressing dose

Harms

- Harms are generally mild and self-limited
- Most common: barotrauma (ear), visual disturbances, oxygen toxicity
- Additional harms mentioned:
 - Severe pulmonary complications
 - Seizures
 - Claustrophobia
 - 2 deaths attributed to HBOT in patients with gas gangrene

Differential Efficacy/Safety and Costs

Differential efficacy and safety

- Insufficient evidence to determine differential effectiveness and safety of HBOT according to sex, race, ethnicity, disability, wound duration, or treatment setting

Costs

- HBOT may be cost-effective under certain conditions, for certain populations and indications (low QOE – most models not robust)

Discussion:

Dr. Enoch Huong, appointed ad hoc expert, stated he had issues with the recommendation of non-coverage for refractory osteomyelitis, sensorineural hearing loss and thermal burns. He understood the conclusion based on the GRADE methodology and the current existing literature but their conclusions *may* be due to methodological issues. He mentioned UHMS asserted that the evidence *does* support those three indications. Huong hoped we can revisit those conditions when we have more data.

For refractory osteomyelitis: Shaffer explained HTAS drew their conclusions from the low evidence quality and mixed results; more quality studies are needed to support coverage.

For thermal burns: Shaffer stated there was similar, low evidence quality and mixed results. It was hard to find the benefit in burn treatment. Huong added a provider must weigh risks with transport from burn center for HBOT at another location; it is usually not practical.

For sensorineural hearing loss: This addressed sudden hearing loss in otherwise healthy people. There are not a lot of effective treatments. The evidence showed decrease in decibel of hearing loss, but the clinical significance was unclear. The WA HTA review found the evidence inconclusive. There was a fair amount of public comment and discussion; details may be found in the [public comment disposition](#).

Shaffer added HTAS accepted HBOT for carbon monoxide poisoning as standard of care, though there was some controversy in the literature and the evidence review found conflict in the trials, stating it is “presumed appropriate for coverage.” However, if you take the current best protocols, there is clearer evidence of benefit. It is currently covered on OHP with no evidence of harms.

MOTION: To approve the proposed coverage guidance for Hyperbaric Oxygen Therapy as presented. Carries 8-0.

Approved Coverage Guidance:

HERC COVERAGE GUIDANCE

Hyperbaric oxygen therapy is recommended for coverage (*strong recommendation*) for diabetic wounds of the lower extremities in patients who meet all of the following criteria:

- Patient has Type 1 or Type 2 diabetes and has a lower extremity wound that is due to diabetes, and
- Patient has a wound classified as Wagner grade III or higher, and
- Patient has failed an adequate course of standard wound therapy including arterial assessment, with no measurable signs of healing after at least thirty days.

Hyperbaric oxygen therapy is recommended for coverage for late radiation tissue injury, and gas gangrene (*strong recommendation*).

Hyperbaric oxygen therapy is recommended for coverage for compromised surgical flaps and grafts, and for crush injuries (*weak recommendation*).

Hyperbaric oxygen therapy is not recommended for coverage for cerebral palsy, multiple sclerosis or chronic sensorineural hearing loss (*strong recommendation*).

Hyperbaric oxygen therapy is not recommended for coverage for the following conditions (*weak recommendation*):

- Venous ulcers,
- Surgical reconstruction without flaps and grafts,
- Refractory osteomyelitis,
- Acute traumatic brain injury,
- Brain injuries other than acute traumatic brain injury,
- Migraines and cluster headaches,
- Acute sensorineural hearing loss,
- Delayed or non-healing fractures,
- Bell's Palsy,
- Malignant otitis externa,
- Vascular dementia,
- Thermal burns, or
- Acute coronary syndrome.

The following indications are presumed to be appropriate for coverage but are excluded from these coverage guidance recommendations: air or gas embolism, acute carbon monoxide poisoning, decompression illness and cyanide poisoning.

Changes for the Prioritized List of Health Services:

The VbBS recommended text from the meeting materials was slightly changed: The wording "is a covered benefit" was changed to "included on these lines" to be consistent with other Prioritized List guideline wording. This does not change the intent of the guideline.

MOTION: To approve the proposed hyperbaric oxygen guideline and corresponding coding changes for the Prioritized List effective January 1, 2015 as shown in Attachment A. Carries 8-0.

Process Discussion

Smits mentioned a recent instance where VbBS reviewed the coverage guidance for Percutaneous Interventions for Cervical Spine Pain recommendation by HTAS, and disagreed with the conclusion. VbBS believed the supporting evidence to be weak, and based on that conclusion, were disinclined to add the service to the Prioritized List. In this case, VbBS expressed concern that HTAS had seemingly relied heavily on expert testimony; HTAS felt this was the best level of evidence they could find, because studies were not particularly helpful.

She asked, in cases like this, when subcommittees disagree, what protocol to follow.

Chan asserted the coverage guidance GRADE table should be robustly detailed, making it easy to follow the originating subcommittee's logic. Gibson and other VbBS members explained they read and understood the GRADE rationale; they just disagreed with the conclusions, feeling that HTAS relied too heavily on expert testimony. VbBS has to decide if the net benefit justifies the cost of covering a condition. Shaffer contended the HTAS/EbGS process includes the addition of ad hoc experts, who fill in gaps of evidence and provide clinical context and info on subpopulations. VbBS does not hear that as strongly.

Saha agreed GRADE should be used by EbGS/HTAS to give rationale for a *coverage guidance*. The VbBS process and products are different; they, like other payers, should use the coverage guidance to make clinical guideline decisions. VbBS must make a cost-benefit analysis across the entire domain of services to cover for the Medicaid population.

Gibson stated that differentiation between subcommittees is good and is expected but cautioned that these decisions are reached in a public process, governed by a political landscape. Careful consideration of dissent is appropriate.

Coffman summarized the discussion by stating there is no direction to VbBS other than to continue to work as they have always done. VbBS will revisit Percutaneous Interventions for Cervical Spine Pain in January, 2015.

Coverage Guidance Updates

[Meeting Materials](#) pages 278-324

Livingston explained the policy for reexamining coverage guidances is to scan for new evidence from trusted sources every two years to determine if the evidence has changed substantively. She asked, what we should do if we note studies are coming out soon? Should we start the re-review as soon as that evidence is available or should we wait until the next official review period 2 years hence?

Gibson weighed in, asserting HERC's credibility counts on us using the best, most recent high quality evidence possible, favoring looking at new evidence, to determine if the new evidence meets the threshold for a new review, as soon as we are able.

Saha argued for striking a balance between daily re-scanning evidence and waiting two years. We should strive to stay up-to-date, whether new evidence comes to us from our scans, the news or the provider community.

Livingston mentioned the topics up for rescanning were completed under our old process, pre-GRADE, and employed a different language structure. She proposed editing guidances to bring the language in-line with our current nomenclature, noting GRADE was not used in those instances. Coffman added each coverage guidance will include a paragraph to explain what evidence was found, if anything, during the rescan and with details listed in a new appendix.

EbGS Coverage Guidance recommended action:

No changes based on updated evidence review:

- Management of chronic otitis media in children
- Indications for planned cesarean section
- Knee arthroscopy for osteoarthritis
- Routine ultrasound in pregnancy
- Non-pharmacologic interventions for treatment-resistant depression, specifically transcranial magnetic stimulation
 - Discussion centered on confusion about the first line of this coverage guidance, which was added as a concession to concerns about under-representing psychotherapy in the role of treating major depressive disorder. Westbrook argued the evidence shows, in publications she reads, the best treatment is a combination of psychotherapy and pharmaceuticals.
 - Commissioners agreed that the actual question being answered by this coverage guidance is specifically focused on *treatment resistant depression*; the lead-in sentence may add confusion as it discusses treating major depressive disorder. This guidance begins once a condition is deemed “treatment resistant.”

MOTION: Delete the first sentence of the coverage guidance. CARRIES: 8-0.

Deleted passage: ~~In patients with an episode of major depressive disorder who have failed an initial trial of antidepressants, psychotherapy should be covered.~~

Review once updated trusted sources are available:

- Neuroimaging in dementia
 - WA HTA – expected December 2014
- Advanced imaging for low back pain
 - source report update – expected late 2015/early 2016
- Low Back Pain: pharmacologic interventions
 - source report update – expected late 2015/early 2016
- Low Back Pain: non-pharmacologic, non-invasive interventions
 - source report update – expected late 2015/early 2016
- Percutaneous interventions for low back pain
 - source report update – expected late 2014/early 2015

HTAS Coverage Guidance recommended actions:

No changes based on updated evidence review:

- Artificial disks
- Lumbar discography
- Hip resurfacing

Review once updated trusted sources are available:

- MRI for breast cancer screening
 - WA HTA expected December 2014; AHRQ report in process – completion date unknown
- Viscosupplementation for osteoarthritis of the knee
 - AHRQ report in process – completion date unknown)

Retreat Follow-up

Staff is creating a work plan and time-line for presentation at the January 8, 2015 meeting that captures many of the action items from the retreat.

Subcommittee restructuring

Coffman reported we are expecting the appointment and potential confirmation of two new Commissioners. Once they are seated, he would like to address the membership inequity in two subcommittees: HTAS and EbGS; EbGS has eight members, while HTAS has four. He would like to work toward an equal balance in terms of membership numbers but also make sure there is a balance between physicians and non-physicians. He will continue to work with leadership after confirmations and hoped Commissioners might be open to switch subcommittees, if that were decided. He mentioned staff would take member's scheduled into account and change meeting dates if necessary.

Coverage guidance review timing

HERC's recent assessment and process improvement project identified an issue with the 2-month gap between the time VbBS reviews a coverage guidance and when HERC completes their review and approvals. This policy seems to cause unnecessary delay. Staff proposed to reduce this delay by having VbBS review the scheduled topic in the morning, and if a recommendation is reached that day, have HERC review both the EbGS/HTAS recommended coverage guidance and VbBS Prioritized List changes on the topic that afternoon. If VbBS does not come to a recommendation, HERC's review would wait for a future meeting.

Motion: To bring coverage guidance recommendation to VbBS and HERC on the same day. CARRIES: 8-0.

Role of experts

Coffman explained staff are working with leadership to look at ways to standardize HERC's use of experts. Areas to address are:

- Defining clear roles
- Early engagement of experts if needed

- Experts' expectations
- Subcommittees' expectations

Searchable Prioritized List

Staff are creating an interactive web-based tool with a rich keyword search function to aid medical directors (and others) who research condition and treatment pairings and guidelines. Implementing this solution will take a most of 2015.

Clinical bottom line

Livingston reported staff is creating a one-or two-sentence summary for coverage guidances specifically aimed at the provider community.

Public Comment

There was no public comment at this time.

Adjournment

Meeting adjourned at 4:30 pm. Next meeting will be from 1:30-4:30 pm on Thursday, January 8, 2015 at Clackamas Community College Wilsonville Training Center, Rooms 111-112, Wilsonville, Oregon.

Attachment A

Changes to the Prioritized List Based on Coverage Guidance on Indications for Hyperbaric Oxygen Treatment

Changes reviewed by HERC on 11/13/2014 to become effective as indicated:

1) Add/delete diagnoses on line 336 as shown below effective January 1, 2015:

Line: 336
Condition: ANAEROBIC INFECTIONS REQUIRING HYPERBARIC OXYGEN (See Guideline Note 107)
Treatment: HYPERBARIC OXYGEN
ICD-9: 040.0, [250.7,250.8,526.4](#), 526.89,639.0,639.6,670.02-670.04,673.00-673.04, ~~686.00-686.09,709.3~~, 728.0,730.91-730.99,785.4, [927-929](#),958.0,990,996.52,996.70-996.79,999.
ICD-10: [E11.5x,E11.621,E11.622,E11.628](#)I70.361-I70.369,I70.461-I70.469,I70.561-I70.569,I70.661-I70.669,I70.761-I70.769,I96,M27.8,~~M46.20-M46.39~~,M60.000-M60.005,M60.011-M60.09,M72.6,~~M86.9~~,O08.0,O88.011-O88.03,[S07.xxx,S17.xxx,S38.xxx](#),S47.1xxA-S47.1xxD,S47.2xxA-S47.2xxD,S47.9xxA-S47.9xxD,[S57.xxx,S67.xxx,S77.xxx,S87.xxx,S97.xxx](#),T66.xxxA-T66.xxxD,T79.0xxA-T79.0xxD,[T79.Axx](#),T80.0xxA-T80.0xxD,T82.898A-T82.898D,T82.9xxA-T82.9xxD,T83.89xA-T83.89xD,T83.9xxA-T83.9xxD,T84.89xA-T84.89xD,T84.9xxA-T84.9xxD,T85.89xA-T85.89xD,T85.9xxA-T85.9xxD,T86.820-T86.829
CPT: 98966-98969,99051,99060,99070,99078,99183,99201-99215,99281-99285,99341-99355,99358-99378,99381-99404,99408-99412,99429-99449,99487-99496,99605-99607
HCPCS: G0396,G0397,G0463

2) For the next biennial review List (October 1, 2015 or January 1, 2016 Prioritized List), combine lines 336 and 373, as shown below, with placement of the combined line at line 336.

- Diagnoses included on new line as shown below
- CPT and HCPCS codes included from both lines
- Keep Guideline Note 107 revisions from January 1, 2015 List

Line: 336
Condition: ~~ANAEROBIC INFECTIONS~~ [CONDITIONS](#) REQUIRING HYPERBARIC OXYGEN [THERAPY](#) (See Guideline Note 107)
Treatment: HYPERBARIC OXYGEN
ICD-9: 040.0,[250.7,250.8,526.4](#), 526.89,639.0,639.6,670.02-670.04,673.00,673.04, ~~686.00,686.01,686.09,709.3~~, 728.0, ~~730.91-730.99~~,785.4,[927-929](#),958.0,990,996.52,996.70-996.79, 986,987.0-987.9,993.3, 999.
ICD-10: [E11.5x,E11.621,E11.622,E11.628](#),I70.361-I70.369,I70.461-I70.469,I70.561-I70.569,I70.661-I70.669,I70.761-I70.769,I96, M27.8,~~M46.20-M46.39~~,M60.000-M60.005,M60.011-M60.09,M72.6,~~M86.9~~,O08.0,O88.011-O88.03,[S07.xxx,S17.xxx,S38.xxx](#),S47.1xxA-S47.1xxD,S47.2xxA-S47.2xxD,S47.9xxA-S47.9xxD,[S57.xxx,S67.xxx,S77.xxx,S87.xxx,S97.xxx](#),T58.01xA-T58.01xD,T58.02xA-T58.02xD,T58.03xA-T58.03xD,T58.04xA-T58.04xD,T58.11xA-T58.11xD,T58.12xA-T58.12xD,T58.13xA-T58.13xD,T58.14xA-T58.14xD,T58.2x1A-T58.2x1D,T58.2x2A-T58.2x2D,T58.2x3A-T58.2x3D,T58.2x4A-T58.2x4D,T58.8x1A-T58.8x1D,T58.8x2A-T58.8x2D,T58.8x3A-T58.8x3D,T58.8x4A-T58.8x4D,T58.91xA-T58.91xD,T58.92xA-T58.92xD,T58.93xA-T58.93xD,T58.94xA-T58.94xD,T59.4x4A-T59.4x4D,T59.93xA-T59.93xD,T66.xxxA-T66.xxxD,T70.3xxA-T70.3xxD,T79.0xxA-T79.0xxD,[T79.Axx](#),T80.0xxA-T80.0xxD,T82.898A-T82.898D,T82.9xxA-T82.9xxD,T83.89xA-T83.89xD,T83.9xxA-T83.9xxD,T84.89xA-T84.89xD,T84.9xxA-T84.9xxD,T85.89xA-T85.89xD,T85.9xxA-T85.9xxD,T86.820-T86.829
CPT: 98966-98969,99051,99060,99070,99078,99183,99201-99215,99281-99285, 99291-99404,99341-99355,99358-99378,99381-99404,99408-99412,99429-99449, 99471-99476,99487-99496,99605-99607
HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,G0463

3) Modify GN 107 as shown below effective January 1, 2015:

GUIDELINE NOTE 107, HYPERBARIC OXYGEN

Lines 336,~~373~~ (delete only for biennial review List)

Hyperbaric oxygen is included on these lines only under the following circumstances:

- ~~when paired with ICD-9-CM code 526.4 for osteomyelitis of the jaw only~~
- when paired with ICD-9-CM codes [250.7x](#) and [250.8x](#)/ICD-10-CM [E11.5x](#) and [E11.621,E11.622,E11.623](#) for diabetic wounds with gangrene OR diabetic wounds of the lower extremities in patients who meet the all of the following criteria:
 - [Patient has Type 1 or Type 2 diabetes and has a lower extremity wound that is due to diabetes, AND](#)
 - [Patient has a wound classified as Wagner grade III or higher, AND](#)

Attachment A

Changes to the Prioritized List Based on Coverage Guidance on Indications for Hyperbaric Oxygen Treatment

- [Patient has failed an adequate course of standard wound therapy including arterial assessment, with no measurable signs of healing after at least thirty days, AND](#)
- [Wounds must be evaluated at least every 30 days during administration of hyperbaric oxygen therapy. Continued treatment with hyperbaric oxygen therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.](#)
- when paired with ICD-9-CM codes 526.89/ ICD-10--CM codes M27.8 for osteoradionecrosis of the jaw only
- when paired with ICD-9-CM codes 639.0, 670.02, and 670.04/ ICD-10--CM codes O08.0, M60.000-M60.09 only if the infection is a necrotizing soft-tissue infection
- ~~when paired with ICD-9-CM codes 730.10-730.99/ICD-10-CM M46.20-M46.39, M86.9 only for chronic refractory osteomyelitis unresponsive to conventional medical and surgical management~~
- when paired with ICD-9-CM codes 927-929/ICD-10 CM codes S07.xxx,S17.xxx,S38.xxx,S47.1xxA-S47.1xxD,S47.2xxA-S47.2xxD,S47.9xxA-S47.9xxD, S57.xxx,S67.xxx, S77.xxx,S87.xxx,S97.xxx, T79.Axx, only for posttraumatic crush injury of Gustilo type III B and C
- when paired with ICD-9-CM codes 990/ ICD-10--CM codes T66.xxxA only for osteoradionecrosis [and soft tissue radiation injury](#)
- when paired with ICD-9-CM codes [996.52](#), 996.7/ ICD-10--CM codes [T86.820-T86.829](#),T82.898A, T82.898D, T82.9xxA, T82.9xxD, T83.89xA, T83.89xD, T83.9xxA, T83.9xxD, T84.89xA, T84.89xD, T84.9xxA, T84.9xxD, T85.89xA, T85.89xD, T859xxA, T859xxD only for compromised myocutaneous flaps

DRAFT

**Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission in November 2014**

*For specific coding recommendations and guideline wording, please see the text of the
11-13-14 VbBS minutes.*

RECOMMENDED CODE MOVEMENT (effective 1/1/15)

- **Add various codes from the former DMAP Excluded List to the Prioritized List as shown in Appendix A**
- Place the 2015 CPT, CDT, and HCPCS codes as shown in Appendix B
- Add several colonoscopy and sigmoidoscopy codes to several covered lines with gastrointestinal diagnoses
- Remove several procedure codes for arthrocentesis from one or more inappropriate lines, but left on other appropriate, covered lines
- Move negative pressure wound therapy procedure codes from the Ancillary File to several covered lines on the Prioritized List
- Move several diagnoses for eye inflammation from one covered line to another
- Remove procedure codes for surgical treatments for atrial fibrillation from three covered lines but leave on another covered line
- Add various oral and facial surgery procedures back to the sleep apnea lines for use in patients with craniofacial anomalies only
- Make various straightforward coding changes and corrections

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- Cardiac PET scan was not recommended to be added to the Prioritized List or Diagnostic List

RECOMMENDED GUIDELINE CHANGES (effective 1/1/15)

- Change the non-prenatal genetic testing guideline to reflect the new genetic testing CPT placements (noting non-covered codes and placing restrictions on use of some codes) and update the references to expert documents.
- Alter the negative pressure wound therapy guideline from an ancillary guideline to a standard guideline as the CPT codes involved were moved from the Ancillary File to the Prioritized List.
- Change the high risk for breast cancer guideline to require women without a history of breast cancer to have services determined based on NCCN requirements and to specify that contralateral mastectomy is a covered service for women with breast cancer.
- Delete the denture guideline and use DMAP rules to determine eligibility for dentures in the future
- Modify the intraocular steroid for chronic non-infectious uveitis guideline to allow treatment for intermediate and pan-uveitis as well as posterior uveitis.
- Modify the intraocular steroid implants for central retinal vein occlusion to allow treatment for macular edema resulting from branch retinal vein occlusion in certain circumstances.
- Modify the sinus surgery guideline to clarify when adenoidectomy is appropriate
- Modify the sleep apnea guideline to clarify when adenoidectomy is appropriate and specify that oral/facial surgery codes are included on the line only for patients with craniofacial anomalies
- Adopt a new guideline regarding surgical treatments for atrial fibrillation
- Adopt a new diagnostic guideline for SPECT imaging
- Adopt a new guideline indicating that breast pumps and supplies are covered for postpartum women when a pump is necessary to establish or maintain milk production in order to maximize availability of breast milk to the baby and that lactation support services are covered for pregnant and postpartum women for 6 months postpartum.

VALUE-BASED BENEFITS SUBCOMMITTEE
Meridian Park Health
Community Health Education Center, Room 117B&C
Tualatin, Oregon
November 13, 2014
8:30 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair (via phone); James Tyack, DMD; David Pollack, MD (left at 1PM); Mark Gibson; Holly Jo Hodges, MD (via phone); Laura Ocker, LAc.

Members Absent: Susan Williams, MD; Irene Crowell, RPh

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

Also Attending: Wally Shaffer, MD, DMAP; Stephen Heitner MD, OHSU; Deirdre Monroe and Jane Stephen, Allergan; Bonnie Ranno, WIC; Katie Noah, Willamette Dental Group; Fiona Clement, UCSF; Bryon Montgomery, Astellas

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

The meeting was called to order at 8:30 am and roll was called. Minutes from the August 8, 2014 VBBS meeting were reviewed and approved. Minutes from the August 14, 2014 VBBS meeting were reviewed and a correction regarding the testimony of Anne Murray was accepted. The amended minutes were approved.

Smits reported on ongoing work on the non-covered tabled, including more detailed information on the reasons for non-coverage.

Coffman reviewed the highlights of the HERC retreat in October. A survey will be coming in the next few weeks asking members about when such a retreat should occur and other retreat related items. He also noted that there are two potential new HERC members which should be announced shortly.

Taray reviewed the new DMAP list structure, which includes conditions not covered (items excluded in rule such as infertility treatments), informational items (diagnosis codes such as status codes), undefined (usually not covered but eligible for review, such as unspecified diagnosis codes), and diagnostic work up file (diagnoses eligible for coverage for diagnostic testing).

Taray and Smits reviewed the work to date by the Back Pain Line Reorganization Task Force. The group met and is very excited about their task. They are proposing reorganizing the lines based on patient risk characteristics rather than presence of complications.

➤ **Topic: Straightforward/Consent Agenda**

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

Recommended Actions:

- 1) Add 61782 (Stereotactic computer-assisted (navigational) procedure; cranial, extradural) to lines 366 ACUTE SINUSITIS, 470 CHRONIC SINUSITIS, 512 NASAL POLYPS, OTHER DISORDERS OF NASAL CAVITY AND SINUSES, 531 BENIGN NEOPLASM OF NASAL CAVITIES, MIDDLE EAR AND ACCESSORY SINUSES, 582 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT
- 2) Rename Line 360 ~~DISEASES~~ CONDITIONS OF PULMONARY ARTERY
- 3) Add 44620-44626 (Closure of enterostomy, large or small intestine) to line 75 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
- 4) Add 61500 (Craniectomy; with excision of tumor or other bone lesion of skull) to line 204 CANCER OF BONES
- 5) Add 32673 (Thoracoscopy, surgical; with resection of thymus, unilateral or bilateral) to line 266 CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS
- 6) Add 32663 (Thoracoscopy, surgical; with lobectomy (single lobe)) to lines 51 DEEP ABSCESSSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS, 62 BRONCHIECTASIS, 266 CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS, 288 CHRONIC OBSTRUCTIVE PULMONARY DISEASE; CHRONIC RESPIRATORY FAILURE, 360 DISEASES OF PULMONARY ARTERY, 376 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS
- 7) Add 31645 and 31646 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with therapeutic aspiration of tracheobronchial tree, initial/subsequent) to line 62 BRONCHIECTASIS
- 8) Add 64455 (Injection(s), anesthetic agent and/or steroid, plantar common digital nerve(s) (eg, Morton's neuroma)) to line 544 LESION OF PLANTAR NERVE; PLANTAR FASCIAL FIBROMATOSIS and remove from all other lines on the Prioritized List
- 9) Remove 99363 and 99364 (Anticoagulant management for an outpatient taking warfarin) from line 579 LYMPHEDEMA
- 10) Add 69717 and 69718 (Replacement (including removal of existing device), osseointegrated implant, with or without mastoidectomy) to lines 317 HEARING LOSS - AGE 5 OR UNDER; MEDICAL THERAPY INCLUDING HEARING AIDS and 450 HEARING LOSS – OVER AGE 5; MEDICAL THERAPY INCLUDING HEARING AIDS
- 11) Remove 69717 and 69718 (Replacement (including removal of existing device), osseointegrated implant, with or without mastoidectomy) from lines 283 SENSORINEURAL HEARING LOSS - AGE 5 OR UNDER; COCHLEAR IMPLANT and 423 SENSORINEURAL HEARING LOSS – OVER AGE 5; COCHLEAR IMPLANT
- 12) Delete the coding specification regarding R49.0 from line 564.
- 13) Remove 26426 (Repair of extensor tendon, central slip, secondary (eg, Boutonniere deformity); using local tissue(s), including lateral band(s), each finger) from line 380 DISRUPTIONS OF THE LIGAMENTS AND TENDONS OF THE ARMS AND LEGS, EXCLUDING THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT

- 14) Add 26426 to line 391 DEFORMITY/CLOSED DISLOCATION OF MINOR JOINT AND RECURRENT JOINT DISLOCATIONS
- 15) Add 64721 (Neuroplasty and/or transposition; median nerve at carpal tunnel) to line 211 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT
- 16) Add 57287 (Removal or revision of sling for stress incontinence (eg, fascia or synthetic)) to line 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
- 17) Add 34203 (Embolectomy or thrombectomy, with or without catheter; popliteal-tibio-peroneal artery, by leg incision) to line 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
- 18) Add 10061 (Incision and drainage of abscess (eg, carbuncle, suppurative hidradenitis, cutaneous or subcutaneous abscess, cyst, furuncle, or paronychia); complicated or multiple) to line 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
- 19) Add 43229 (Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)) to line 519 ESOPHAGITIS AND GERD; ESOPHAGEAL SPASM; ASYMPTOMATIC DIAPHRAGMATIC HERNIA
- 20) Add line 300 APLASTIC ANEMIAS to GN7 ERYTHROPOIESIS-STIMULATING AGENT (ESA) GUIDELINE
- 21) Remove 27236 (Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement) from line 358 CLOSED FRACTURE OF EXTREMITIES (EXCEPT MINOR TOES)
- 22) Remove 27267 and 27268 (Closed treatment of femoral fracture, proximal end, head; without/with manipulation) from lines 358 CLOSED FRACTURE OF EXTREMITIES (EXCEPT MINOR TOES), 362 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS, and 391 DEFORMITY/CLOSED DISLOCATION OF MINOR JOINT AND RECURRENT JOINT DISLOCATIONS
- 23) Move A90-A94 (arthropod borne fevers), A95 (Yellow Fever), A98.0 (Crimean-Congo hemorrhagic fever), A98.1 (Omsk hemorrhagic fever), and A98.2 (Kyasanur Forest disease) from line 660 INFECTIOUS DISEASES WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY to line 271 RICKETTSIAL AND OTHER ARTHROPOD-BORNE DISEASES
- 24) Move A96 (Arenaviral hemorrhagic fever), A98.3 (Marburg virus disease), A 98.4 (Ebola virus disease), and A98.5 (Hemorrhagic fever with renal syndrome) from line 623 OTHER VIRAL INFECTIONS to line 186 SEPTICEMIA
- 25) Move A98.8 (Other specified viral hemorrhagic fevers) and A99 (Unspecified viral hemorrhagic fever) from line 660 INFECTIOUS DISEASES WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY to line 186 SEPTICEMIA
- 26) Remove 92015 (DETERMINATION OF REFRACTIVE STATE) from all lines except line 455 DISORDERS OF REFRACTION AND ACCOMODATION
- 27) 266 codes currently on the Excluded List at DMAP were reviewed for placement on the Prioritized List. Placement recommended as shown in Appendix A

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

➤ **Topic: 2015 CPT, CDT, and HCPCS codes**

Discussion: There was a general request to re-organize this review for next year. A group of straightforward codes (e.g. codes that have similar codes already on List) should be separated into a consent agenda. The more difficult codes which require discussion would be discussed in order with their supporting materials, and be organized in an easier to follow format.

The following codes had specific discussion:

- 1) 52441 and 52442 (Cystourethroscopy, with insertion of permanent adjustable transprostatic implant): it was noted that the HTAS is reviewing minimally invasive procedures for prostate cancer. When this HTAS review is available, these codes may need to be re-reviewed.
- 2) 64486-64489 (Transversus abdominis plane (TAP) block): there was concern that these codes may be used for expensive devices rather than simple local anesthetic injections. HERC staff was asked to review whether any proprietary devices can be used for this type of procedure; if one or more are found, staff will draft a guideline limiting use of these CPT codes to simple injections and bring back to VbBS for consideration
- 3) 81415-81417 (exome sequencing): there was concern for abnormal results that do not relate to the condition being investigated, and how these results would be handled, as well as the anxiety these abnormalities might pose to patients and family. There was discussion about adding a guideline limiting use of the test to situations where cost of the exome sequencing is found to be less than the expected cost of individual tests being considered. The decision was to readdress need for a guideline if the plans or others report problems with overuse or with complications from testing.
- 4) 91200 (Liver elastography): The VbBS discussion centered around the fact that there is no standard use for this test in clinical practice as yet. The VBBS voted to place this code on the Non-Covered Table until clinical utility was clarified. *NOTE—the recommendation for non-coverage from VbBS was not accepted by HERC, and no final placement decision was made. See 11-13-14 HERC minutes for discussion.*
- 5) G0473 (Face-to-face behavioral counseling for obesity, group (2-10), 30 minutes) was added to the lower obesity line as well as the upper obesity line. The intent is that this service is covered on the upper line only when it qualifies as intensive counseling.
- 6) S8032 (Low-dose computer tomography for lung cancer screening) was not added to the lower prevention line. This will be consistent with other screening tests that only are indicated for certain populations, such as mammography. The USPSTF criteria for eligibility for this screening test will apply through the prevention guideline. Note, a typographical error listed this code as S0832 in the meeting materials.

Recommended Actions:

- 1) Adopt 2015 CPT, CDT, and HCPCS codes as shown in Appendix B
- 2) Placement of CPT 91200 (Liver elastography) was recommended for the Non-Covered List; however this placement was not accepted by HERC and final placement will be determined at a future meeting
- 3) Add 44379 (Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, including ileum; with transendoscopic stent) to lines 32 REGIONAL

- ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE, 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS, and 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
- 4) Remove 20600 (Arthrocentesis, aspiration and/or injection, small joint or bursa (eg, fingers, toes); without ultrasound guidance) from lines 51 DEEP ABSCESES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS, 422 DISORDERS OF SHOULDER, INCLUDING SPRAINS/STRAINS GRADE 3 THROUGH 6, 430 ACUTE PERIPHERAL MOTOR AND DIGITAL NERVE INJURY, 509 OTHER DISORDERS OF SYNOVIUM, TENDON AND BURSA, COSTOCHONDRITIS, AND CHONDRODYSTROPHY, 601 GANGLION, 612 DISORDERS OF SOFT TISSUE
 - 5) Remove 20605 (Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); without ultrasound guidance) from lines 51 DEEP ABSCESES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS, 422 DISORDERS OF SHOULDER, INCLUDING SPRAINS/STRAINS GRADE 3 THROUGH 6, 430 ACUTE PERIPHERAL MOTOR AND DIGITAL NERVE INJURY, 544 LESION OF PLANTAR NERVE; PLANTAR FASCIAL FIBROMATOSIS, 601 GANGLION, 612 DISORDERS OF SOFT TISSUE
 - 6) Remove 20610 (Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance) from lines 51 DEEP ABSCESES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS, 145 SYSTEMIC LUPUS ERYTHEMATOSUS, OTHER DIFFUSE DISEASES OF CONNECTIVE TISSUE, 359 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE Treatment: ARTHROPLASTY/RECONSTRUCTION, 430 ACUTE PERIPHERAL MOTOR AND DIGITAL NERVE INJURY, 509 OTHER DISORDERS OF SYNOVIUM, TENDON AND BURSA, COSTOCHONDRITIS, AND CHONDRODYSTROPHY, 601 GANGLION, 612 DISORDERS OF SOFT TISSUE
 - 7) Add 20600 and 20605 to line 533 BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE INCLUDING OSTEOID OSTEOMAS; BENIGN NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE
 - 8) Add 45327 (Proctosigmoidoscopy, rigid; with transendoscopic stent placement (includes predilation)) to lines 32 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE and 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS
 - 9) Add 45386 (Colonoscopy, flexible; with transendoscopic balloon dilation) to line 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
 - 10) HERC staff will review whether any proprietary devices can be used for transverse abdominus plane (TAP) blocks; if one or more are found, staff will draft a guideline limiting use of these CPT codes 64486-64489 to simple injections and bring back to VbBS for consideration
 - 11) Add 66185 (Revision of aqueous shunt to extraocular equatorial plate reservoir; with graft) to line 247 PRIMARY ANGLE-CLOSURE GLAUCOMA
 - 12) Place all negative pressure wound therapy CPT codes (CPT 97605-97608) and appropriate HCPCS codes (HCPCS G0456 and G0457) on lines 8,30,51,84,209,211,239, 290, 383, 427
 - a. Advise DMAP to remove CPT 97605 and 97606 and HCPCS G0456 and G0457 from the Ancillary File
 - 13) The negative pressure wound therapy guideline was amended as shown in Appendix C

- a. Note: the wording approved at the meeting was later amended by HERC staff. The wording “is a covered benefit” was changed to “included on these lines” to be consistent with other Prioritized List guideline wording. This does not change the intent of the guideline.
- 14) The non-prenatal genetic testing guideline was amended as shown in Appendix C
 - a. Note: the guideline in the meeting materials contained a typographical error. “CPT 81415-81417, exome testing” should read “CPT 81415-81416, exome testing.” The version verbally presented and discussed at the meeting reflected the correct version of the guideline.
 - 15) Delete guideline note 62 REMOVEABLE PROSTHODONTICS
 - 16) Add 44392 (Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps) and 44394 (snare technique) and 45333 (Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps) to line 60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE

MOTION: To recommend the code placements and guideline note changes as presented or amended. CARRIES 6-0.

➤ **Topic: High risk for breast cancer guideline**

Discussion: The proposed guideline revisions defining high risk for breast cancer was introduced by Smits. There was minimal discussion regarding the first clause, which changed the definition of high risk for breast cancer for women without a diagnosis of breast cancer to refer to current National Comprehensive Cancer Network (NCCN) guidelines on this topic. The second clause, which defined what would make a woman with breast cancer eligible for a contralateral mastectomy was discussed in detail. There was concern that a woman with breast cancer was, by definition, at high risk for breast cancer as she has already developed the disease. There was discussion that contralateral mastectomy is the community standard. There was also discussion about the fact that the Prioritized List already allows bilateral breast reconstruction, and the additional mastectomy on the contralateral breast is not much more of a surgical intervention than many types of reconstructions currently allowed. It may also make the reconstruction more straightforward in some cases. The subcommittee decided to change the suggested guideline wording to reflect that any woman with breast cancer could elect to have a contralateral mastectomy, without restrictions.

Recommended Actions:

- 1) Amend GN3 was as shown in Appendix C

MOTION: To recommend the guideline note change as amended. CARRIES 6-0.

➤ **Topic: Unilateral tonsillar hypertrophy**

Discussion: Tabled until the January 1, 2015 VbBS meeting

Recommended Actions:

- Tabled until the January 1, 2015 VbBS meeting

➤ **Topic: Hemangiomas**

Discussion: Tabled until the January 1, 2015 VbBS meeting

Recommended Actions:

- Tabled until the January 1, 2015 VbBS meeting

➤ **Topic: Intraocular steroid implants**

Discussion: Smits reviewed the summary document on this topic.

Testimony was heard from Deirdre Monroe from Allergan. Ms. Monroe testified regarding the revised FDA approval for use of Ozurdex. The FDA has removed the phakic/pseudophakic wording from their indications. Ms. Monroe testified that the FDA removed this requirement as a reflection of the already very high risk of cataract development among diabetic patients. If the proposed guideline wording restricting use in diabetic macular edema to patients with phakic/pseudophakic eyes, it would exclude many patients from this therapy who could benefit from its use. She also noted that systemic therapy with steroids has many complications in diabetic patients and is generally not done in this population and should not be a requirement in the guideline. Ms. Monroe testified that the NICE guidelines cited in the summary were based on Retisert data, which is not comparable to Ozurdex. She also noted that patients cannot have cataract surgery with swelling inside the eye that is not controlled; therefore, requiring surgery first may not be feasible. Allergan's request is that the new guideline be modified to remove the restriction to phakic/pseudophakic eyes.

The subcommittee discussed the Allergan testimony. Olson suggested that HERC staff review coverage criteria for intraocular steroids in diabetic macular edema and bring this topic back to a future meeting. Therefore, the proposed new guideline regarding intraocular steroids for diabetic macular edema was tabled. All other coding and guideline note changes were considered appropriate and approved. GN117 had additional wording requiring anti-VEGF treatment failure prior to branch retinal vein occlusion treatment, to parallel the requirements for central retinal vein occlusion.

Recommended Actions:

- 1) Add panuveitis (ICD-9 360.12/ICD-10 H44.11x) and sympathetic uveitis (ICD-9 360.11/ICD-10 H44.131-9) to line 363 CHORIORETINAL INFLAMMATION and remove from line 269 ACUTE, SUBACUTE, CHRONIC AND OTHER TYPES OF IRIDOCYCLITIS
- 2) Add pars planitis (ICD-9 363.21/ICD-10 H30.2x) to line 363 CHORIORETINAL INFLAMMATION and remove from line 387 CENTRAL SEROUS CHORIORETINOPATHY
- 3) Modify GN 10 as shown in Appendix C
- 4) Modify GN 116 as shown in Appendix C
- 5) Modify GN 117 as shown in Appendix C

- 6) The proposed new guideline regarding intraocular steroids for diabetic macular edema was tabled, as was the proposal to add CPT 67027 and 67028 to line 100 DIABETIC AND OTHER RETINOPATHY. HERC staff will review FDA criteria and the medical evidence and bring back an updated proposal to a future meeting.

**MOTION: To recommend the code and guideline note changes as amended.
CARRIES 6-0.**

➤ **Topic: Coverage guidance: Percutaneous Interventions for Cervical Spine Pain**

Discussion: Smits introduced the summary document. VbBS members continued to voice their concerns that the HTAS recommendations for the addition of various percutaneous interventions for cervical spine pain were based on weak evidence. VbBS members requested clarification of their role in making recommendations for changes to the Prioritized List when the VbBS members do not agree with HTAS or EbGS's recommendations. There was some support for the idea that VbBS had the authority to act independently and recommend whatever they felt was most appropriate for the Prioritized List. It was noted that VbBS determined Prioritized List contents, but that EbGS and HTAS made coverage guidances for a wider audience, including private payers.

There was discussion about having a standard level of acceptable evidence that was consistent between subcommittees. If HTAS/EbGS made recommendations based on a low level of evidence, VbBS members requested that there be supplementary information in the HTAS/EbGS report about why this recommendation was made in order to assist VbBS.

There were concerns about the actual report contents. There was concern raised as to why cervical epidural steroid injections were being considered for non-coverage when lumbar injections were covered. Livingston noted that lumbar injections had a better level of evidence (mixed-moderate benefit in some studies, none in others) than cervical injections. There was concern about the use of expert opinion in the HTAS report. Shaffer noted that HTAS/EbGS used expert opinion when the evidence is low as a way of clarifying the literature/evidence.

The VbBS decided to have HERC staff ask the HERC for guidance about what should be done if the VbBS does not agree with HTAS and EbGS recommendations. Does VbBS have the authority to make recommendations that conflict with HTAS or EbGS? Or should VbBS sent the report back to these other groups if there is significant disagreement? Or should HERC make the final decision in these cases? VbBS members also asked for clarification from the HERC on what other factors were appropriate for VbBS to take into account when discussing coverage guidance reports with weak evidence; for example, should availability of alternate therapies, the types of studies possible in the field under debate, avoidance of expensive surgeries, and other factors be included in the VbBS decision making process?

Recommended Action:

- 1) This topic was tabled until further HERC input could be obtained. HERC staff will bring this back to the January, 2015 VbBS meeting unless HERC acts on this topic at the November, 2014 HERC meeting.
-

➤ **Topic: Coverage guidance: Ablation for Atrial Fibrillation**

Discussion: There was minimal discussion on this topic.

Recommended Actions:

- 1) Remove maze procedures (CPT 33254-33259, 33265, 33266) from line 286 LIFE-THREATENING CARDIAC ARRHYTHMIAS
- 2) Remove 33261 (Operative ablation of ventricular arrhythmogenic focus with cardiopulmonary bypass) from lines 73 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION and 193 CHRONIC ISCHEMIC HEART DISEASE
- 3) Add a new guideline regarding treatments for atrial fibrillation to line 350 as shown in Appendix D

MOTION: To approve the recommended changes to the Prioritized List based on the draft Ablation for Atrial Fibrillation Coverage Guidance scheduled for review by HERC at their January 2015 meeting. CARRIES 6-0.

➤ **Topic: Coverage guidance: Nuclear Cardiac Imaging**

Discussion: Smits introduced a summary document. Dr. Heitner testified that the proposed new SPECT guideline should allow for variations based on local availability of expert providers. Smits indicated that the phrase “is unavailable” in the SPECT guideline would cover the situations in which no expert provider is available. The VbBS agreed with this interpretation.

Recommended Actions:

- 1) Make no change in current non-coverage of cardiac PET scan
 - a. CPT 78459, 78491, and 78492 are in the Excluded File
 - b. Add entries to the non-covered table for these CPT codes
- 2) Adopt the new diagnostic guideline for SPECT imaging as shown in Appendix D

MOTION: To approve the recommended changes to the Prioritized List based on the draft Nuclear Cardiac Imaging Coverage Guidance scheduled for review by HERC at their January, 2015 meeting. CARRIES 6-0.

➤ **Topic: Surgical treatment of sleep apnea in children with craniofacial anomalies**

Discussion: Smits presented the issue summary. There was no discussion.

Recommended Actions:

Note: the line number in the issue summary (210) was from the October 1, 2014 Prioritized List; the correct line placement for the January 1, 2015 Prioritized List is line 206.

- 1) Add 21193-21235 (Mandible and facial bone reconstruction procedures), 30117 (Excision or destruction (eg, laser), intranasal lesion), 30140 (Submucous resection inferior turbinate, partial or complete), 30520 (Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft), 42140-42160 (Palate and uvula procedures) to line 206 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER
 - a. Advise DMAP to remove 42140 (Uvulectomy, excision of uvula) from the Excluded File
- 2) Delete the coding specification from line 206
 - ~~42299 Unlisted procedure, palate, uvula (use for laser assisted uvulopalatoplasty (LAUP), somnoplasty, palatal implants) does not pair on Line 210 with obstructive sleep apnea in adults.~~
- 3) Modify GN27 as shown in Appendix C
- 4) Modify GN 118 as shown in Appendix C and presented in the next section

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

➤ **Topic: Adenoidectomy – revisions to the obstructive sleep apnea guideline and sinusitis surgery guideline**

Discussion: There was no discussion.

Recommended Actions:

- 1) Modify GN35 as shown in Appendix C
- 2) Modify GN 118 as shown in Appendix C

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

➤ **Topic: Retained tympanostomy tube guideline**

Discussion: Tabled until the January, 2015 VbBS meeting

Recommended Actions:

- Tabled until the January, 2015 VBBS meeting
-

➤ **Topic: Breastfeeding support and pumping supplies**

Discussion: Livingston presented an issue summary.

Bonnie Ranno, Breastfeeding Coordinator for WIC, presented public testimony. She discussed the importance of breastfeeding and discussed WIC's role as providing primary prevention services. Some agencies cover additional peer support and provide a limited number of multiuser pumps.

Subcommittee members discussed the proposed language and determined that medical necessity should not be a requirement and that the goal of providing breast pumps is in order to maximize the availability of breast milk to the baby. Concerns were shared that this was a significant departure from current coverage, and would potentially greatly expand OHPs role in the provision of breast pumps. Members stated that they thought that would be appropriate given the health benefits of breast milk. The guideline was reworded to further remove barriers. Additionally, members suggested requiring breast pumps to be provided within 24 hours given how important a rapid turnaround would be for ensuring ongoing milk production.

Recommended Actions:

- a. Add codes S9443 (Lactation classes, non-physician provider, per session), V24.1 (Postpartum care and examination of lactating mother), and Z39.1 (Encounter for care and examination of lactating mother) to Line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
- b. A new guideline was adopted as shown in Appendix D

**MOTION: To recommend the code and guideline note changes as presented.
CARRIES 6-0.**

➤ **Public Comment:**

No additional public comment was received.

➤ **Issues for next meeting:**

- Liver elastoplasty
- Hemangiomas
- Retained tympanostomy tubes guideline
- Unilateral tonsillar hypertrophy
- Intraocular steroids for diabetic macular edema
- Percutaneous interventions for cervical spine pain
- Wearable cardiac defibrillators
- Cochlear implants guideline
- Stereotactic radiation
- PET scan for fever of unknown origin
- Catheter thrombolysis for pulmonary embolism
- Intensive counseling for overweight with cardiovascular risk factors

➤ **Next meeting:**

January 8, 2015 at Clackamas Community College, Wilsonville Training Center,
Wilsonville Oregon, Rooms 111-112.

➤ **Adjournment:**

The meeting adjourned at 1:30 PM.

DRAFT

Appendix A
Codes Moved from DMAP Excluded File to the Prioritized List

ICD-9	Diagnosis Description	Current file	Recommended Placement
051.1	Pseudocowpox	EXCLUDED FILE	623 OTHER VIRAL INFECTIONS
051.2	Contagious pustular dermatitis	EXCLUDED FILE	623
051.9	Paravaccinia, unspecified	EXCLUDED FILE	623
173.00	Unspecified malignant neoplasm of skin of lip	EXCLUDED FILE	279 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
173.10	Unspecified malignant neoplasm of eyelid, including	EXCLUDED FILE	279
173.20	Unspecified malignant neoplasm of skin of ear and external auditory canal	EXCLUDED FILE	279
173.30	Unspecified malignant neoplasm of skin of other and unspecified parts of face	EXCLUDED FILE	279
173.40	Unspecified malignant neoplasm of scalp and skin of	EXCLUDED FILE	279
173.50	Unspecified malignant neoplasm of skin of trunk, except scrotum	EXCLUDED FILE	279
173.60	Unspecified malignant neoplasm of skin of upper limb, including shoulder	EXCLUDED FILE	279
173.70	Unspecified malignant neoplasm of skin of lower limb, including hip	EXCLUDED FILE	279
173.80	Unspecified malignant neoplasm of other specified	EXCLUDED FILE	279
173.90	Unspecified malignant neoplasm of skin, site	EXCLUDED FILE	279
228.09	Hemangioma of other sites	ANCILLARY CODES	636
278.02	Overweight	EXCLUDED FILE	661 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
278.8	Other hyperalimentation	EXCLUDED FILE	661

Appendix A
Codes Moved from DMAP Excluded File to the Prioritized List

ICD-9	Diagnosis Description	Current file	Recommended Placement
284.2	Myelophthisis	EXCLUDED FILE	118 APLASTIC ANEMIAS; AGRANULOCYTOSIS 300 APLASTIC ANEMIAS
300.20	Phobia, unspecified	EXCLUDED FILE	463 SIMPLE PHOBIAS AND SOCIAL ANXIETY DISORDER
300.89	Other somatoform disorders	EXCLUDED FILE	497 SOMATIZATION DISORDER, SOMATOFORM PAIN DISORDER, CONVERSION DISORDER
302.51	Trans-sexualism with asexual history	EXCLUDED FILE	413 GENDER DYSPHORIA
302.52	Trans-sexualism with homosexual history	EXCLUDED FILE	413
302.53	Trans-sexualism with heterosexual history	EXCLUDED FILE	413
302.81	Fetishism	EXCLUDED FILE	501 PARAPHILIAS AND OTHER PSYCHOSEXUAL DISORDERS
302.82	Voyeurism	EXCLUDED FILE	501
302.83	Sexual masochism	EXCLUDED FILE	501
302.84	Sexual sadism	EXCLUDED FILE	501
302.89	Other specified psychosexual disorders	EXCLUDED FILE	501
307.40	Nonorganic sleep disorder, unspecified	EXCLUDED FILE	614 DISORDERS OF SLEEP WITHOUT SLEEP APNEA
312.30	Impulse control disorder, unspecified	EXCLUDED FILE	467 OBSESSIVE-COMPULSIVE DISORDERS

Appendix A
Codes Moved from DMAP Excluded File to the Prioritized List

ICD-9	Diagnosis Description	Current file	Recommended Placement
315.4	Developmental coordination disorder	EXCLUDED FILE	297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 381 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
315.5	Mixed development disorder	EXCLUDED FILE	297,381
315.8	Other specified delays in development	EXCLUDED FILE	297,381
315.9	Unspecified delay in development	EXCLUDED FILE	297,381
321.0	Cryptococcal meningitis	EXCLUDED FILE	113 SUBACUTE MENINGITIS (EG. TUBERCULOSIS, CRYPTOCOCCOSIS)
321.1	Meningitis in other fungal diseases	EXCLUDED FILE	113
321.2	Meningitis due to viruses not elsewhere classified	EXCLUDED FILE	554 ASEPTIC MENINGITIS
321.3	Meningitis due to trypanosomiasis	EXCLUDED FILE	113
321.4	Meningitis in sarcoidosis	EXCLUDED FILE	113
321.8	Meningitis due to other nonbacterial organisms classified elsewhere	EXCLUDED FILE	113,554
323.01	Encephalitis and encephalomyelitis in viral diseases classified elsewhere	EXCLUDED FILE	540 VIRAL, SELF-LIMITING ENCEPHALITIS, MYELITIS AND ENCEPHALOMYELITIS
323.02	Myelitis in viral diseases classified elsewhere	EXCLUDED FILE	540
323.1	Encephalitis, myelitis, and encephalomyelitis in rickettsial diseases classified elsewhere	EXCLUDED FILE	540
323.2	Encephalitis, myelitis, and encephalomyelitis in protozoal diseases classified elsewhere	EXCLUDED FILE	540

Appendix A
Codes Moved from DMAP Excluded File to the Prioritized List

ICD-9	Diagnosis Description	Current file	Recommended Placement
323.41	Other encephalitis and encephalomyelitis due to other infections classified elsewhere	EXCLUDED FILE	540
323.42	Other myelitis due to other infections classified	EXCLUDED FILE	540
323.61	Infectious acute disseminated encephalomyelitis	EXCLUDED FILE	540
323.62	Other postinfectious encephalitis and	EXCLUDED FILE	540
323.63	Postinfectious myelitis	EXCLUDED FILE	540
323.71	Toxic encephalitis and encephalomyelitis	EXCLUDED FILE	540
323.72	Toxic myelitis	EXCLUDED FILE	540
327.01	Insomnia due to medical condition classified	EXCLUDED FILE	614
327.02	Insomnia due to mental disorder	EXCLUDED FILE	614
327.14	Hypersomnia due to medical condition classified	EXCLUDED FILE	614
327.15	Hypersomnia due to mental disorder	EXCLUDED FILE	614
330.2	Cerebral degeneration in generalized lipidoses	EXCLUDED FILE	75,297,349,381
330.3	Cerebral degeneration of childhood in other diseases classified elsewhere	EXCLUDED FILE	75,297,349,381
336.2	Subacute combined degeneration of spinal cord in diseases classified elsewhere	EXCLUDED FILE	75,297,349,381
336.3	Myelopathy in other diseases classified elsewhere	EXCLUDED FILE	75,297,349,381
337.1	Peripheral autonomic neuropathy in disorders classified elsewhere	EXCLUDED FILE	75,297,349,381
347.10	Narcolepsy in conditions classified elsewhere, without cataplexy	EXCLUDED FILE	614
347.11	Narcolepsy in conditions classified elsewhere, with	EXCLUDED FILE	614
357.1	Polyneuropathy in collagen vascular disease	EXCLUDED FILE	515 PERIPHERAL NERVE DISORDERS
357.3	Polyneuropathy in malignant disease	EXCLUDED FILE	515
357.4	Polyneuropathy in other diseases classified elsewhere	EXCLUDED FILE	515
366.41	Diabetic cataract	EXCLUDED FILE	301 CATARACT
366.42	Tetanic cataract	EXCLUDED FILE	301
366.43	Myotonic cataract	EXCLUDED FILE	301
366.44	Cataract associated with other syndromes	EXCLUDED FILE	301

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Codes Moved from DMAP Excluded File to the Prioritized List

ICD-9	Diagnosis Description	Current file	Recommended Placement
372.15	Parasitic conjunctivitis	EXCLUDED FILE	508 CHRONIC CONJUNCTIVITIS, BLEPHAROCONJUNCTIVITIS
373.4	Infective dermatitis of eyelid of types resulting in	EXCLUDED FILE	575 BLEPHARITIS
373.5	Other infective dermatitis of eyelid	EXCLUDED FILE	575
373.6	Parasitic infestation of eyelid	EXCLUDED FILE	575
377.00	Papilledema, unspecified	ANCILLARY CODES	659 INTRACRANIAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
377.9	Unspecified disorder of optic nerve and visual	EXCLUDED FILE	659
378.9	Unspecified disorder of eye movements	EXCLUDED FILE	398 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN
420.0	Acute pericarditis in diseases classified elsewhere	EXCLUDED FILE	86 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS
421.1	Acute and subacute infective endocarditis in diseases classified elsewhere	EXCLUDED FILE	86
484.1	Pneumonia in cytomegalic inclusion disease	EXCLUDED FILE	208 PNEUMOCOCCAL PNEUMONIA, OTHER BACTERIAL PNEUMONIA, BRONCHOPNEUMONIA
484.3	Pneumonia in whooping cough	EXCLUDED FILE	208
484.5	Pneumonia in anthrax	EXCLUDED FILE	208
484.6	Pneumonia in aspergillosis	EXCLUDED FILE	208
484.7	Pneumonia in other systemic mycoses	EXCLUDED FILE	208
484.8	Pneumonia in other infectious diseases classified	EXCLUDED FILE	208
521.41	Pathological resorption, internal	EXCLUDED FILE	654

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Codes Moved from DMAP Excluded File to the Prioritized List

ICD-9	Diagnosis Description	Current file	Recommended Placement
521.42	Pathological resorption, external	EXCLUDED FILE	654
521.49	Other pathological resorption	EXCLUDED FILE	654
521.5	Hypercementosis	ANCILLARY CODES	654
523.00	Acute gingivitis, plaque induced	ANCILLARY CODES	222 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
523.01	Acute gingivitis, non-plaque induced	ANCILLARY CODES	222
523.10	Chronic gingivitis, plaque induced	ANCILLARY CODES	222
523.11	Chronic gingivitis, non-plaque induced	ANCILLARY CODES	222
523.20	Gingival recession, unspecified	ANCILLARY CODES	222
523.21	Gingival recession, minimal	ANCILLARY CODES	222
523.22	Gingival recession, moderate	ANCILLARY CODES	222
523.23	Gingival recession, severe	ANCILLARY CODES	222
523.24	Gingival recession, localized	ANCILLARY CODES	222
523.25	Gingival recession, generalized	ANCILLARY CODES	222
523.30	Aggressive periodontitis, unspecified	ANCILLARY CODES	222
523.31	Aggressive periodontitis, localized	ANCILLARY CODES	222
523.32	Aggressive periodontitis, generalized	ANCILLARY CODES	222
523.33	Acute periodontitis	ANCILLARY CODES	222
523.40	Chronic periodontitis, unspecified	ANCILLARY CODES	222
523.41	Chronic periodontitis, localized	ANCILLARY CODES	222
523.42	Chronic periodontitis, generalized	ANCILLARY CODES	222
523.5	Periodontosis	ANCILLARY CODES	222
523.6	Accretions on teeth	ANCILLARY CODES	654
523.8	Other specified periodontal diseases	ANCILLARY CODES	222
523.9	Unspecified gingival and periodontal disease	ANCILLARY CODES	222
524.32	Excessive spacing of teeth	ANCILLARY CODES	626 DENTAL CONDITIONS (EG.
525.0	Exfoliation of teeth due to systemic causes	ANCILLARY CODES	655

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Codes Moved from DMAP Excluded File to the Prioritized List

ICD-9	Diagnosis Description	Current file	Recommended Placement
525.10	Acquired absence of teeth, unspecified	EXCLUDED FILE	457 DENTAL CONDITIONS (EG. MISSING TEETH, PROSTHESIS FAILURE)
525.11	Loss of teeth due to trauma	EXCLUDED FILE	457
525.12	Loss of teeth due to periodontal disease	EXCLUDED FILE	457
525.13	Loss of teeth due to caries	EXCLUDED FILE	457
525.19	Other loss of teeth	EXCLUDED FILE	457
525.61	Open restoration margins	EXCLUDED FILE	347 DENTAL CONDITIONS (EG. CARIES, FRACTURED TOOTH)
525.62	Unrepairable overhanging of dental restorative	EXCLUDED FILE	347
525.63	Fractured dental restorative material without loss of material	EXCLUDED FILE	347 DENTAL CONDITIONS (EG. CARIES, FRACTURED TOOTH)
525.64	Fractured dental restorative material with loss of	EXCLUDED FILE	347
525.65	Contour of existing restoration of tooth biologically incompatible with oral health	EXCLUDED FILE	347
525.66	Allergy to existing dental restorative material	EXCLUDED FILE	347
525.8	Other specified disorders of the teeth and supporting	ANCILLARY CODES	655
526.61	Perforation of root canal space	EXCLUDED FILE	655
526.62	Endodontic overfill	EXCLUDED FILE	655
526.63	Endodontic underfill	EXCLUDED FILE	655
526.69	Other periradicular pathology associated with previous endodontic treatment	EXCLUDED FILE	655
573.1	Hepatitis in viral diseases classified elsewhere	EXCLUDED FILE	202 CHRONIC HEPATITIS; VIRAL HEPATITIS
573.2	Hepatitis in other infectious diseases classified	EXCLUDED FILE	202
595.4	Cystitis in diseases classified elsewhere	EXCLUDED FILE	278 UROLOGIC INFECTIONS
601.4	Prostatitis in diseases classified elsewhere	EXCLUDED FILE	521 CHRONIC PROSTATITIS, OTHER DISORDERS OF PROSTATE
604.91	Orchitis and epididymitis in diseases classified	EXCLUDED FILE	278

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Codes Moved from DMAP Excluded File to the Prioritized List

ICD-9	Diagnosis Description	Current file	Recommended Placement
608.81	Disorders of male genital organs in diseases classified elsewhere	EXCLUDED FILE	667 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
608.85	Stricture of male genital organs	ANCILLARY CODES	667
608.86	Edema of male genital organs	EXCLUDED FILE	667
608.89	Other specified disorders of male genital organs	EXCLUDED FILE	667
629.0	Hematocele, female, not elsewhere classified	EXCLUDED FILE	536 CHRONIC PELVIC INFLAMMATORY DISEASE, PELVIC PAIN SYNDROME,
629.9	Unspecified disorder of female genital organs	EXCLUDED FILE	667
711.10	Arthropathy associated with Reiter's disease and nonspecific urethritis, site unspecified	EXCLUDED FILE	668 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
711.11	Arthropathy associated with Reiter's disease and nonspecific urethritis, shoulder region	EXCLUDED FILE	668
711.12	Arthropathy associated with Reiter's disease and nonspecific urethritis, upper arm	EXCLUDED FILE	668
711.13	Arthropathy associated with Reiter's disease and nonspecific urethritis, forearm	EXCLUDED FILE	668
711.14	Arthropathy associated with Reiter's disease and nonspecific urethritis, hand	EXCLUDED FILE	668
711.15	Arthropathy associated with Reiter's disease and nonspecific urethritis, pelvic region and thigh	EXCLUDED FILE	668
711.16	Arthropathy associated with Reiter's disease and nonspecific urethritis, lower leg	EXCLUDED FILE	668
711.17	Arthropathy associated with Reiter's disease and nonspecific urethritis, ankle and foot	EXCLUDED FILE	668
711.18	Arthropathy associated with Reiter's disease and nonspecific urethritis, other specified sites	EXCLUDED FILE	668
711.19	Arthropathy associated with Reiter's disease and nonspecific urethritis, multiple sites	EXCLUDED FILE	668

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Codes Moved from DMAP Excluded File to the Prioritized List

ICD-9	Diagnosis Description	Current file	Recommended Placement
711.20	Arthropathy in Behcet's syndrome, site unspecified	EXCLUDED FILE	668
711.21	Arthropathy in Behcet's syndrome, shoulder region	EXCLUDED FILE	668
711.22	Arthropathy in Behcet's syndrome, upper arm	EXCLUDED FILE	668
711.23	Arthropathy in Behcet's syndrome, forearm	EXCLUDED FILE	668
711.24	Arthropathy in Behcet's syndrome, hand	EXCLUDED FILE	668
711.25	Arthropathy in Behcet's syndrome, pelvic region and	EXCLUDED FILE	668
711.26	Arthropathy in Behcet's syndrome, lower leg	EXCLUDED FILE	668
711.27	Arthropathy in Behcet's syndrome, ankle and foot	EXCLUDED FILE	668
711.28	Arthropathy in Behcet's syndrome, other specified	EXCLUDED FILE	668
711.29	Arthropathy in Behcet's syndrome, multiple sites	EXCLUDED FILE	668
711.30	Postdysenteric arthropathy, site unspecified	EXCLUDED FILE	668
711.31	Postdysenteric arthropathy, shoulder region	EXCLUDED FILE	668
711.32	Postdysenteric arthropathy, upper arm	EXCLUDED FILE	668
711.33	Postdysenteric arthropathy, forearm	EXCLUDED FILE	668
711.34	Postdysenteric arthropathy, hand	EXCLUDED FILE	668
711.35	Postdysenteric arthropathy, pelvic region and thigh	EXCLUDED FILE	668
711.36	Postdysenteric arthropathy, lower leg	EXCLUDED FILE	668
711.38	Postdysenteric arthropathy, other specified sites	ANCILLARY CODES	668
711.39	Postdysenteric arthropathy, multiple sites	ANCILLARY CODES	668
711.40	Arthropathy associated with other bacterial diseases, site unspecified	ANCILLARY CODES	668
711.41	Arthropathy associated with other bacterial diseases, shoulder region	ANCILLARY CODES	668
711.42	Arthropathy associated with other bacterial diseases, upper arm	ANCILLARY CODES	668
711.43	Arthropathy associated with other bacterial diseases,	ANCILLARY CODES	668
711.44	Arthropathy associated with other bacterial diseases,	ANCILLARY CODES	668
711.45	Arthropathy associated with other bacterial diseases, pelvic region and thigh	ANCILLARY CODES	668
711.46	Arthropathy associated with other bacterial diseases,	ANCILLARY CODES	668

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Codes Moved from DMAP Excluded File to the Prioritized List

ICD-9	Diagnosis Description	Current file	Recommended Placement
711.47	Arthropathy associated with other bacterial diseases, ankle and foot	ANCILLARY CODES	668
711.48	Arthropathy associated with other bacterial diseases, other specified sites	ANCILLARY CODES	668
711.49	Arthropathy associated with other bacterial diseases, multiple sites	ANCILLARY CODES	668
711.50	Arthropathy associated with other viral diseases, site unspecified	ANCILLARY CODES	668
711.51	Arthropathy associated with other viral diseases, shoulder region	ANCILLARY CODES	668
711.52	Arthropathy associated with other viral diseases, upper	ANCILLARY CODES	668
711.53	Arthropathy associated with other viral diseases,	ANCILLARY CODES	668
711.54	Arthropathy associated with other viral diseases, hand	ANCILLARY CODES	668
711.55	Arthropathy associated with other viral diseases, pelvic region and thigh	ANCILLARY CODES	668
711.56	Arthropathy associated with other viral diseases, lower	ANCILLARY CODES	668
711.57	Arthropathy associated with other viral diseases, ankle and foot	ANCILLARY CODES	668
711.58	Arthropathy associated with other viral diseases, other specified sites	ANCILLARY CODES	668
711.59	Arthropathy associated with other viral diseases,	ANCILLARY CODES	668
711.60	Arthropathy associated with mycoses, site unspecified	ANCILLARY CODES	668
711.61	Arthropathy associated with mycoses, shoulder region	ANCILLARY CODES	668
711.62	Arthropathy associated with mycoses, upper arm	ANCILLARY CODES	668
711.63	Arthropathy associated with mycoses, forearm	ANCILLARY CODES	668
711.64	Arthropathy associated with mycoses, hand	ANCILLARY CODES	668
711.65	Arthropathy associated with mycoses, pelvic region	ANCILLARY CODES	668
711.66	Arthropathy associated with mycoses, lower leg	ANCILLARY CODES	668
711.67	Arthropathy associated with mycoses, ankle and foot	ANCILLARY CODES	668
711.68	Arthropathy associated with mycoses, other specified	ANCILLARY CODES	668

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Codes Moved from DMAP Excluded File to the Prioritized List

ICD-9	Diagnosis Description	Current file	Recommended Placement
711.69	Arthropathy associated with mycoses, involving	ANCILLARY CODES	668
711.70	Arthropathy associated with helminthiasis, site	ANCILLARY CODES	668
711.71	Arthropathy associated with helminthiasis, shoulder	ANCILLARY CODES	668
711.72	Arthropathy associated with helminthiasis, upper arm	ANCILLARY CODES	668
711.73	Arthropathy associated with helminthiasis, forearm	ANCILLARY CODES	668
711.74	Arthropathy associated with helminthiasis, hand	ANCILLARY CODES	668
711.75	Arthropathy associated with helminthiasis, pelvic region and thigh	ANCILLARY CODES	668
711.76	Arthropathy associated with helminthiasis, lower leg	ANCILLARY CODES	668
711.77	Arthropathy associated with helminthiasis, ankle and	ANCILLARY CODES	668
711.78	Arthropathy associated with helminthiasis, other	ANCILLARY CODES	668
711.79	Arthropathy associated with helminthiasis, multiple	ANCILLARY CODES	668
711.80	Arthropathy associated with other infectious and parasitic diseases, site unspecified	ANCILLARY CODES	668
711.81	Arthropathy associated with other infectious and parasitic diseases, shoulder region	ANCILLARY CODES	668
711.82	Arthropathy associated with other infectious and parasitic diseases, upper arm	ANCILLARY CODES	668
711.83	Arthropathy associated with other infectious and parasitic diseases, forearm	ANCILLARY CODES	668
711.84	Arthropathy associated with other infectious and parasitic diseases, hand	ANCILLARY CODES	668
711.85	Arthropathy associated with other infectious and parasitic diseases, pelvic region and thigh	ANCILLARY CODES	668
711.86	Arthropathy associated with other infectious and parasitic diseases, lower leg	ANCILLARY CODES	668
711.87	Arthropathy associated with other infectious and parasitic diseases, ankle and foot	ANCILLARY CODES	668
711.88	Arthropathy associated with other infectious and parasitic diseases, other specified sites	ANCILLARY CODES	668

Appendix A
Codes Moved from DMAP Excluded File to the Prioritized List

ICD-9	Diagnosis Description	Current file	Recommended Placement
711.89	Arthropathy associated with other infectious and parasitic diseases, multiple sites	ANCILLARY CODES	668
713.0	Arthropathy associated with other endocrine and metabolic disorders	ANCILLARY CODES	668
713.1	Arthropathy associated with gastrointestinal conditions other than infections	ANCILLARY CODES	668
713.2	Arthropathy associated with hematological disorders	ANCILLARY CODES	668
713.3	Arthropathy associated with dermatological disorders	ANCILLARY CODES	668
713.4	Arthropathy associated with respiratory disorders	ANCILLARY CODES	668
713.6	Arthropathy associated with hypersensitivity reaction	ANCILLARY CODES	668
713.7	Other general diseases with articular involvement	ANCILLARY CODES	668
713.8	Arthropathy associated with other conditions classifiable elsewhere	ANCILLARY CODES	668
718.70	Developmental dislocation of joint, site unspecified	ANCILLARY CODES	668
718.70	Developmental dislocation of joint, site unspecified	ANCILLARY CODES	668
718.88	Other joint derangement, not elsewhere classified, other specified sites	ANCILLARY CODES	668
718.88	Other joint derangement, not elsewhere classified, other specified sites	ANCILLARY CODES	668
720.81	Inflammatory spondylopathies in diseases classified elsewhere	EXCLUDED FILE	545 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT
727.01	Synovitis and tenosynovitis in diseases classified	EXCLUDED FILE	612 DISORDERS OF SOFT TISSUE
730.70	Osteopathy resulting from poliomyelitis, site unspecified	ANCILLARY CODES	297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 381 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE
730.71	Osteopathy resulting from poliomyelitis, shoulder	ANCILLARY CODES	297,381
730.72	Osteopathy resulting from poliomyelitis, upper arm	ANCILLARY CODES	297,381

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Codes Moved from DMAP Excluded File to the Prioritized List

ICD-9	Diagnosis Description	Current file	Recommended Placement
730.73	Osteopathy resulting from poliomyelitis, forearm	ANCILLARY CODES	297,381
730.74	Osteopathy resulting from poliomyelitis, hand	ANCILLARY CODES	297,381
730.75	Osteopathy resulting from poliomyelitis, pelvic region and thigh	ANCILLARY CODES	297,381
730.76	Osteopathy resulting from poliomyelitis, lower leg	ANCILLARY CODES	297,381
730.77	Osteopathy resulting from poliomyelitis, ankle and	ANCILLARY CODES	297,381
730.78	Osteopathy resulting from poliomyelitis, other	ANCILLARY CODES	297,381
730.79	Osteopathy resulting from poliomyelitis, multiple sites	ANCILLARY CODES	297,381
730.80	Other infections involving bone in diseases classified elsewhere, site unspecified	ANCILLARY CODES	258 CHRONIC OSTEOMYELITIS
730.81	Other infections involving bone in diseases classified elsewhere, shoulder region	ANCILLARY CODES	258
730.82	Other infections involving bone in diseases classified elsewhere, upper arm	ANCILLARY CODES	258
730.83	Other infections involving bone in diseases classified elsewhere, forearm	ANCILLARY CODES	258
730.84	Other infections involving bone in diseases classified elsewhere, hand	ANCILLARY CODES	258
730.85	Other infections involving bone in diseases classified elsewhere, pelvic region and thigh	ANCILLARY CODES	258
730.86	Other infections involving bone in diseases classified elsewhere, lower leg	ANCILLARY CODES	258
730.87	Other infections involving bone in diseases classified elsewhere, ankle and foot	ANCILLARY CODES	258
730.88	Other infections involving bone in diseases classified elsewhere, other specified sites	ANCILLARY CODES	258
730.89	Other infections involving bone in diseases classified elsewhere, multiple sites	DIAGNOSTIC WORD	258
731.3	Major osseous defects	DIAGNOSTIC WORD	534 DEFORMITIES OF UPPER BODY AND ALL
731.8	Other bone involvement in diseases classified	DIAGNOSTIC WORD	668

Appendix A
Codes Moved from DMAP Excluded File to the Prioritized List

ICD-9	Diagnosis Description	Current file	Recommended Placement
733.99	Other disorders of bone and cartilage	EXCLUDED FILE	668
737.40	Curvature of spine, unspecified, associated with other conditions	DIAGNOSTIC WORD	412 SPINAL DEFORMITY, CLINICALLY SIGNIFICANT
737.41	Kyphosis associated with other conditions	DIAGNOSTIC WORD	412,588
737.42	Lordosis associated with other conditions	DIAGNOSTIC WORD	412,588
737.43	Scoliosis associated with other conditions	DIAGNOSTIC WORD	412,588
756.81	Absence of muscle and tendon	EXCLUDED FILE	668
759.3	Situs inversus	EXCLUDED FILE	662 CARDIOVASCULAR CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
774.5	Perinatal jaundice from other causes	DIAGNOSTIC WORD	106 HEMOLYTIC DISEASE DUE TO ISOIMMUNIZATION, ANEMIA DUE TO TRANSPLACENTAL HEMORRHAGE, AND FETAL
779.31	Feeding problems in newborn	EXEMPT FILE	19 FEEDING PROBLEMS IN NEWBORNS
779.32	Bilious vomiting in newborn	DIAGNOSTIC WORD	2 BIRTH OF INFANT
779.34	Failure to thrive in newborn	EXEMPT FILE	19
848.0	Sprain of septal cartilage of nose	EXCLUDED FILE	616 SPRAINS AND STRAINS OF ADJACENT MUSCLES AND JOINTS, MINOR
848.2	Sprain of thyroid region	EXCLUDED FILE	616

Appendix B
2015 CPT, CDT, and HCPCS Codes

Code	Code Descriptions	Placement
20604	Arthrocentesis, aspiration and/or injection, small joint or bursa (eg, fingers, toes); with ultrasound guidance, with permanent recording and reporting	50 RHEUMATOID ARTHRITIS AND OTHER INFLAMMATORY POLYARTHROPATHIES 157 PYOGENIC ARTHRITIS 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 306 GOUT 468 OSTEOARTHRITIS AND ALLIED DISORDERS 511 PERIPHERAL ENTHESOPATHIES 533 BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE INCLUDING OSTEOID OSTEOMAS; BENIGN NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE 597 SYNOVITIS AND TENOSYNOVITIS
20606	Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting	50, 157, 290, 306, 468, 511, 533, 597
20611	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting	50, 157, 290, 306, 422, 468, 511, 533, 597 435 INTERNAL DERANGEMENT OF KNEE AND LIGAMENTOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT
20983	Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; cryoablation	Non-Covered List
21811	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 1-3 ribs	112 FRACTURE OF RIBS AND STERNUM, OPEN
21812	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 4-6 ribs	112 FRACTURE OF RIBS AND STERNUM, OPEN
21813	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 7 or more ribs	112 FRACTURE OF RIBS AND STERNUM, OPEN

Appendix B
2015 CPT, CDT, and HCPCS Codes

Code	Code Descriptions	Placement
22510	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic	484 CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT SPINAL CORD INJURY
22511	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral	484 CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT SPINAL CORD INJURY
22512	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body (List separately in addition to code f	484 CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT SPINAL CORD INJURY
22513	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic	484 CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT SPINAL CORD INJURY
22514	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar	484 CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT SPINAL CORD INJURY
22515	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional vertebral body	484 CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT SPINAL CORD INJURY
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection); second level, cervical	374 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT 545 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT

Appendix B
2015 CPT, CDT, and HCPCS Codes

Code	Code Descriptions	Placement
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device	187 FRACTURE OF PELVIS, OPEN AND CLOSED
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or	103 CARDIOMYOPATHY 115 CONGENITAL HEART BLOCK; OTHER OBSTRUCTIVE ANOMALIES OF HEART 286 LIFE-THREATENING CARDIAC ARRHYTHMIAS 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
33271	Insertion of subcutaneous implantable defibrillator electrode	103, 115, 286, 290
33272	Removal of subcutaneous implantable defibrillator electrode	103, 115, 286, 290
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode	103, 115, 286, 290
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis	73 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 86 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS 93 DISCORDANT CARDIOVASCULAR CONNECTIONS 94 CONGENITAL MITRAL VALVE STENOSIS/INSUFFICIENCY 115 CONGENITAL HEART BLOCK; OTHER OBSTRUCTIVE ANOMALIES OF HEART 190 RHEUMATIC MULTIPLE VALVULAR DISEASE 193 CHRONIC ISCHEMIC HEART DISEASE 261 DISEASES OF MITRAL, TRICUSPID, AND PULMONARY VALVES 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 368 ALLERGIC BRONCHOPULMONARY ASPERGILLOSIS
33419	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)	73, 86, 94, 115, 190, 193, 261, 290, 368

Appendix B
2015 CPT, CDT, and HCPCS Codes

Code	Code Descriptions	Placement
33946	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; initiation, veno-venous	11 RESPIRATORY CONDITIONS OF FETUS AND NEWBORN 48 COARCTATION OF THE AORTA 71 VENTRICULAR SEPTAL DEFECT 73 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 74 CONGENITAL PULMONARY VALVE ANOMALIES 81 PATENT DUCTUS ARTERIOSUS; AORTIC PULMONARY FISTULA/WINDOW 86 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS 89 ENDOCARDIAL CUSHION DEFECTS 90 CONGENITAL PULMONARY VALVE ATRESIA 93 DISCORDANT CARDIOVASCULAR CONNECTIONS 94 CONGENITAL MITRAL VALVE STENOSIS/INSUFFICIENCY 102 HEART FAILURE 109 TETRALOGY OF FALLOT (TOF); CONGENITAL VENOUS ABNORMALITIES 110 CONGENITAL STENOSIS AND INSUFFICIENCY OF AORTIC VALVE 115 CONGENITAL HEART BLOCK; OTHER OBSTRUCTIVE ANOMALIES OF HEART 123 ATRIAL SEPTAL DEFECT, SECUNDUM 132 COMMON TRUNCUS 134 TOTAL ANOMALOUS PULMONARY VENOUS CONNECTION 138 INTERRUPTED AORTIC ARCH 142 EBSTEIN'S ANOMALY 180 COMMON VENTRICLE 186 SEPTICEMIA 192 CONGENITAL TRICUSPID ATRESIA AND STENOSIS 236 HYPOPLASTIC LEFT HEART SYNDROME 237 ADULT RESPIRATORY DISTRESS SYNDROME; ACUTE RESPIRATORY FAILURE; RESPIRATORY CONDITIONS DUE TO PHYSICAL AND CHEMICAL AGENTS 244 CONDITIONS REQUIRING HEART-LUNG AND LUNG TRANSPLANTATION 267 CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND
33947	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; initiation, veno-arterial	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33948	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; daily management, each day, veno-venous	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267

Appendix B
2015 CPT, CDT, and HCPCS Codes

Code	Code Descriptions	Placement
33949	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; daily management, each day, veno-arterial	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33951	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age (includes fluoroscopic guidance, when performed)	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33952	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed)	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33953	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33954	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), open, 6 years and older	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33955	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of central cannula(e) by sternotomy or thoracotomy, birth through 5 years of age	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33956	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of central cannula(e) by sternotomy or thoracotomy, 6 years and older	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267

Appendix B
2015 CPT, CDT, and HCPCS Codes

Code	Code Descriptions	Placement
33957	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age (includes fluoroscopic guidance, when performed)	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33958	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed)	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33959	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age (includes fluoroscopic guidance, when performed)	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33962	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), open, 6 years and older (includes fluoroscopic guidance, when performed)	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33963	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition of central cannula(e) by sternotomy or thoracotomy, birth through 5 years of age (includes fluoroscopic guidance, when performed)	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33964	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition central cannula(e) by sternotomy or thoracotomy, 6 years and older (includes fluoroscopic guidance, when performed)	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33965	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267

Appendix B
2015 CPT, CDT, and HCPCS Codes

Code	Code Descriptions	Placement
33966	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33969	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33984	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), open, 6 years and older	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33985	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of central cannula(e) by sternotomy or thoracotomy, birth through 5 years of age	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33986	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of central cannula(e) by sternotomy or thoracotomy, 6 years and older	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33987	Arterial exposure with creation of graft conduit (eg, chimney graft) to facilitate arterial perfusion for ECMO/ECLS (List separately in addition to code for primary procedure)	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33988	Insertion of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ECMO/ECLS	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
33989	Removal of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ECMO/ECLS	11, 48, 71, 73, 74, 81, 86, 89, 90, 93, 94, 102, 109, 110, 115, 123, 132, 134, 138, 142, 180, 186, 192, 236, 237, 244, 267
34839	Physician planning of a patient-specific fenestrated visceral aortic endograft requiring a minimum of 90 minutes of physician time	84 INJURY TO INTERNAL ORGANS 257 ARTERIAL EMBOLISM/THROMBOSIS: ABDOMINAL AORTA, THORACIC AORTA 280 INJURY TO BLOOD VESSELS OF THE THORACIC CAVITY 289 DISSECTING OR RUPTURED AORTIC ANEURYSM 330 NON-DISSECTING ANEURYSM WITHOUT RUPTURE

Appendix B
2015 CPT, CDT, and HCPCS Codes

Code	Code Descriptions	Placement
37218	Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery, open or percutaneous antegrade approach, including angioplasty, when performed, and radiological supervision and interpretation	322 STROKE 419 TRANSIENT CEREBRAL ISCHEMIA; OCCLUSION/STENOSIS OF PRECEREBRAL ARTERIES WITHOUT OCCLUSION
43180	Esophagoscopy, rigid, transoral with diverticulectomy of hypopharynx or cervical esophagus (eg, Zenker's diverticulum), with cricopharyngeal myotomy, includes use of telescope or operating microscope and repair, when performed	384 ESOPHAGITIS; ESOPHAGEAL AND INTRAESOPHAGEAL HERNIAS 519 ESOPHAGITIS AND GERD; ESOPHAGEAL SPASM; ASYMPTOMATIC DIAPHRAGMATIC HERNIA
44381	Ileoscopy, through stoma; with transendoscopic balloon dilation	32 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE 46 INTUSSUSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
44384	Ileoscopy, through stoma; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)	32 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE 46 INTUSSUSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
44401	Colonoscopy through stoma; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre-and post-dilation and guide wire passage, when performed)	46 INTUSSUSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 170 ANAL, RECTAL AND COLONIC POLYPS 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM

Appendix B
2015 CPT, CDT, and HCPCS Codes

Code	Code Descriptions	Placement
44402	Colonoscopy through stoma; with endoscopic stent placement (including pre- and post-dilation and guide wire passage, when performed)	32 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE 46 INTUSSUSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
44403	Colonoscopy through stoma; with endoscopic mucosal resection	Diagnostic Procedures List
44404	Colonoscopy through stoma; with directed submucosal injection(s), any substance	32 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE 46 INTUSSUSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 170 ANAL, RECTAL AND COLONIC POLYPS 189 DIVERTICULITIS OF COLON 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
44405	Colonoscopy through stoma; with transendoscopic balloon dilation	32 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE 46 INTUSSUSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
44406	Colonoscopy through stoma; with endoscopic ultrasound examination, limited to the sigmoid, descending, transverse, or ascending colon and cecum and adjacent structures	Diagnostic Procedures List
44407	Colonoscopy through stoma; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy(s), includes endoscopic ultrasound examination limited to the sigmoid, descending, transverse, or ascending colon and cecum and adjace	Diagnostic Procedures List

Appendix B
2015 CPT, CDT, and HCPCS Codes

Code	Code Descriptions	Placement
44408	Colonoscopy through stoma; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed	46 INTUSSUSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION
45346	Sigmoidoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	46 INTUSSUSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 170 ANAL, RECTAL AND COLONIC POLYPS 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
45347	Sigmoidoscopy, flexible; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)	32 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE 46 INTUSSUSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
45349	Sigmoidoscopy, flexible; with endoscopic mucosal resection	Diagnostic Procedures List
45350	Sigmoidoscopy, flexible; with band ligation(s) (eg, hemorrhoids)	480 THROMBOSED AND COMPLICATED HEMORRHOIDS 629 UNCOMPLICATED HEMORRHOIDS
45388	Colonoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	46 INTUSSUSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 170 ANAL, RECTAL AND COLONIC POLYPS 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM

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Code	Code Descriptions	Placement
45389	Colonoscopy, flexible; with endoscopic stent placement (includes pre- and post-dilation and guide wire passage, when performed)	32 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE 46 INTUSSUSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
45390	Colonoscopy, flexible; with endoscopic mucosal resection	Diagnostic Procedures List
45393	Colonoscopy, flexible; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed	46 INTUSSUSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION
45398	Colonoscopy, flexible; with band ligation(s) (eg, hemorrhoids)	480 THROMBOSED AND COMPLICATED HEMORRHOIDS 629 UNCOMPLICATED HEMORRHOIDS
45399	Unlisted procedure, colon	Ancillary Codes File
46601	Anoscopy; diagnostic, with high-resolution magnification (HRA) (eg, colposcope, operating microscope) and chemical agent enhancement, including collection of specimen(s) by brushing or washing, when performed	Diagnostic Procedures List
46607	Anoscopy; with high-resolution magnification (HRA) (eg, colposcope, operating microscope) and chemical agent enhancement, with biopsy, single or multiple	Diagnostic Procedures List
47383	Ablation, 1 or more liver tumor(s), percutaneous, cryoablation	Non-Covered List
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant	331 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)	331 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
62302	Myelography via lumbar injection, including radiological supervision and interpretation; cervical	Diagnostic Procedures List

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Code	Code Descriptions	Placement
62303	Myelography via lumbar injection, including radiological supervision and interpretation; thoracic	Diagnostic Procedures List
62304	Myelography via lumbar injection, including radiological supervision and interpretation; lumbosacral	Diagnostic Procedures List
62305	Myelography via lumbar injection, including radiological supervision and interpretation; 2 or more regions (eg, lumbar/thoracic, cervical/thoracic, lumbar/cervical, lumbar/thoracic/cervical)	Diagnostic Procedures List
64486	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by injection(s) (includes imaging guidance, when performed)	Ancillary Codes File
64487	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by continuous infusion(s) (includes imaging guidance, when performed)	Ancillary Codes File
64488	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by injections (includes imaging guidance, when performed)	Ancillary Codes File
64489	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by continuous infusions (includes imaging guidance, when performed)	Ancillary Codes File
66179	Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft	143 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE 247 PRIMARY ANGLE-CLOSURE GLAUCOMA
66184	Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft	143 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE 247 PRIMARY ANGLE-CLOSURE GLAUCOMA
76641	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete	Diagnostic Procedures List
76642	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; limited	Diagnostic Procedures List

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Code	Code Descriptions	Placement
77061	Digital breast tomosynthesis; unilateral	Non-Covered List
77062	Digital breast tomosynthesis; bilateral	Non-Covered List
77063	Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)	Non-Covered List
77085	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine), including vertebral fracture assessment	Diagnostic Procedures List
77086	Vertebral fracture assessment via dual-energy X-ray absorptiometry (DXA)	Diagnostic Procedures List
77306	Teletherapy isodose plan; simple (1 or 2 unmodified ports directed to a single area of interest), includes basic dosimetry calculation(s)	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241, 242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
77307	Teletherapy isodose plan; complex (multiple treatment areas, tangential ports, the use of wedges, blocking, rotational beam, or special beam considerations), includes basic dosimetry calculation(s)	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241, 242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
77316	Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s)	117, 137, 161, 195, 203, 212, 262, 265, 266, 274, 291, 292, 299, 320, 333, 376, 439, 465, 600
77317	Brachytherapy isodose plan; intermediate (calculation[s] made from 5 to 10 sources, or remote afterloading brachytherapy, 2-12 channels), includes basic dosimetry calculation(s)	117, 137, 161, 195, 203, 212, 262, 265, 266, 274, 291, 292, 299, 320, 333, 376, 439, 465, 600
77318	Brachytherapy isodose plan; complex (calculation[s] made from over 10 sources, or remote afterloading brachytherapy, over 12 channels), includes basic dosimetry calculation(s)	117, 137, 161, 195, 203, 212, 262, 265, 266, 274, 291, 292, 299, 320, 333, 376, 439, 465, 600
77385	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241, 242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611

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Code	Code Descriptions	Placement
77386	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
77387	Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed	41,75,85,97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
80163	Digoxin; free	Diagnostic Procedures List
80165	Valproic acid (dipropylacetic acid); free	Diagnostic Procedures List
80300	Drug screen, any number of drug classes from Drug Class List A; any number of non-TLC devices or procedures, (eg, immunoassay) capable of being read by direct optical observation, including instrumented-assisted when performed (eg, dipsticks, cups, cards,	Diagnostic Procedures List
80301	Drug screen, any number of drug classes from Drug Class List A; single drug class method, by instrumented test systems (eg, discrete multichannel chemistry analyzers utilizing immunoassay or enzyme assay), per date of service	Diagnostic Procedures List
80302	Drug screen, presumptive, single drug class from Drug Class List B, by immunoassay (eg, ELISA) or non-TLC chromatography without mass spectrometry (eg, GC, HPLC), each procedure	Diagnostic Procedures List
80303	Drug screen, any number of drug classes, presumptive, single or multiple drug class method; thin layer chromatography procedure(s) (TLC) (eg, acid, neutral, alkaloid plate), per date of service	Diagnostic Procedures List
80304	Drug screen, any number of drug classes, presumptive, single or multiple drug class method; not otherwise specified presumptive procedure (eg, TOF, MALDI, LDTD, DESI, DART), each procedure	Diagnostic Procedures List
80320	Alcohols	Diagnostic Procedures List
80321	Alcohol biomarkers; 1 or 2	Diagnostic Procedures List

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Code	Code Descriptions	Placement
80322	Alcohol biomarkers; 3 or more	Diagnostic Procedures List
80323	Alkaloids, not otherwise specified	Diagnostic Procedures List
80324	Amphetamines; 1 or 2	Diagnostic Procedures List
80325	Amphetamines; 3 or 4	Diagnostic Procedures List
80326	Amphetamines; 5 or more	Diagnostic Procedures List
80327	Anabolic steroids; 1 or 2	Diagnostic Procedures List
80328	Anabolic steroids; 3 or more	Diagnostic Procedures List
80329	Analgesics, non-opioid; 1 or 2	Diagnostic Procedures List
80330	Analgesics, non-opioid; 3-5	Diagnostic Procedures List
80331	Analgesics, non-opioid; 6 or more	Diagnostic Procedures List
80332	Antidepressants, serotonergic class; 1 or 2	Diagnostic Procedures List
80333	Antidepressants, serotonergic class; 3-5	Diagnostic Procedures List
80334	Antidepressants, serotonergic class; 6 or more	Diagnostic Procedures List
80335	Antidepressants, tricyclic and other cyclicals; 1 or 2	Diagnostic Procedures List
80336	Antidepressants, tricyclic and other cyclicals; 3-5	Diagnostic Procedures List
80337	Antidepressants, tricyclic and other cyclicals; 6 or more	Diagnostic Procedures List
80338	Antidepressants, not otherwise specified	Diagnostic Procedures List
80339	Antiepileptics, not otherwise specified; 1-3	Diagnostic Procedures List

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Code	Code Descriptions	Placement
80340	Antiepileptics, not otherwise specified; 4-6	Diagnostic Procedures List
80341	Antiepileptics, not otherwise specified; 7 or more	Diagnostic Procedures List
80342	Antipsychotics, not otherwise specified; 1-3	Diagnostic Procedures List
80343	Antipsychotics, not otherwise specified; 4-6	Diagnostic Procedures List
80344	Antipsychotics, not otherwise specified; 7 or more	Diagnostic Procedures List
80345	Barbiturates	Diagnostic Procedures List
80346	Benzodiazepines; 1-12	Diagnostic Procedures List
80347	Benzodiazepines; 13 or more	Diagnostic Procedures List
80348	Buprenorphine	Diagnostic Procedures List
80349	Cannabinoids, natural	Diagnostic Procedures List
80350	Cannabinoids, synthetic; 1-3	Diagnostic Procedures List
80351	Cannabinoids, synthetic; 4-6	Diagnostic Procedures List
80352	Cannabinoids, synthetic; 7 or more	Diagnostic Procedures List
80353	Cocaine	Diagnostic Procedures List
80354	Fentanyl	Diagnostic Procedures List
80355	Gabapentin, non-blood	Diagnostic Procedures List
80356	Heroin metabolite	Diagnostic Procedures List
80357	Ketamine and norketamine	Diagnostic Procedures List

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Code	Code Descriptions	Placement
80358	Methadone	Diagnostic Procedures List
80359	Methylenedioxyamphetamines (MDA, MDEA, MDMA)	Diagnostic Procedures List
80360	Methylphenidate	Diagnostic Procedures List
80361	Opiates, 1 or more	Diagnostic Procedures List
80362	Opioids and opiate analogs; 1 or 2	Diagnostic Procedures List
80363	Opioids and Opiate analogs; 3 or 4	Diagnostic Procedures List
80364	Opioids and Opiate analogs; 5 or more	Diagnostic Procedures List
80365	Oxycodone	Diagnostic Procedures List
80366	Pregabalin	Diagnostic Procedures List
80367	Propoxyphene	Diagnostic Procedures List
80368	Sedative hypnotics (non-benzodiazepines)	Diagnostic Procedures List
80369	Skeletal muscle relaxants; 1 or 2	Diagnostic Procedures List
80370	Skeletal muscle relaxants; 3 or more	Diagnostic Procedures List
80371	Stimulants, synthetic	Diagnostic Procedures List
80372	Tapentadol	Diagnostic Procedures List
80373	Tramadol	Diagnostic Procedures List
80374	Stereoisomer (enantiomer) analysis, single drug class	Diagnostic Procedures List
80375	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 1-3	Diagnostic Procedures List

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Code	Code Descriptions	Placement
80376	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 4-6	Diagnostic Procedures List
80377	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 7 or more	Diagnostic Procedures List
81246	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; tyrosine kinase domain (TKD) variants (eg, D835, I836)	97 CHILDHOOD LEUKEMIAS 401 ACUTE PROMYELOCYTIC LEUKEMIA 402 ACUTE MYELOID LEUKEMIA Treatment: BONE MARROW TRANSPLANT 241 MYELOID DISORDERS
81288	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; promoter methylation analysis	161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS
81313	PCA3/KLK3 (prostate cancer antigen 3 [non-protein coding]/kallikrein-related peptidase 3 [prostate specific antigen]) ratio (eg, prostate cancer)	Non-Covered List
81410	Aortic dysfunction or dilation (eg, Marfan syndrome, Loeys Dietz syndrome, Ehler Danlos syndrome type IV, arterial tortuosity syndrome); genomic sequence analysis panel, must include sequencing of at least 9 genes, including FBN1, TGFBR1, TGFBR2, COL3A1,	Diagnostic List
81411	Aortic dysfunction or dilation (eg, Marfan syndrome, Loeys Dietz syndrome, Ehler Danlos syndrome type IV, arterial tortuosity syndrome); duplication/deletion analysis panel, must include analyses for TGFBR1, TGFBR2, MYH11, and COL3A1	Diagnostic List
81415	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis	Diagnostic List
81416	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator exome (eg, parents, siblings) (List separately in addition to code for primary procedure)	Diagnostic List
81417	Exome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence (eg, updated knowledge or unrelated condition/syndrome)	Non-Covered List

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Code	Code Descriptions	Placement
81420	Fetal chromosomal aneuploidy (eg, trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21	1 PREGNANCY
81425	Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis	Non-Covered List
81426	Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (eg, parents, siblings) (List separately in addition to code for primary procedure)	Non-Covered List
81427	Genome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (eg, updated knowledge or unrelated condition/syndrome)	Non-Covered List
81430	Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); genomic sequence analysis panel, must include sequencing of at least 60 genes, including CDH23, CLRN1, GJB2, GPR98, MTRNR1, MYO7A, MYO15A, PCDH15, OTOF, SLC26A4, TMC1, TMPRSS3	Diagnostic List
81431	Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); duplication/deletion analysis panel, must include copy number analyses for STRC and DFNB1 deletions in GJB2 and GJB6 genes	Diagnostic List
81435	Hereditary colon cancer syndromes (eg, Lynch syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include analysis of at least 7 genes, including APC, CHEK2, MLH1, MSH2, MSH6, MUTYH, and PMS2	Diagnostic List
81436	Hereditary colon cancer syndromes (eg, Lynch syndrome, familial adenomatosis polyposis); duplication/deletion gene analysis panel, must include analysis of at least 8 genes, including APC, MLH1, MSH2, MSH6, PMS2, EPCAM, CHEK2, and MUTYH	Diagnostic List

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Code	Code Descriptions	Placement
81440	Nuclear encoded mitochondrial genes (eg, neurologic or myopathic phenotypes), genomic sequence panel, must include analysis of at least 100 genes, including BCS1L, C10orf2, COQ2, COX10, DGUOK, MPV17, OPA1, PDSS2, POLG, POLG2, RRM2B, SCO1, SCO2, SLC25A4, S	Diagnostic List
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or re	Diagnostic List
81450	Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA and RNA analysis when performed, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants	Diagnostic List
81455	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA and RNA analysis when performed, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, N	Diagnostic List
81460	Whole mitochondrial genome (eg, Leigh syndrome, mitochondrial encephalomyopathy, lactic acidosis, and stroke-like episodes [MELAS], myoclonic epilepsy with ragged-red fibers [MERFF], neuropathy, ataxia, and retinitis pigmentosa [NARP], Leber hereditary op	Diagnostic List
81465	Whole mitochondrial genome large deletion analysis panel (eg, Kearns-Sayre syndrome, chronic progressive external ophthalmoplegia), including heteroplasmy detection, if performed	Diagnostic List
81470	X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); genomic sequence analysis panel, must include sequencing of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL,	Non-Covered List

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Code	Code Descriptions	Placement
81471	X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); duplication/deletion gene analysis, must include analysis of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL,	Non-Covered List
81519	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score	195 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
83006	Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)	Non-Covered List
87505	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe tech, 3-5 targets	Diagnostic Procedures List
87506	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe tech, 6-11 targets	Diagnostic Procedures List
87507	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe tech, 12-25 targets	Diagnostic Procedures List
87623	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), low-risk types (eg, 6, 11, 42, 43, 44)	Diagnostic Procedures List
87624	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68)	Diagnostic Procedures List

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Code	Code Descriptions	Placement
87625	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), types 16 and 18 only, includes type 45, if performed	Diagnostic Procedures List
87806	Infectious agent antigen detection by immunoassay with direct optical observation; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies	Diagnostic Procedures List
88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure)	Diagnostic Procedures List
88344	Immunohistochemistry or immunocytochemistry, per specimen; each multiplex antibody stain procedure	Diagnostic Procedures List
88364	In situ hybridization (eg, FISH), per specimen; each additional single probe stain procedure (List separately in addition to code for primary procedure)	Diagnostic Procedures List
88366	In situ hybridization (eg, FISH), per specimen; each multiplex probe stain procedure	Diagnostic Procedures List
88369	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each additional single probe stain procedure (List separately in addition to code for primary procedure)	Diagnostic Procedures List
88373	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each additional single probe stain procedure (List separately in addition to code for primary procedure)	Diagnostic Procedures List
88374	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each multiplex probe stain procedure	Diagnostic Procedures List
88377	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each multiplex probe stain procedure	Diagnostic Procedures List
89337	Cryopreservation, mature oocyte(s)	Non-Covered List

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Code	Code Descriptions	Placement
90630	Influenza virus vaccine, quadrivalent (IIV4), split virus, preservative free, for intradermal use	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
90651	Human Papillomavirus vaccine types 6, 11, 16, 18, 31, 33, 45, 52, 58, nonavalent (HPV), 3 dose schedule, for intramuscular use	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
91200	Liver elastography, mechanically induced shear wave (eg, vibration), without imaging, with interpretation and report	***TBD***
92145	Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report	Non-Covered List
93260	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care	Ancillary Codes File
93261	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator sy	Ancillary Codes File

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Code	Code Descriptions	Placement
93355	Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg, TAVR, transcatheter pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial ap	48 COARCTATION OF THE AORTA 71 VENTRICULAR SEPTAL DEFECT 73 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 74 CONGENITAL PULMONARY VALVE ANOMALIES 81 PATENT DUCTUS ARTERIOSUS; AORTIC PULMONARY FISTULA/WINDOW 86 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS 89 ENDOCARDIAL CUSHION DEFECTS 90 CONGENITAL PULMONARY VALVE ATRESIA 93 DISCORDANT CARDIOVASCULAR CONNECTIONS 94 CONGENITAL MITRAL VALVE STENOSIS/INSUFFICIENCY 102 HEART FAILURE 109 TETRALOGY OF FALLOT (TOF); CONGENITAL VENOUS ABNORMALITIES 110 CONGENITAL STENOSIS AND INSUFFICIENCY OF AORTIC VALVE 115 CONGENITAL HEART BLOCK; OTHER OBSTRUCTIVE ANOMALIES OF HEART 123 ATRIAL SEPTAL DEFECT, SECUNDUM 132 COMMON TRUNCUS 134 TOTAL ANOMALOUS PULMONARY VENOUS CONNECTION 138 INTERRUPTED AORTIC ARCH 142 EBSTEIN'S ANOMALY 180 COMMON VENTRICLE 190 RHEUMATIC MULTIPLE VALVULAR DISEASE 192 CONGENITAL TRICUSPID ATRESIA AND STENOSIS 193 CHRONIC ISCHEMIC HEART DISEASE 227 DISEASES AND DISORDERS OF AORTIC VALVE 236 HYPOPLASTIC LEFT HEART SYNDROME 261 DISEASES OF MITRAL, TRICUSPID, AND PULMONARY VALVES
93644	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic pa	103 CARDIOMYOPATHY 115 CONGENITAL HEART BLOCK; OTHER OBSTRUCTIVE ANOMALIES OF HEART 286 LIFE-THREATENING CARDIAC ARRHYTHMIAS 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
93702	Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)	Non-Covered List
93895	Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral	Non-Covered List

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96127	Brief emotional/behavioral assessment (eg, depression inventory, attention-deficit/hyperactivity disorder [ADHD] scale), with scoring and documentation, per standardized instrument	Inpatient and outpatient medical lines
97607	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ong	8,30,51,84,209,211,239, 290, 383, 427, 503, 612
97608	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ong	8,30,51,84,209,211,239, 290, 383, 427, 503, 612
99184	Initiation of selective head or total body hypothermia in the critically ill neonate, includes appropriate patient selection by review of clinical, imaging and laboratory data, confirmation of esophageal temperature probe location, evaluation of amplitude	Inpatient medical lines
99188	Application of topical fluoride varnish by a physician or other qualified health care professional	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS 57 PREVENTIVE DENTAL SERVICES
99490	Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected	Outpatient medical visit lines
99497	Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with	Outpatient medical visit lines
99498	Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; each additional 30 minutes (List sep	Outpatient medical visit lines

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Dental Codes		
D0171	re-evaluation – post-operative office visit	Non-Covered List
D0351	3D PHOTOGRAPHIC IMAGE-This procedure is for dental or maxillofacial diagnostic purposes. Not applicable for a CAD-CAM procedure	Non-Covered List
D1353	SEALANT REPAIR-PER TOOTH	57 PREVENTIVE DENTAL SERVICES
D6110	implant /abutment supported removable denture for edentulous arch – maxillary	627 DENTAL CONDITIONS (EG. MISSING TEETH) Treatment: IMPLANTS
D6111	implant /abutment supported removable denture for edentulous arch – mandibular	627 DENTAL CONDITIONS (EG. MISSING TEETH) Treatment: IMPLANTS
D6112	implant /abutment supported removable denture for partially edentulous arch – maxillary	627 DENTAL CONDITIONS (EG. MISSING TEETH) Treatment: IMPLANTS
D6113	implant /abutment supported removable denture for partially edentulous arch – mandibular	627 DENTAL CONDITIONS (EG. MISSING TEETH) Treatment: IMPLANTS
D6114	implant /abutment supported fixed denture for edentulous arch – maxillary	627 DENTAL CONDITIONS (EG. MISSING TEETH) Treatment: IMPLANTS
D6115	implant /abutment supported fixed denture for edentulous arch – mandibular	627 DENTAL CONDITIONS (EG. MISSING TEETH) Treatment: IMPLANTS
D6116	implant /abutment supported fixed denture for partially edentulous arch – maxillary	627 DENTAL CONDITIONS (EG. MISSING TEETH) Treatment: IMPLANTS
D6117	implant /abutment supported fixed denture for partially edentulous arch – mandibular	627 DENTAL CONDITIONS (EG. MISSING TEETH) Treatment: IMPLANTS
D6549	RESIN RETAINER--FOR RESIN BONDED FIXED PROSTHESIS	609 DENTAL CONDITIONS (EG. MISSING TEETH) Treatment: COMPLEX PROSTHODONTICS
D9931	Cleaning and inspection of a removable appliance. This procedure does not include any required adjustments	457 DENTAL CONDITIONS (EG. MISSING TEETH, PROSTHESIS FAILURE) Treatment: REMOVABLE PROSTHODONTICS
D9936	missed appointment	Non-Covered List
D9987	Cancelled appointment	Non-Covered List
D9219	evaluation for deep sedation or general anesthesia	Ancillary List

HCPCS Codes

C9741	Right heart catheterization with implantation of wireless pressure sensor in the pulmonary artery, including any type of measurement, angiography, imaging supervision, interpretation, and report	Diagnostic List
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Appendix B
2015 CPT, CDT, and HCPCS Codes

Code	Code Descriptions	Placement
C9742	Laryngoscopy, flexible fiberoptic, with injection into vocal cord(s), therapeutic, including diagnostic laryngoscopy, if performed	209 SUPERFICIAL ABSCESSSES AND CELLULITIS 364 DYSTONIA (UNCONTROLLABLE); LARYNGEAL SPASM AND STENOSIS
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval	336 ANAEROBIC INFECTIONS REQUIRING HYPERBARIC OXYGEN 373 TOXIC EFFECT OF GASES, FUMES, AND VAPORS REQUIRING HYPERBARIC OXYGEN
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to g0204 or g0206)	Non-Covered List
G0464	Colorectal cancer screening; stool-based dna and fecal occult hemoglobin (e.g., kras, ndrg4 and bmp3)	Non-Covered List
G0466	Federally qualified health center (fqhc) visit, new patient; a medically-necessary, face-to-face encounter (one-on-one) between a new patient and a fqhc practitioner during which time one or more fqhc services are rendered and includes a typical bundle of	Outpatient medical lines
G0467	Federally qualified health center (fqhc) visit, established patient; a medically-necessary, face-to-face encounter (one-on-one) between an established patient and a fqhc practitioner during which time one or more fqhc services are rendered and includes a	Outpatient medical lines
G0468	Federally qualified health center (fqhc) visit, ippe or awv; a fqhc visit that includes an initial preventive physical examination (ippe) or annual wellness visit (awv) and includes a typical bundle of medicare-covered services that would be furnished per	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
G0469	Federally qualified health center (fqhc) visit, mental health, new patient; a medically-necessary, face-to-face mental health encounter (one-on-one) between a new patient and a fqhc practitioner during which time one or more fqhc services are rendered and	Mental health lines
G0470	Federally qualified health center (fqhc) visit, mental health, established patient; a medically-necessary, face-to-face mental health encounter (one-on-one) between an established patient and a fqhc practitioner during which time one or more fqhc services	Mental health lines

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Code	Code Descriptions	Placement
G0471	Collection of venous blood by venipuncture or urine sample by catheterization from an individual in a skilled nursing facility (snf) or by a laboratory on behalf of a home health agency (hha)	Diagnostic List
G0472	Hepatitis c antibody screening, for individual at high risk and other covered indication(s)	Diagnostic List
G0473	Face-to-face behavioral counseling for obesity, group (2-10), 30 minutes	325 OBESITY (ADULT BMI \geq 30, CHILDHOOD BMI \geq 95 PERCENTILE) 594 OBESITY (ADULT BMI \geq 30, CHILDHOOD BMI \geq 95 PERCENTILE)
G6001	Ultrasonic guidance for placement of radiation therapy fields	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
G6002	Stereoscopic x-ray guidance for localization of target volume for the delivery of radiation therapy	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
G6003	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: up to 5mev	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
G6004	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 6-10mev	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
G6005	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 11-19mev	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
G6006	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 20mev or greater	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
G6007	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks: up to 5mev	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
G6008	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks: 6-10mev	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
G6009	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks: 11-19mev	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611

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2015 CPT, CDT, and HCPCS Codes

Code	Code Descriptions	Placement
G6010	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks: 20 mev or greater	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
G6011	Radiation treatment delivery,3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; up to 5mev	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
G6012	Radiation treatment delivery,3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 6-10mev	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
G6013	Radiation treatment delivery,3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 11-19mev	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
G6014	Radiation treatment delivery,3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 20mev or greater	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
G6015	Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic mlc, per treatment session	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611
G6017	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (eg,3d positional tracking, gating, 3d surface tracking), each fraction of treatment	97,116,117,119,129,130,133,137,139,161,195,199,203,204,212,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611

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Code	Code Descriptions	Placement
G6018	Ileoscopy,through stoma; with transendoscopic stent placement (includes predilation)	32 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE 46 INTUSSUCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
G6019	Colonoscopy through stoma; with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique	46 INTUSSUCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 170 ANAL, RECTAL AND COLONIC POLYPS 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
G6020	Colonoscopy through stoma; with transendoscopic stent placement (includes predilation)	32 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE 46 INTUSSUCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
G6021	Unlisted procedure, intestine	Ancillary Codes File
G6022	Sigmoidoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesions(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique	46 INTUSSUCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 170 ANAL, RECTAL AND COLONIC POLYPS 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM

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Code	Code Descriptions	Placement
G6023	Sigmoidoscopy, flexible; with transendoscopic stent placement (includes predilation)	32 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE 46 INTUSSUCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
G6024	Colonoscopy, flexible; proximal to splenic flexure; with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique	46 INTUSSUCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 170 ANAL, RECTAL AND COLONIC POLYPS 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
G6025	Colonoscopy, flexible, proximal to splenic flexure; with transendoscopic stent placement (includes predilation)	32 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE 46 INTUSSUCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
G6027	Anoscopy, high resolution (hra) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed	Diagnostic List
G6028	Anoscopy, high resolution (hra) (with magnification and chemical agent enhancement); with biopsy(ies)	Diagnostic List
G6030	Amitriptyline	Diagnostic List
G6031	Benzodiazepines	Diagnostic List
G6032	Desipramine	Diagnostic List
G6034	Doxepin	Diagnostic List
G6035	Gold	Diagnostic List
G6036	Assay of imipramine	Diagnostic List
G6037	Nortriptyline	Diagnostic List
G6038	Salicylate	Diagnostic List

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Code	Code Descriptions	Placement
G6039	Acetaminophen	Diagnostic List
G6040	Alcohol (ethanol); any specimen except breath	Diagnostic List
G6041	Alkaloids, urine, quantitative	Diagnostic List
G6042	Amphetamine or methamphetamine	Diagnostic List
G6043	Barbiturates, not elsewhere specified	Diagnostic List
G6044	Cocaine or metabolite	Diagnostic List
G6045	Dihydrocodeinone	Diagnostic List
G6046	Dihydromorphinone	Diagnostic List
G6047	Dihydrotestosterone	Diagnostic List
G6048	Dimethadione	Diagnostic List
G6049	Epiandrosterone	Diagnostic List
G6050	Ethchlorvynol	Diagnostic List
G6051	Flurazepam	Diagnostic List
G6052	Meprobamate	Diagnostic List
G6053	Methadone	Diagnostic List
G6054	Methsuximide	Diagnostic List
G6055	Nicotine	Diagnostic List
G6056	Opiate(s), drug and metabolites, each procedure	Diagnostic List
G6057	Phenothiazine	Diagnostic List
G6058	Drug confirmation, each procedure	Diagnostic List
S0832	Low-dose computer tomography for lung cancer screening	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

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ANCILLARY GUIDELINE A1 GUIDELINE NOTE XXX, NEGATIVE PRESSURE WOUND THERAPY

Lines 8,30,51,84,209,211,239,290,383,427

Negative pressure wound therapy ([CPT 97605-97608](#), [HCPCS G0456, G0457](#) ~~97605, 97606~~) is included on these lines only for patients who:

- Have wounds that are refractory to or have failed standard therapies;
- Are not suitable candidates for surgical wound closure; or,
- Are at high risk for delayed or non-healing wounds due to factors such as compromised blood flow, diabetic complications, wounds with high risk of fecal contamination, extremely exudative wounds, and similar situations.

DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE

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

- A) Related to genetic testing for patients with breast/ovarian and colon/endometrial cancer or other related cancers suspected to be hereditary, or patients at increased risk to due to family history.
- 1) Services are provided according to the Comprehensive Cancer Network Guidelines.
 - a) Lynch syndrome (hereditary colorectal and endometrial cancer, and other cancers associated with Lynch syndrome) services (CPT [81288](#), 81292-81300, 81317-81319, [81435](#), [81436](#)) and familial adenomatous polyposis (FAP) services (CPT 81201-81203) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. ~~Colorectal Cancer Screening Genetic/Familial High-Risk Assessment: Colorectal. V.2.2014 V.1.2013 (5/13/13 5/19/14).~~ www.nccn.org
 - b) BRCA1/BRCA2 testing services (CPT 81211-81217) for women without a personal history of breast, ovarian and other associated cancers should be provided to high risk women as defined ~~in Guideline Note 3 or as otherwise defined~~ by the US Preventive Services Task Force or according to the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovarian. V.2.2014 (9/23/14). www.nccn.org.
 - c) BRCA1/BRCA2 testing services (CPT 81211-81217) for women with a personal history of breast, ovarian and other associated cancers and for men with breast cancer should be provided according to the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovarian. V.2.2014 (9/23/14) V.1.2011 (4/7/11). www.nccn.org
 - d) PTEN (Cowden syndrome) services (CPT 81321-81323) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Colorectal Screening. V.1.2013 (5/13/13). www.nccn.org.
 - 2) Genetic counseling should precede genetic testing for hereditary cancer whenever possible.
 - a) Pre and post-test genetic counseling should be covered when provided by a suitably trained health professional with expertise and experience in cancer genetics

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- i) "Suitably trained" is defined as board certified or active candidate status from the American Board of Medical Genetics, American Board of Genetic Counseling, or Genetic Nursing Credentialing Commission.
 - b) If timely pre-test genetic counseling is not possible for time-sensitive cases, appropriate genetic testing accompanied by pre- and post- test informed consent and post-test disclosure performed by a board-certified physician with experience in cancer genetics should be covered.
 - i) Post-test genetic counseling should be performed as soon as is practical.
 - 3) If the mutation in the family is known, only the test for that mutation is covered. For example, if a mutation for BRCA 1 has been identified in a family, a single site mutation analysis for that mutation is covered (CPT 81215), while a full sequence BRCA 1 and 2 (CPT 81211) analyses is not. There is one exception, for individuals of Ashkenazi Jewish ancestry with a known mutation in the family, the panel for Ashkenazi Jewish BRCA mutations is covered (CPT 81212).
 - 4) Costs for rush genetic testing for hereditary breast/ovarian and colon/endometrial cancer is not covered.
- B) Related to diagnostic evaluation of individuals with intellectual disability (defined as a full scale or verbal IQ < 70 in an individual > age 5), developmental delay (defined as a cognitive index <70 on a standardized test appropriate for children < 5 years of age), Autism Spectrum Disorder, or multiple congenital anomalies:
 - 1) CPT 81228, Cytogenomic constitutional microarray analysis for copy number variants for chromosomal abnormalities: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder. In 2012, this test may also be billed using one of CPT 88384-88386, or stacking CPTs 83890-83915.
 - 2) CPT 81229, Cytogenomic constitutional microarray analysis for copy number variants for chromosomal abnormalities; plus cytogenetic constitutional microarray analysis for single nucleotide polymorphism (SNP) variants for chromosomal abnormalities: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder; only if (a) consanguinity and recessive disease is suspected, or (b) uniparental disomy is suspected, or (c) another mechanism is suspected that is not detected by the copy number variant test alone. In 2012, this test may also be billed using one of CPT 88384-88386, or stacking CPTs 83890-83915.
 - 3) CPT 81243, 81244, Fragile X genetic testing is covered for individuals with intellectual disability/developmental delay. Although the yield of Fragile X is 3.5-10%, this is included because of additional reproductive implications.
 - 4) A visit with the appropriate specialist (often genetics, developmental pediatrics, or child neurology), including physical exam, medical history, and family history is covered. Physical exam, medical history, and family history by the appropriate specialist, prior to any genetic testing is often the most cost-effective strategy and is encouraged.
- c) Related to other tests with specific CPT codes:
 - 1) The following tests are not covered:

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- a) CPT 81225, CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)
 - b) CPT 81226, CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *9, *10, *17, *19, *29, *35, *41, *1XN, *2XN, *4XN).
 - c) CPT 81227, CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)
 - d) CPT 81287, MGMT (O-6-methylguanine-DNA methyltransferase) (eg, glioblastoma multiforme), methylation analysis
 - e) CPT 81291, MTHFR (5,10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis, common variants (eg, 677T, 1298C)
 - f) CPT 81330, SMPD1(sphingomyelin phosphodiesterase 1, acid lysosomal) (eg, Niemann-Pick disease, Type A) gene analysis, common variants (eg, R496L, L302P, fsP330)
 - g) CPT 81350, UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (eg, irinotecan metabolism), gene analysis, common variants (eg, *28, *36, *37)
 - h) CPT 81355, VKORC1 (vitamin K epoxide reductase complex, subunit 1) (eg, warfarin metabolism), gene analysis, common variants (eg, -1639/3673)
 - i) [CPT 81417, re-evaluation of whole exome sequencing](#)
 - j) [CPT 81425-81427, Genome sequence analysis](#)
 - k) [CPT 81470, 81471, X-linked intellectual disability \(XLID\) genomic sequence panels](#)
 - l) CPT 81504, Oncology (tissue of origin), microarray gene expression profiling of > 2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores
- 2) The following tests are covered only if they meet the criteria for the Non-Prenatal Genetic Testing Algorithm AND the specified situations:
- a) CPT 81205, BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (eg, Maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X): Cover only when the newborn screening test is abnormal and serum amino acids are normal
 - b) Diagnostic testing for cystic fibrosis (CF)
 - i) CFTR, cystic fibrosis transmembrane conductance regulator tests. CPT 81220, 81223, 81222: For infants with a positive newborn screen for cystic fibrosis or who are symptomatic for cystic fibrosis, or for clients that have previously been diagnosed with cystic fibrosis but have not had genetic testing, CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered. If two mutations are not identified, CFTR full gene sequencing (CPT 81223) is covered. If two mutations are still not identified, duplication/deletion testing (CPT 81222) is covered. These tests may be ordered as reflex testing on the same specimen.
 - c) Carrier testing for cystic fibrosis
 - i) CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered.
 - d) CPT 81240. F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant: Factor 2 20210G>A testing should not be covered for adults with idiopathic venous thromboembolism; for asymptomatic family members of patients with venous thromboembolism and a

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- Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.
- e) CPT 81241. F5 (coagulation Factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant: Factor V Leiden testing should not be covered for: adults with idiopathic venous thromboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.
 - f) CPT 81256, HFE (hemochromatosis) (eg, hereditary hemochromatosis) gene analysis, common variants (eg, C282Y, H63D): Covered for diagnostic testing of patients with elevated transferrin saturation or ferritin levels. Covered for predictive testing ONLY when a first degree family member has treatable iron overload from HFE.
 - g) CPT 81332 SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1) (eg, alpha-1-antitrypsin deficiency), gene analysis, common variants (eg, *S and *Z): The alpha-1-antitrypsin protein level should be the first line test for a suspected diagnosis of AAT deficiency in symptomatic individuals with unexplained liver disease or obstructive lung disease that is not asthma or in a middle age individual with unexplained dyspnea. Generic testing or the alpha-1 phenotype test is appropriate if the protein test is abnormal or borderline. The genetic test is appropriate for siblings of people with AAT deficiency regardless of the AAT protein test results.
 - h) [CPT 81415-81416, exome testing: A genetic counseling/geneticist consultation is required prior to ordering test](#)
 - i) [CPT 81430-81431, Hearing loss \(eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome\); genomic sequence analysis panel: Testing for mutations in GJB2 and GJB6 need to be done first and be negative in non-syndromic patients prior to panel testing.](#)
 - j) [CPT 81440, 81460, 81465, mitochondrial genome testing: A genetic counseling/geneticist or metabolic consultation is required prior to ordering test.](#)
- 3) Do not cover a more expensive genetic test (generally one with a wider scope or more detailed testing) if a cheaper (smaller scope) test is available and has, in this clinical context, a substantially similar sensitivity. For example, do not cover CFTR gene sequencing as the first test in a person of Northern European Caucasian ancestry because the gene panels are less expensive and provide substantially similar sensitivity in that context.

GUIDELINE NOTE 62, REMOVEABLE PROSTHODONTICS

~~—Line 477~~

~~Must have one or more anterior teeth missing or four or more posterior teeth missing per arch with resulting space equivalent to that loss demonstrating inability to masticate; third molars are not a consideration when counting missing teeth (D5211, D5212).~~

Appendix C Revised Guidelines

GUIDELINE NOTE 3, PROPHYLACTIC TREATMENT FOR PREVENTION OF BREAST CANCER IN HIGH RISK WOMEN

Line 195

Bilateral prophylactic breast removal ~~and/or oophorectomy~~ is are included on Line 195 for women without a personal history of invasive breast cancer who meet the criteria in the NCCN Clinical Practice Guidelines in Oncology. Breast Cancer Risk Reduction. V.1.2014 (1/20/14). www.nccn.org. ~~are at high risk for breast cancer.~~ Prior to surgery, women without a personal history of breast cancer must have a genetics consultation as defined in section A2 of the DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE. ~~High risk is defined as~~

- ~~A) Having a BRCA1/BRCA2 mutation;~~
- ~~B) Having a strong family history of breast cancer, defined as one of the following:
 - ~~1) 2 first-degree or second-degree relatives diagnosed with breast cancer at younger than an average age of 50 years (at least one must be a first-degree relative);~~
 - ~~2) 3 first-degree or second-degree relatives diagnosed with breast cancer at younger than an average age of 60 years (at least one must be a first-degree relative);~~
 - ~~3) 4 relatives diagnosed with breast cancer at any age (at least one must be a first-degree relative);~~
 - ~~4) 1 relative with ovarian cancer at any age and, on the same side of the family, either 1 first-degree relative (including the relative with ovarian cancer) or second-degree relative diagnosed with breast cancer at younger than age 50 years, or 2 first-degree or second-degree relatives diagnosed with breast cancer at younger than an average age of 60 years, or another ovarian cancer at any age;~~
 - ~~5) 1 first-degree relative with cancer diagnosed in both breasts at younger than an average age of 50 years;~~
 - ~~6) 1 first-degree or second-degree relative diagnosed with bilateral breast cancer and one first-degree or second-degree relative diagnosed with breast cancer at younger than an average age of 60 years; or,~~
 - ~~7) a male relative with breast cancer at any age and on the same side of the family at least 1 first-degree or second-degree relative diagnosed with breast cancer at younger than age 50 years, or 2 first-degree or second-degree relatives diagnosed with breast cancer at younger than an average age of 60 years.~~~~
- ~~C) A history of LCIS with a family history of breast cancer; or,~~
- ~~D) A history of treatment with thoracic radiation between ages 10 and 30.~~

Contralateral prophylactic mastectomy is included on Line 195 for women with a personal history of breast cancer. ~~and any of the high-risk categories listed above. In addition, contralateral prophylactic mastectomy of the unaffected breast is indicated for women with invasive lobular carcinoma.~~

~~Prophylactic oophorectomy is included on Line 195 for women who have the BRCA1/BRCA2 mutation.~~

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GUIDELINE NOTE 10, CENTRAL SEROUS CHORIORETINOPATHY AND POSTERIOR CYCLITIS

Line ~~363~~, 387

Central serous chorioretinopathy (H35.71x) is included on ~~this~~ line ~~363~~ only for treatment when the condition has been present for 3 months or longer. Posterior Cyclitis (H30.2x) should only be treated in patients with 20/40 or worse vision.

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

Line ~~400~~~~363~~

Intraocular steroid implants (CPT 67027, 67028) are only included on Line ~~400~~~~363~~ for pairing with uveitis (ICD-9-CM codes ~~360.12~~, 363.0x, 363.1x, ~~363.2x~~, ~~363.20~~ and ~~363.22~~/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 affecting the posterior segment of the eye~~, and there has been appropriate trial and failure, or intolerance of therapy, with local and systemic corticosteroids and/or immunosuppressive agents.

GUIDELINE NOTE 117, INTRAOCULAR STEROID IMPLANTS FOR CENTRAL RETINAL VEIN OCCLUSION

Line 445

Intraocular steroid implants (CPT 67028) are only included on Line 445 for treatment of macular edema due to

- 1) central retinal vein occlusion (ICD-9-CM 362.35/ICD-10-CM code H34.81x) in those individuals who have failed anti-VEGF therapy.
- 2) branch retinal vein occlusion (ICD-9-CM 362.36/ICD-10-CM code H34.83x) when treatment with laser photocoagulation has not been beneficial, or treatment with laser photocoagulation is not considered suitable because of the extent of macular hemorrhage in those individuals who have failed anti-VEGF therapy.

GUIDELINE NOTE 27, TREATMENT OF SLEEP APNEA IN ADULTS

Line 206

CPAP is covered initially when all of the following conditions are met:

- 12 week 'trial' period to determine benefit. This period is covered if apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour; or if between 5 and 14 events with additional symptoms including one or more of the following:
 - excessive daytime sleepiness defined as either an Epworth Sleepiness Scale score >10 or daytime sleepiness interfering with ADLs, that is not attributable to another modifiable sedating condition (e.g. narcotic dependence), or
 - documented hypertension, or
 - ischemic heart disease, or
 - history of stroke;

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- Providers must provide education to patients and caregivers prior to use of CPAP machine to ensure proper use; and
- Positive diagnosis through polysomnogram (PSG) or Home Sleep Test (HST).

CPAP coverage subsequent to the initial 12 weeks is based on documented patient tolerance, compliance, and clinical benefit. Compliance (adherence to therapy) is defined as use of CPAP for at least four hours per night on 70% of the nights during a consecutive 30 day period.

Mandibular advancement devices (oral appliances) are covered for those for whom CPAP fails or is contraindicated.

Surgery for sleep apnea in adults is not covered (due to lack of evidence of efficacy).

~~Tonsillectomy and adenoidectomy~~ [Surgical](#) codes are included on this line only for children who meet criteria according to Guideline Note 118 OBSTRUCTIVE SLEEP APNEA DIAGNOSIS AND TREATMENT IN CHILDREN.

GUIDELINE NOTE 35, SINUS SURGERY

Lines 366,470

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

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

OR

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

- Several courses of antibiotics AND
- Trial of inhaled and/or oral steroids AND
- Allergy assessment and treatment when indicated

AND

- One or more of the following:
- Findings of obstruction of active infection on CT scan
- Symptomatic mucocele
- Negative CT scan but significant disease found on nasal endoscopy

OR

C) Nasal polyposis causing or contributing to sinusitis

OR

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

OR

E) Invasive or allergic fungal sinusitis

OR

F) Tumor of nasal cavity or sinuses

OR

G) CSF rhinorrhea

[Adenoidectomy \(CPT 42830, 428305\) is included on line 470 only for treatment of children with chronic sinusitis who fail appropriate medical therapy.](#)

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GUIDELINE NOTE 118, OBSTRUCTIVE SLEEP APNEA DIAGNOSIS AND TREATMENT FOR CHILDREN

Line 206

Obstructive sleep apnea (OSA) in children (18 or younger) must be diagnosed by

1. nocturnal polysomnography with an AHI >5 episodes/h or AHI >1 episodes/h with history and exam consistent with OSA, OR
2. nocturnal pulse oximetry with 3 or more SpO₂ drops <90% and 3 or more clusters of desaturation events, or alternatives desaturation (>3%) index >3.5 episodes/h, OR
3. use of a validated questionnaire (such as the Pediatric Sleep Questionnaire or OSA 18), OR
4. consultation with a sleep medicine specialist.

Polysomnography and/or consultation with a sleep medicine specialist to support the diagnosis of OSA and/or to identify perioperative risk is recommended for

1. high risk children (i.e. children with cranio-facial abnormalities, neuromuscular disorders, Down syndrome, etc.)
2. children with equivocal indications for adenotonsillectomy (such as discordance between tonsillar size on physical examination and the reported severity of sleep-disordered breathing),
3. children younger than three years of age

Adenotonsillectomy is an appropriate first line treatment for children with OSA. Weight loss is recommended in addition to other therapy in patients who are overweight or obese.

[Adenoidectomy without tonsillectomy is only covered when a child with OSA has previously had a tonsillectomy, when tonsillectomy is contraindicated, or when tonsillar hypertrophy is not present. More complex surgical treatments are only included on this line for children with craniofacial anomalies.](#)

Intranasal corticosteroids are an option for children with mild OSA in whom adenotonsillectomy is contraindicated or for mild postoperative OSA.

CPAP is covered for a 3 month trial for children through age 18 who have

1. undergone surgery or are not candidates for surgery, AND
2. have documented residual sleep apnea symptoms (sleep disruption and/or significant desaturations) with residual daytime symptoms (daytime sleepiness or behavior problems)

CPAP will be covered for children through age 18 on an ongoing basis if:

- There is documentation of improvement in sleep disruption and daytime sleepiness and behavior problems with CPAP use
- Annual re-evaluation for CPAP demonstrates ongoing clinical benefit and compliance with use, defined as use of CPAP for at least four hours per night on 70% of the nights in a consecutive 30 day period

Appendix D New Guidelines

GUIDELINE NOTE XXX, ABLATION PROCEDURES FOR ATRIAL FIBRILLATION

Line 350

AV nodal ablation (CPT 33250, 33251, 33261, 93650) pairs with atrial fibrillation (ICD-9 427.31/ICD-10 I48.0, I48.1, I48.2, I48.91) only for patients with inadequate ventricular rate control resulting in symptoms, left ventricular systolic dysfunction or substantial risk of left ventricular systolic dysfunction, when pharmacological therapy for rate control is ineffective or not tolerated

Transcatheter pulmonary vein isolation (93656-93657) pairs with atrial fibrillation (ICD-9 427.31/ICD-10 I48.0, I48.1, I48.2, I48.91) only for patients who remain symptomatic from atrial fibrillation despite rate control medications and antiarrhythmic medications.

Surgical ablation (pulmonary vein isolation or Maze procedure) (CPT 33254-33259, 33265, 33266) only pairs with atrial fibrillation (ICD-9 427.31/ICD-10 I48.0, I48.1, I48.2, I48.91) at the time of other cardiac surgery for patients who remain symptomatic despite rate control medications.

DIAGNOSTIC GUIDELINE DXX, SPECT

SPECT (CPT 78451, 78452) is not covered for screening for coronary artery disease in asymptomatic patients.

SPECT is only covered for diagnosis or risk stratification of coronary artery disease in patients for whom stress imaging is required and stress ECHO is contraindicated, is unavailable or would provide suboptimal imaging (i.e. pre-existing cardiomyopathy, baseline regional wall motion abnormalities, left bundle branch block, paced rhythm, unsuitable acoustic windows due to body habitus, inability to utilize dobutamine in a setting where exercise is not possible or when the target workload is not achievable).

GUIDELINE NOTE XXX, BREASTFEEDING SUPPORT AND SUPPLIES

Line 3

Breast pumps and supplies are covered for postpartum women when a pump is necessary to establish or maintain milk production in order to maximize availability of breast milk to the baby.

For cases in which there is a medical indication for breast pumps, the pumps should be supplied, whenever possible, within 24 hours to allow for continued milk production.

Lactation support services (including education and counseling by trained providers) are covered for pregnant and postpartum women for 6 months postpartum.

MINUTES

Health Technology Assessment Subcommittee
Meridian Park Community Health Education Center
19300 SW 65th Avenue, Tualatin, OR
November 24, 2014
1:00-4:00pm

Members Present: James MacKay, MD, Chair Pro Tempore; Gerald Ahmann, MD; George Waldmann, MD; Timothy Keenen, MD.

Members Absent: None

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

Also Attending: Alison Little, MD, Robyn Liu, MD and Jill Scantlan (CEBP); Bridget Kiene, American Cancer Society; Eugene Fuchs, MD (OHSU).

1. CALL TO ORDER

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

2. MINUTES REVIEW

No changes were made to the September, 2014 draft minutes.
Minutes approved 3-0 (Keenen absent).

3. STAFF REPORT

Darren Coffman reported on the HERC retreat. Some of the items that are a part of the workplan emanating from the retreat include a more searchable Prioritized List for the HERC web site, increased systematic outreach to stakeholders as well as potential membership changes for HTAS and EbGS to rebalance these committees. Also, two full HERC members are up for confirmation in December. As these changes develop, some HTAS members may be asked to move to another subcommittee and the date and time of meetings may change.

Coffman also reported that Alison Little will be leaving her position at the Center for Evidence-based Policy (CEbP) in December. Little introduced Robyn Liu, who will serve as her replacement, and Jill Scantlan, a research associate, who will collaborate on the research. Members expressed their appreciation for Little's work and wished her well.

4. REVIEW OF PUBLIC COMMENTS

A) Alternatives to Transurethral Resection of the Prostate

Alison Little reviewed the public comments and the CEBP's recommended responses. She also noted that the subcommittee has received additional evidence through a comment after the deadline on prostatic urethral lifts. Coffman said that because of this comment and the decision at the retreat to conduct additional outreach, the subcommittee might consider putting the coverage guidance out for a second public comment period. The subcommittee agreed to repost the coverage guidance, but discussed the existing comments first.

Shaffer led the subcommittee through several decisions related to public comment. MacKay proposed deleting the weak recommendation for coverage of bipolar TUVP. Fuchs said that they are really the same procedure. Monopolar procedures have the risk of water absorption which can cause "TURP syndrome". Bipolar was slow to be accepted because the instrument was so small it took a long time to complete the procedure. Newer bipolar instruments are larger and allow for quicker surgery without the risks associated with the monopolar procedure. Devices used include the "button" and "standard resectoscope". Little explained that the evidence for the older monopolar procedure is of high quality but older. The only reason we have limited evidence for the bipolar TUVP may be that it's newer. After discussion, the subcommittee decided to eliminate the strong recommendation for (Monopolar) TUVP with a rationale in the GRADE table that this procedure is no longer in use. In addition, they decided to leave the weak recommendation for Bipolar TUVP, noting that it is also known as the "button procedure."

The subcommittee then discussed the Thulium laser. Fuchs said these are available locally. Little said there is one study of the Thulium laser, and NICE gave it a moderate rating though they didn't mention it in their recommendation. After discussion the subcommittee decided to keep its strong recommendation for photovaporization (PVP), but to make a weak recommendation for coverage of the Thulium laser vaporization/resection. Fuchs said that the GOLIATH study would show better evidence of effectiveness when compared to TURP with less risk, but it was not considered as only short-term outcomes are available at this time.

Discussion moved to prostatic urethral lifts. Little said she found insufficient evidence, but CMS is covering it. There is one additional trial which will be reviewed at the February meeting as part of the new public comment. The subcommittee made no changes during this meeting.

Gingerich drew the attention to three rows of the GRADE table (laser coagulation (VLAP), prostatic artery embolization and prostatic urethral lifts) for interventions mentioned in the box but not in the GRADE table. These had earlier been deleted since the studies did not compare them to TURP and have been added back for consistency.

Fuchs asked about the use of the word "or" versus "and" in the first sentence of the coverage guidance. After discussion, the group agreed that this sentence should read, "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.” This is to clarify that a trial of medical therapy should be required before trying any of these surgical interventions. They agreed the “or are not appropriate” would cover exceptions requiring immediate surgery.

A motion was made to put the revised draft coverage guidance out for comment for an additional 21-day period. **Motion approved 4-0.**

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 Electro vaporization 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

B) Advanced imaging for the staging of prostate cancer

Alison Little reviewed the public comments and the recommended responses, which centered around PET for prostate cancer. Ahmann said PET is not likely to find an isolated metastasis and so is not useful for prostate cancer, as PSA level alone is adequate for treatment planning. The subcommittee discussed the Medicare coverage criteria included in the meeting materials. Medicare does not cover it for initial staging, but covers up to three PET scans for restaging.

No changes were made to the draft coverage guidance.

A motion was made to approve the draft coverage guidance as written and forward to HERC. **Motion approved 4-0.**

HERC COVERAGE GUIDANCE

To determine risk status and treatment options, prostate cancer clinical staging that includes PSA level and prostate biopsy with Gleason score is recommended for coverage.

MRI is recommended for coverage for men with histologically proven prostate cancer if knowledge of the T or N stage could affect management. (*strong recommendation*)

CT of the pelvis is not recommended for coverage in men with low- to intermediate-risk localized prostate cancer, unless MRI is contraindicated. (*strong recommendation*)

Radionuclide bone scanning is not recommended for routine coverage in men with localized prostate cancer. (*weak recommendation*)

Radionuclide bone scanning is recommended for coverage when hormone therapy is being deferred (through watchful waiting) in asymptomatic men who are at high risk of developing bone complications. (*strong recommendation*)

PET imaging is not recommended for coverage in prostate cancer. (*strong recommendation*)

4. REVIEW OF NEW DRAFT COVERAGE GUIDANCES

A. Genetic tests of cancer tissue for prognosis and potential response to treatment

Wally Shaffer presented the new draft coverage guidance. Subcommittee members discussed their clinical experience with these tests and agreed that some of them are useful for some patients.

Shaffer reviewed the evidence for the various breast cancer tests, and the review indicates that only the Oncotype DX had clinical utility, especially patients who are lymph-node negative. Discussion focused on patients who are lymph-node positive, most of whom will want treatment regardless of test results. Shaffer said there were three relatively small trials showing prognostic efficacy for this group, but there is not evidence it produces changes in clinical decision-making. After discussion the subcommittee decided to recommend against coverage in this population due to insufficient evidence of clinical utility, using a path of IIA1a on the coverage guidance framework (insufficient/mixed evidence, alternatives available, less risk, similar or more cost).

Discussion moved to the other tests. Ahmann said that KRAS in colorectal cancer and EGFR in lung cancer definitely change the choice of treatment. These have been in common use for several years. They also discussed the ALK test; Ahmann said the yield is much lower with ALK. Ahmann said the BRAF test for melanoma also shows utility (This test was not mentioned in the draft coverage guidance). The subcommittee asked

staff to look at the drug literature for the utility of these tests. Little said that the Center can search additional sources. The subcommittee asked for additional research on KRAS in colorectal cancer, EGFR in lung cancer and BRAF for melanoma.

The subcommittee did request that staff change the title of the coverage guidance to "Biomarker tests of cancer tissue for prognosis or treatment response." This name change had also been requested by VbBS to clarify that the topic does not involve germ line genetic testing.

Action:

The coverage guidance was renamed "biomarker tests of cancer tissue for prognosis or treatment response." Staff will perform additional research and bring a revised draft to the next meeting.

5. ADJOURNMENT

The meeting was adjourned at 4:00 pm. The next meeting is scheduled for February 23, 2015 from 1:00-4:00 pm in Room 117B&C of the Meridian Park Hospital Community Health Education Center in Tualatin.

MINUTES

Evidence-based Guidelines Subcommittee
Meridian Park Community Health Education Center, Room 117B&C
19300 SW 65th Avenue, Tualatin, OR
November 6, 2014
2:00-5:00pm

Members Present: Wiley Chan, MD, Chair; Vern Saboe, DC; Beth Westbrook, PsyD; Leda Garside, RN, MBA (via phone); Bob Joondeph, JD

Members Absent: Steve Marks, MD, Vice-Chair; Eric Stecker, MD, MPH; Som Saha, MD, MPH

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

Also Attending: Alison Little, MD (CEbP) ; Duncan Neilson, MD (Legacy Health); Melissa Cheyney, PhD, CPM, LDM; Leigh Hess (OHSU); Wayne Powell and Arthur Lee, MD (Society for Cardiovascular Angiography and Interventions); Ed Toggart, MD; John Rudoff; Carole LeVanda; Sharron Fuchs.

1. CALL TO ORDER

Wiley Chan called the meeting of the Evidence-based Guidelines Subcommittee (EbGS) to order at 2:04 pm.

2. MINUTES REVIEW

There was a correction made to the September 4, 2014 minutes, Beth was not in attendance. **Minutes approved with correction 5-0.**

3. REVIEW PREVIOUSLY DISCUSSED COVERAGE GUIDANCE

A) HOME BIRTH

Livingston reviewed the interim changes to the Home Birth Draft Coverage Guidance document and answered clarifying questions. There was an extensive discussion about the level of evidence that was appropriate given the absence of RCTs, the reliance on large cohort studies, and the risk of internal biases which lead to an initial “low quality” assessment. Because of the further external validity concerns this was downgraded to “very low.” It was further decided that the consistency of evidence could not upgrade the level based on GRADE methodology, which does not permit upgrading of an observational study that has been downgraded for any reason.

Dr. Neilson and Dr. Cheyney provided expert input stating that there is significant recent US data that may obviate the external validity issue. Dr. Cheyney also shared that a

new Dutch study was published in October that discredited the Wax study. It reportedly included more years of data and extended mortality up to 28 days (Wax apparently had only gone out to 7 days). She explained the mortality rate is likely due to intrapartum transfer delays, and is also deeply regulated by client selection. They stated these studies may change the concerns about external validity, given that one uses a large US database, which may result in a strengthening of the quality of evidence.

Subcommittee members discussed the impact of costs (with home birth being much less expensive than hospital birth) as well as the strong preference of some members of the public to have a home birth. The final recommendation for coverage of home birth in low risk women places a high value on decreased bad outcomes, and also recognizes that patient preferences and resource considerations support this. The final algorithm pathway for low risk women is II A1b.

There was a discussion about the utility of including infant emergencies and obstetric emergencies that would require transfer. The group felt it was useful to include as a reference.

Experts and members expressed concerns that the list of high risk conditions may not be exhaustive. They decided to add the language “including, but not limited to”. In the discussion of safety systems and training, they thought this should be attributed to the evidence base.

Actions:

- 1) Approved draft with the following changes:
 - GRADE table modifications for low risk women
 - Expand details in the values and preferences section
 - Downgrade quality of evidence to Very Low – due to external validity concerns
 - Final recommendations: weak recommendation for low risk women, strong against among unselected pregnancies
 - Modifications to language around high risk conditions to qualify that the list is not exhaustive
 - Attribute language around safety to underlying evidence base

Motion to accept as edited. Motion approved 5-0.

4. REVIEW OF NEW DRAFT COVERAGE GUIDANCES

A) INFERIOR VENA CAVA FILTERS FOR PREVENTION OF PULMONARY EMBOLISM

The appointed expert was introduced: Dr. Andy Felcher, hospitalist at Kaiser Sunnyside, served as head of the Kaiser anticoagulation clinic for 8 years. He shared his experience is with filters involving medical patients and that Kaiser has a registry for IVC filter patients. No conflicts were declared.

Little reviewed the evidence. Livingston reviewed the draft GRADE table and proposed algorithm pathways. Discussion of IVC filters in trauma patients ensued. There was a discussion about the endpoints of pulmonary embolism (PE) versus mortality and the risks of increasing deep vein thrombosis (DVT). Clarifying questions were asked of the expert about when IVC filters are placed. Dr. Felcher stated that in medical patients with contraindication to anticoagulation; if they have had a recent clot, generally they do put in a filter, and when anticoagulation is feasible again, retrieve the filter and restart anticoagulation. He shared that nationally only a third of patients get their IVC filters removed and stated that removal is definitely indicated due to the risk of DVT. Trauma patients in particular may have less follow up. Locally, two health systems apparently have conflicting standards with OHSU putting them in none of their trauma patients and Legacy putting them in all. Members were quite interested in this divergence in practice and requested staff to request information about protocols and rationale from the trauma surgery departments at each institution.

For IVC filters in hospitalized trauma patients, the algorithm would lead to a strong recommendation for coverage (1A1b). This was downgraded to a weak recommendation because of harms (DVT), issues of retrievability, and a lack of benefit on mortality.

For IVC filters in bariatric surgery patients, the group agreed that sufficient evidence demonstrates higher mortality and no benefit from IVC filters and thus made a strong recommendation against.

For IVC filters in populations with proximal DVT who are candidates for anticoagulation, there is insufficient evidence of effectiveness, but more risk than not using IVC filters. The group made a strong recommendation against.

For IVC filters in those with proximal DVT or PE and contraindication to anticoagulation a strong recommendation for was made. This was based on insufficient evidence, recognizing the unlikelihood of a study ever being conducted given many patients would choose this procedure to be protected against fatal PE. It follows the coverage guidance development framework pathway IIb1a2 and is upgraded from a weak to a strong recommendation based on preferences and the low likelihood of additional evidence.

There was a discussion about the statement about retrieving filters. Dr. Felcher stated that it is strongly recommended to remove IVC filters (within a limited window of time) whenever possible because of the long-term known risk of DVT.

Actions:

1. GRADE table was modified as discussed
2. Staff to follow up with trauma surgeons at Legacy and OHSU to ask what are their policies and the rationale supporting them
3. Staff to obtain estimates of cost related to IVC filters

A motion was made to approve the draft coverage guidance as edited and post it for public comment. **Motion approved 5-0.**

B) CORONARY ARTERY REVASCULARIZATION FOR STABLE ANGINA

Little reviewed the evidence. Livingston reviewed the draft GRADE tables and algorithm pathways. The appointed expert, Dr. Ed Toggart , interventional cardiologist, was introduced. There was an extensive discussion as to whether the studies included in the evidence review were examining optimal medical therapy (OMT) in contrast to PCI alone or PCI plus OMT. The evidence appears to be a mixture of these two, while Dr. Toggart stated that guideline-directed medical therapy is preferable for patients with stable ischemic heart disease, compared to initial treatment with PCI. He addressed the complexity of the topic and discussed the guideline endorsed by three specialties that has 879 references. He disagreed about the quality assessment of this guideline. Little clarified the reason why it did not receive a higher quality rating is because there is no description of quality assessment of the studies, which is a required standard for higher quality guidelines. Toggart also raised the concern that risk assessments would guide different types of therapy.

After extensive discussion, the GRADE table was modified to state the comparator is PCI plus OMT vs. OMT in patients with non-acute coronary heart disease. Dr. Toggart proposed to add coverage for high risk cases that failed medical therapy. There was a lack of clarity on what the definition of failed therapy would be.

There were questions asked about COURAGE trial results as well as the rationale for rating the evidence very low for several indications that had 1-2 RCTs. Dr. Little said she will re-review these RCTs and gain further details on the quality assessment.

A proposal was put forth to change the indications to revascularization as a group, rather than treatment with PCI or with CABG. There were concerns raised that the literature does not demonstrate equivalency. There was significant concern about the >75 years of age designation and clarification that evidence was better for that group than in <75, but the recommendation against seemed inappropriate. They gave illustrative examples that simply because there isn't data in African Americans a recommendation should not be made against a treatments use in that population. The group decided to remove this recommendation.

Action:

1. This topic will be addressed further at the February EbGS meeting.

5. PUBLIC COMMENT

Prior to ending discussion of the draft coverage guidance for Revascularization for Chronic Stable Angina, the subcommittee received the following public testimony.

Dr. Arthur Lee, representing the Oregon Chapter of the American College of Cardiology (ACC) and Society for Cardiovascular Angiography and Interventions (SCIA), provided public comment and declared no conflicts of interest. He discussed a problem with the literature reviewed in that most of the studies looked at bare metal stents while contemporary studies with drug-eluting stents show better outcomes. He also provided

written testimony that recommended guideline-directed medical therapy be tried and revascularization reserved for those who fail. He stated that there are robust studies demonstrating improvement in quality of life and this is a key outcome. He also took issue with the quality rating of the specialty guideline, raised concerns about the >75 years of age statement, and recommended the inclusion of a PCI guideline. He also provided a NICE guidance reference and raised concerns about poor candidates for CABG who may be good PCI candidates.

6. ADJOURNMENT

The meeting was adjourned at 4:59 pm. The next meeting is scheduled for February 5, 2015 from 2:00-5:00pm in Room 117B of the Meridian Park Hospital Community Health Education Center in Tualatin.

DRAFT

Section 2.0

Staff Report

Corrections, Changes, Additions, and Edits for the January 1, 2015 Prioritized List

HERC staff has made the following changes prior to the publication of the January 1, 2015 Prioritized List.

- 1) ICD-9 codes which were located only on deleted lines were identified and the most appropriate placements on the new List were identified.
- 2) Negative pressure wound therapy guideline wording change: "covered" was changed to "included"
- 3) Neonatal intensive care CPT codes (CPT 99468 and 99469) were added to all lines with hospital E&M codes (expanded from 25 lines). Neonatologist identified multiple lines which required these codes
- 4) The E&M codes on the mental health and chemical dependency lines were returned to match the October, 2014 prioritized list.
- 5) Intravitreal steroid injections/implants (CPT 67027 and 67028) were added to line 363 CHORIORETINAL INFLAMMATION. At the November, 2014 VBBS meeting, a guideline regarding the use of these codes on this line was approved but the codes themselves were not added to the line in error.

Section 3.0

VbBS Report

Straightforward Issues—January, 2015

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
			GN 117, INTRAOCULAR STEROID IMPLANTS FOR CENTRAL RETINAL VEIN OCCLUSION was modified to include branch retinal vein occlusion at the November, 2015 VBBS meeting. However, the title of the GN was not changed to match the expanded coverage in the guideline.	Change the title of GN 117 to INTRAOCULAR STEROID IMPLANTS FOR CENTRAL RETINAL VEIN OCCLUSION
50820	Ureteroileal conduit (ileal bladder), including intestine anastomosis (Bricker operation)	274 CANCER OF BLADDER AND URETER	DMAP is requesting that 50820 be added to line 274. Currently, 50820 is only on line 25 VESICoureTERAL REFLUX. Similar CPT codes appear on line 274.	Add 50820 to line 274
54408 54410, 54411, 54416, 54417 54406, 54415	Repair of component(s) of a multi-component, inflatable penile prosthesis Removal and replacement of all component(s) of a multi-component, non-inflatable/inflatable penile prosthesis Removal of all components of a penile prosthesis without replacement of prosthesis	290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 413 GENDER DYSPHORIA 529 SEXUAL DYSFUNCTION	DMAP requested that 54408-54417 be removed from lines 290 and 413. Removal of the penile prosthetic should still be covered on the complication line (54406, 54415) but should be removed from line 413. All codes would remain on the sexual dysfunction line as all are treatments for impotence.	Remove 54408, 54410, 54411, 54416, 54417 from lines 290 and 413 Remove 54406 and 54415 from line 413

Straightforward Issues—January, 2015

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
V49.75	Below knee amputation status	381 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	DMAP requested that V49.75 be moved from 534 DEFORMITIES OF UPPER BODY AND ALL LIMBS to line 381. The services that would be associated with this code are mainly use of prosthetics, which are located on line 381.	Move V49.71 from line 534 to line 381
28446	Open osteochondral autograft, talus	359 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE	DMAP requested that 28466 be added to line 359 to pair with 732.7 (Osteochondritis Dissecans). 28466 is currently on line 358 CLOSED FRACTURE OF EXTREMITIES (EXCEPT MINOR TOES).	Add 28446 to line 359

VbBS Issue Summary (1/2015)

Prevention Services Guideline Updates

Issue: the prevention table needs 2 edits:

- 1) Updating the link to the Bright Futures Guidelines
- 2) Change the reference to the immunizations. Have a link simply to the Advisory Committee on Immunization Practices (ACIP) links, and take out the reference to the Oregon Immunization program. This change is consistent with the requirements of the ACA

HERC staff recommendation:

- 1) Make the following changes to the Prevention Services Guideline

GUIDELINE NOTE106, PREVENTIVE SERVICES

Line 3

Included on this line are the following preventive services:

1. US Preventive Services Task Force (USPSTF) "A" and "B" Recommendations (as of May 2012): <http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/>
2. American Academy of Pediatrics (AAP) Bright Futures Guidelines (published 2008):
~~http://brightfutures.aap.org/pdfs/Guidelines_PDF/20-Appendices_PeriodicitySchedule.pdf~~
http://www.aap.org/en-us/professional-resources/practice-support/Periodicity/Periodicity%20Schedule_FINAL.pdf
3. Health Resources and Services Administration (HRSA) Women's Preventive Services - Required Health Plan Coverage Guidelines: (approved with Affordable Care Act on March 23, 2010)
<http://www.hrsa.gov/womensguidelines/>
4. Immunizations as recommended by the Advisory Committee on Immunization Practices (ACIP) ~~and approved for the Oregon Immunization Program:~~

~~<http://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Documents/DMAPvactable.pdf>~~ <http://www.cdc.gov/vaccines/schedules/hcp/index.html>

Inpatient services for autism self injury and stereotypy

Question: Inpatient services for autism self injury and stereotypy

Question source: HERC Staff

Relevant Lines

313 AUTISM SPECTRUM DISORDERS

442 STEREOTYPY/HABIT DISORDER AND SELF-ABUSIVE BEHAVIOR DUE TO NEUROLOGICAL DYSFUNCTION

Issue: Staff identified that there is a discrepancy between the autism line and the stereotypy line with regard to inpatient codes. The stereotypy line has inpatient codes as of January 1, 2015, while the autism line does not. Staff recommends placing the inpatient codes on the autism line as well. There are mechanisms in place to ensure that inpatient treatment is covered when appropriate.

Recommendations: Add inpatient codes to autism line.

96127 Code Placement

Issue: CPT code 96127 (Brief emotional/behavioral assessment (e.g., depression inventory, attention-deficit/hyperactivity disorder [ADHD] scale), with scoring and documentation, per standardized instrument) was placed on all lines with SBIRT codes (approximately 650 lines) during the 2015 CPT code review. However, this code actually is not related to SBIRT, but rather to screening for depression and monitoring for depression treatment response. CMS lists this code as for use with the “Beck Youth Inventory,” which is a pediatric/adolescent screening and assessment tool, which is listed as a screening and assessment tool, and a tool for assessing post-treatment outcomes. Its use is closer to 99420 (Administration and interpretation of health risk assessment instrument (e.g., health hazard appraisal)), which is Diagnostic. Given its use for monitoring treatment, the best location for this code is the Ancillary List.

HERC staff recommendations:

- 1) Remove 96127 (Brief emotional/behavioral assessment (e.g., depression inventory, attention-deficit/hyperactivity disorder [ADHD] scale), with scoring and documentation, per standardized instrument) from all current Prioritized List lines
- 2) Advise DMAP to place 96127 on the Ancillary List

VbBS Issue Summaries 1/6/2015

Liver Elastography

Issue: A new code for liver elastography was released with the 2015 CPT codes (CPT 91200). This technology was reviewed at the November, 2014 VBBS meeting and the staff recommendation to place on the Non-Covered List was accepted. This recommendation was based on unclear utility in distinguishing lower grades of liver fibrosis other than cirrhosis. It was noted in the meeting materials that non-invasive testing for liver fibrosis is a rapidly evolving field and that this area should be re-reviewed in the near future. The only currently FDA approved liver elastography measurement device is called Fibroscan™.

At the November, 2014 HERC meeting, this topic was discussed at considerable length. Wally Shaffer, medical director at DMAP, gave testimony that liver elastography is an essential part of the DMAP hepatitis C medication PA algorithm, used to determine eligibility for certain high cost drugs. This algorithm was developed based on community hepatology advisory workgroup input, which had heavy involvement from several OHP CCO's, which are very vested in this algorithm. Experts have told DMAP and the CCOs that there would be an 80% cost savings in using liver elastography rather than routine liver biopsy.

HERC members felt that coverage of this test would minimize disruption of care to OHP patients until the HERC can identify enough data to make a clear, evidence-based decision. There was some discussion about concern over making policy based on community standard as well as concern about the higher standard required to remove a procedure from the Prioritized List once placed there.

Liver elastography was proposed for placement on the hepatitis C line only (line 202 CHRONIC HEPATITIS; VIRAL HEPATITIS) for use with OHP and CCO hepatitis C treatment algorithms. A guideline was proposed which would restrict use to clinical situations in which liver elastography would replace liver biopsy for treatment decisions. The HERC requested the OHP algorithm to review at a future meeting.

The final decision was to table the decision on liver elastography until a future meeting. For the January 1, 2015 Prioritized List, the code will appear nowhere and CCOs and DMAP can determine for themselves whether to cover the test. HERC staff was directed to review the DMAP criteria and develop a placement proposal with a guideline to review at the January, 2015 VBBS/HERC meeting.

Further information:

The entire DMAP hepatitis C treatment algorithm can be reviewed at <http://www.oregon.gov/oha/healthplan/tools/Oregon%20Medicaid%20PA%20Criteria,%20October%202014.pdf>. The Hepatitis C drugs start on page 86 of the pdf.

The pertinent portion of the current DMAP Hepatitis C treatment algorithm:

If patient has chronic hepatitis C, genotype 1 (without Q80K polymorphism) and request is for telaprevir, boceprevir, simeprevir or sofosbuvir:

Liver Elastography

Does the patient have a biopsy or other noninvasive technology (Fibroscan), including serum tests (Fibrosure, Fibrotest) to indicate severe fibrosis (stage 3 or greater) OR radiologic, laboratory, or clinical evidence of cirrhosis? OR has extrahepatic manifestations (vasculitis, glomerulonephritis, cryoglobulins).

A no response results in denial. A yes response continues through other medical appropriateness questions.

Pertinent wording from Aetna 2014 coverage criteria

Aetna considers transient elastography (e.g., FibroScan) medically necessary for distinguishing hepatic cirrhosis from noncirrhosis in persons with hepatitis C or other chronic liver diseases. Performance of transient elastography more than twice per year is considered not medically necessary. Performance of transient elastography within six months following a liver biopsy is considered not medically necessary. Transient elastography is considered experimental and investigational for all other indications.

HERC staff recommendations:

- 1) Place liver elastography (CPT 91200) on line 202 CHRONIC HEPATITIS; VIRAL HEPATITIS)
- 2) Adopt the guideline below for line 202

GUIDELINE XXX LIVER ELASTOGRAPHY

Line 202

Liver elastography (CPT 91200) is included on this line only when the non-invasive test would replace liver biopsy for determination of eligibility for medications for chronic hepatitis C.

Back Pain Lines and Guidelines

DRAFT LINES:

Medical line: This line includes all diagnoses from the old back pain lines (lines 374,412,545,588) except cauda equina syndrome. This line includes medical office visits, patient education, medications, OMT/CMT, acupuncture, PT/OT, and cognitive behavioral therapy. These services will be governed by a new guideline. No percutaneous interventions or surgeries will appear on these lines—see the surgical lines below.

Line: XXX

CONDITIONS OF THE BACK AND SPINE

TREATMENT: MEDICAL THERAPY

ICD-9: 336.0, 349.2, 720.2,720.82,721.0-721.6,721.7-8,721.90,721.91,722.0,722.10-722.93,723.0,723.1,723.3-723.9,724.0-724.2,723.4,724.40724.6,724.70-724.9,731.0,732.0,737.0-737.39,737.8-737.9,738.4-738.5,739.0-739.9,742.59,754.1,754.2,756.10-756.19,756.3,839.20-839.21,847.0-847.9V57.1,V57.21-V57.3, V57.81-V57.89,V57.1,V57.21-V57.3,V57.81-V57.89

ICD-10:

CPT: 90785-90853 (mental health visits, counseling), 96127, 96150-4 (health and behavior assessment codes), 97001-97004, 97022, 97110-97124, 97140, 97150, 97540, 97535 (PT/OT evaluation and treatment), 97810-97814 (acupuncture), 98925-98929, 98940-98942 (OMT/CMT), 98966-98968, 98969, 99051, 99060, 99201-99215 (outpatient medical visits), 99401-99404 (risk factor reduction intervention), 99408, 99409, 99411, 99412, 99441-99444

HPCPS:

Back Pain Lines and Guidelines

Surgical lines: There will be 2 surgical lines, with the higher priority line containing those diagnoses with urgent/emergent surgical indications and a lower priority line (currently scored below the funding line) with spinal surgical treatments and percutaneous interventions. The lower surgical line will not include diagnoses generally seen as only medication, such as 724.x (pain in spine, lumbago, sciatica).

The taskforce was interested in an alternative: have a single surgical line, with the urgent surgical indications added to line 154 CERVICAL VERTEBRAL DISLOCATIONS/FRACTURES, OPEN OR CLOSED; OTHER VERTEBRAL DISLOCATIONS/FRACTURES, OPEN OR UNSTABLE; SPINAL CORD INJURIES WITH OR WITHOUT EVIDENCE OF VERTEBRAL INJURY. However, HERC staff on review found that this would not be workable as line 154 is a category 6 line, and the diagnoses identified are all category 7. No other appropriate lines were identified. Therefore HERC staff felt that 2 surgical lines would be the most appropriate strategy.

Line: AAA

CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS
TREATMENT: SURGICAL THERAPY

ICD-9: 344.60-344.61 [cauda equina], 721.1, 723.0, 724.0x (spinal stenosis), 721.91 (spondylosis of unspecified site with myelopathy); 722.7x (intervertebral disc disorder with myelopathy), 724.41-724.42 (Spondylosis with myelopathy), 737.30, 737.32, 737.34, 737.39 (scoliosis)

ICD-10:

CPT: 20930-20938,21720,21725,22206-22226,22532-22855,29000-29046,29710-29720,62287,63001-63091,63170,63180-63200,63295-63610,63650,63655,63685 [all surgical codes from line 412], 96127, 96150-4 (health and behavior assessment codes), 98966-98968, 98969, 99051, 99060, 99201-99215 (outpatient medical visits), 99401-99404 (risk factor reduction intervention), 99408, 99409, 99411, 99412, 99441-99444

HPCPS:

Note: also proposed for addition by Susan Williams: spondylolisthesis (when unstable). This diagnosis is coded with 738.4 (Acquired spondylolisthesis) or 756.12 (Spondylolisthesis). Both of these codes are currently only on the lower, uncovered line (588) and therefore were not proposed for this line by HERC staff.

Line: BBB

CONDITIONS OF THE BACK AND SPINE
TREATMENT: SURGICAL THERAPY

ICD-9: [all from lines 374,412, limited from 545 and 588] 336.0, 349.2,720.82,721.0, 721.2-721.6,721.7-8,721.90,722.0,722.10-722.2, 722.5-722.6, 722.8-722.93, 723.1,723.3-723.9, 731.0,732.0,737.0-737.39,737.8-737.9,738.4-738.5,742.59,754.2, 756.10-756.12,839.20-839.21,V57.1,V57.21-V57.3,V57.81-V57.89,V57.1,V57.21-V57.22,V57.81-V57.89

ICD-10:

CPT: 20930-20938,21720,21725,22206-22226,22532-22855,29000-29046,29710-29720,62287,63001-63091,63170,63180-63200,63295-63610,63650,63655,63685 [all surgical codes from line 412], 96127, 96150-4 (health and behavior assessment codes), 98966-98968, 98969, 99051, 99060, 99201-99215 (outpatient medical visits), 99401-99404 (risk factor reduction intervention), 99408, 99409, 99411, 99412, 99441-99444

HPCPS:

Back Pain Lines and Guidelines

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

Lines XXX

If a patient scores as low risk based on a validated assessment tool (e.g. Start Back Assessment Tool) OR has back pain present for less than 4 weeks and there are no red-flag symptoms present, then the patient should receive only limited care, to include office evaluation and education, and up to 4 visits of OMT/CMT, acupuncture, massage, and/or PT/OT. Short term use of medications such as NSAIDs, acetaminophen, and/or muscle relaxers can be considered, and opioids are considered second line therapy due to their potential risks.

Patients who score as high risk on a validated assessment tool or who have back pain of more than 4 weeks duration should receive office evaluation and education, and may receive cognitive behavioral therapy and medications if medically indicated. The necessity for cognitive behavioral therapy should be re-evaluated every 90 days and treatment only 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. Opioids should not be prescribed for more than 90 days. Access to addiction treatment should be available if needed.

High risk patients and patients with chronic back pain may receive a total of 30 visits per year of any combination of the following therapies when medically appropriate:

- 1) Rehabilitative therapy (physical and/or occupational therapy), if provided according to GUIDELINE NOTE 6, REHABILITATIVE SERVICES.
- 2) Chiropractic or osteopathic manipulation
- 3) Acupuncture
- 4) Massage therapy
- 5) Exercise therapy
- 6) Intensive interdisciplinary rehabilitation.
- 7) Biofeedback

Treatment with these therapies will be subject to Guideline Note 6, REHABILITATIVE SERVICES, where applicable. Ongoing coverage within the applicable limits is subject to clinically significant objectively measurable gains toward the goals of a treatment plan.

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>

Back Pain Lines and 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 (Carefully consider risks/harms)	Acetaminophen	●	●
	NSAIDs	●(▲)	●(▲)
	Skeletal muscle relaxants	●	
	Antidepressants (TCA)		●
	<i>Benzodiazepines**</i>	●(▲)	●(▲)
	<i>Tramadol, opioids**</i>	●(▲)	●(▲)
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.

GUIDELINE NOTE YYY SURGICAL AND PERCUTANEOUS INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE

Lines AAA, BBB

Surgical consultation/consideration for surgical intervention and/or percutaneous interventions are included on lines AAA and BBB for patients with persistent pain (>4 weeks duration) AND with neurological complications, defined as showing 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

It is recommended that shared decision-making regarding epidural steroid injection include a specific discussion about inconsistent evidence showing moderate short-term

Back Pain Lines and Guidelines

benefits, and lack of long-term benefits. If an epidural steroid injection does not offer benefit, repeated injections should not be covered. Epidural steroid injections are not covered for spinal stenosis or for patients with low back pain without radiculopathy.

Surgical interventions may be considered for patients with neurological complications as defined above but without urgent surgical indications (e.g. cauda equina syndrome, progressive neurological changes, etc.) only after the patient has completed at least 6 months of conservative treatment, to include at least intensive interdisciplinary rehabilitation and cognitive behavioral therapy, and may include acupuncture, chiropractic or osteopathic manipulation, massage, exercise therapy and/or biofeedback.

Surgical correction of scoliosis is only covered for children and adolescents with a spinal curvature of greater than 50 degrees.

The following interventions are not covered due to lack of evidence of effectiveness for 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

Back Pain Lines and Guidelines

Existing guidelines to be modified or retained

GUIDELINE NOTE 72, ELECTRONIC ANALYSIS OF INTRATHECAL PUMPS

Lines 400,562,634

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

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

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 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.

Back Pain Lines and Guidelines

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 101, ARTIFICIAL DISC REPLACEMENT

Lines ~~374,545~~ [AAA](#), [BBB](#)

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

Lumbar artificial disc replacement

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

Cervical artificial disc replacement

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

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

~~Lines 50,374,412,545,588,616~~

~~Epidural steroid injections (CPT 62311, 64483, 64484) are covered for patients with persistent radiculopathy due to herniated disc, where radiculopathy is as defined in Guideline Note 37 as showing 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~~

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

Back Pain Lines and 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

DRAFT
VbBS Issue Summaries 1/8/2015

Back Pain Lines and Guidelines

Line scoring

Scoring—Line XXX medical treatments

Category: 7

HL: 5

Suffering: 3

Population effects: 0

Vulnerable population: 0

Tertiary prevention: 3

Effectiveness: 3

Need for service: 0.9

Net cost: 2

Score: 594

Approximate line placement: 376

Scoring—Line AAA urgent surgical

[scoring for line 374]

Category: 7

HL: 5

Suffering: 3

Population effects: 0

Vulnerable population: 0

Tertiary prevention: 2

Effectiveness: 3

Need for service: 1

Net cost: 2

Score: 600

Approximate line placement: 374

Scoring—Line BBB surgical

[scores from line 545]

Category: 7

HL: 4

Suffering: 2

Population effects: 0

Vulnerable population: 0

Tertiary prevention: 0

Effectiveness: 1

Need for service: 0.8

Net cost: 2

Score: 96

Approximate line placement: 545

Spinal Fusion

Issue: there is a lot of controversy in the medical literature about the effectiveness of various vertebral fusion procedures for the treatment of back pain conditions. HERC staff conducted a brief literature review with guidance from the Center for Evidence Based Policy.

HERC staff evidence summary:

Surgical treatments for discogenic or non-specific lumbar and cervical back conditions has equivalent outcomes to conservative treatment, but at considerably higher risk and cost. Surgical treatments have better outcomes than conservative therapy for spinal stenosis and spondylothesis.

Evidence reviews

- 1) **WA HTA 2013**, cervical fusion surgery for degenerative disk disease
 - a. spinal fusion appeared to provide faster relief of pain and symptoms than conservative management (i.e., physical therapy or cervical collar immobilization) in the short term. Over time, however, these differences diminished and no material differences in outcome were observed by 12 months after intervention.
 - b. Because of this, and because spinal fusion may cause relatively rare but significant complications, we deemed the overall comparative clinical effectiveness of fusion to conservative management “Comparable”
 - c. Fusion is a high-cost intervention; as illustrated by our decision analysis, even the greater short-term clinical and return-to-work benefits assumed for fusion cannot offset its much higher costs relative to conservative management, particularly because these benefits wane over longer time horizons; as such, fusion is associated with high cost-effectiveness ratios and costs per treatment responder at 1 year that only increase over time. As such, the comparative value of fusion vs. conservative management is deemed to be “Low”.
- 2) **ICER 2011**, treatment of low back pain
 - a. Discectomy vs conservative treatment for lumbar disc disease
 - i. Small benefit seen with surgery for pain, function and quality of life at less than 12 months
 - ii. No difference found in pain, function, quality of life, return to work at 12 months.
 - b. Surgery vs conservative treatment for lumbar spinal stenosis
 - i. Laminectomy had a high certainty of a small health benefit at all time points compared to conservative therapy for function, pain and quality of life. No difference found on return to work
 - c. Surgery vs conservative treatment for degenerative spondylolisthesis
 - i. Fusion had a high certainty of a small health benefit at all time points compared to conservative therapy for function, pain and quality of life. No difference found on return to work
 - d. Surgery vs conservative treatment for non-specific low back pain
 - i. No difference found in pain, function, quality of life or return to work for fusion vs conservative treatment at any time point
- 3) **Chou 2010**, review of all types of therapy for low back pain
 - a. N=4 systematic reviews
 - b. Compared with non-surgical treatment, fusion surgery may be more effective than standard rehabilitation for improving pain, function, and return to work at 2

Spinal Fusion

- years, but may be no more effective than intensive rehabilitation with a cognitive-behavioral component for improving pain, function or return to work at 1 to 2 years. (moderate-quality evidence)
- c. Risks of fusion included Major complications included deep wound infection, major bleeding during surgery, thrombosis, acute respiratory distress syndrome, pulmonary oedema, and heart failure
 - d. Note: 3 of the 4 RCTs did not find clinically significant improvement in the fusion group vs the conservative therapy group
- 4) **NICE 2011** Transaxial interbody lumbar fusion
 - a. Current evidence on the efficacy of transaxial interbody lumbosacral fusion is limited in quantity but shows symptom relief in the short term in some patients. Evidence on safety shows that there is a risk of rectal perforation. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
 - 5) **NICE 2010**, non-rigid stabilisation procedures for the treatment of low back pain
 - a. Current evidence on the efficacy of non-rigid stabilisation techniques for the treatment of low back pain shows that these procedures are efficacious for a proportion of patients with intractable back pain.
 - 6) **NICE 2009**, lateral lumbar spinal fusion
 - a. Current evidence on the safety and efficacy of lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research
 - 7) **NICE 2009**, management of low back pain
 - b. Consider referral for an opinion on spinal fusion for people who have completed an optimal package of care, including a combined physical and psychological treatment programme and still have severe non-specific low back pain for which they would consider surgery.

Meta-analyses

- 1) **Mannion 2013**, meta-analysis of fusion vs conservative treatment for chronic low back pain
 - a. N=3 RCTs (473 patients)
 - b. The intention-to-treat analysis showed no statistically or clinically significant differences between treatment groups for ODI scores at LTFU (adjusted for baseline ODI, previous surgery, duration of LBP, sex, age, and smoking habit): the mean adjusted treatment effect of fusion was -0.7 points on the 0–100 ODI scale (95% confidence interval [CI], -5.5 to 4.2). An as-treated analysis similarly demonstrated no advantage of surgery (treatment effect, -0.8 points on the ODI (95% CI, -5.9 to 4.3). The results for the secondary outcomes were largely consistent with those of the ODI, showing no relevant group differences.
 - c. Conclusions: After an average of 11 years follow-up, there was no difference in patient self-rated outcomes between fusion and multidisciplinary cognitive-behavioral and exercise rehabilitation for cLBP.
- 2) **Bydon 2014**, meta-analysis of surgery vs conservative management for discogenic LBP
 - a. N=5 RCTs (707 pts)
 - i. 523 fusion, 134 conservative management
 - b. The pooled mean difference in ODI (final ODI - initial ODI) between the nonoperative and lumbar fusion groups across all studies was -7.39 points (95%

Spinal Fusion

confidence interval: $[-20.26, 5.47]$ in favor of lumbar fusion, but this difference was not statistically significant ($P=0.26$).

- c. Conclusions: Despite the significant improvement in ODI in the lumbar fusion groups in 3 studies, pooled data revealed no significant difference when compared with the nonoperative group. Although there was an overall improvement of 7.39 points in the ODI in favor of lumbar fusion, it is unclear that this change in ODI would lead to a clinically significant difference.
- 3) **Wang 2014**, meta-analysis of surgery vs conservative management for discogenic LBP
- a. N=6 RCTs (889 pts)
 - b. RESULTS: Meta-analysis revealed no difference in Oswestry Disability Index (ODI) score for DLBP between the fusion surgery and nonsurgical groups (mean difference, 1.94; 95% confidence interval [CI], $[-6.02, 2.14]$). Postsurgical complication rate significantly differed between the 2 groups (risk ratio, 22.11; 95% CI, 55.99–81.60).
 - c. Conclusions: fusion surgery was not superior to non-surgical treatment for discogenic LBP

VbBS Issue Summaries 1/8/2015

Intensive Counseling For Overweight/Obesity and Cardiovascular Risk Factors

Question: Should the guideline note on obesity be modified to reflect updated USPSTF recommendations on overweight with cardiovascular disease risk factors?

Question source: HERC Staff

Issue: As of August 2014, the USPSTF has released a new recommendation about counseling interventions for overweight and obese patients with additional cardiovascular disease risk factors.

Behavioral Counseling to Promote a Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors
August 2014

The USPSTF recommends offering or referring adults who are overweight or obese and have additional cardiovascular disease (CVD) risk factors to intensive behavioral counseling interventions to promote a healthful diet and physical activity for CVD prevention.

Grade: B Recommendation.

Related recommendations include:

Screening for and Management of Obesity in Adults
June 2012

The USPSTF recommends screening all adults for obesity. Clinicians should offer or refer patients with a body mass index (BMI) of 30 kg/m² or higher to intensive, multicomponent behavioral interventions.

Grade: B Recommendation.

Behavioral Counseling to Promote a Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults

June 2012

Population: General adult population without a known diagnosis of hypertension, diabetes, hyperlipidemia, or cardiovascular disease.

Recommendation: Although the correlation among healthful diet, physical activity, and the incidence of cardiovascular disease is strong, existing evidence indicates that the health benefit of initiating behavioral counseling in the primary care setting to promote a healthful diet and physical activity is small. Clinicians may choose to selectively counsel patients rather than incorporate counseling into the care of all adults in the general population.

Considerations: Issues to consider include other risk factors for cardiovascular disease, a patient's readiness for change, social support and community resources that support behavioral change, and other health care and preventive service priorities.

Potential Harms: Harms may include the lost opportunity to provide other services that have a greater health effect.

Grade: C Recommendation.

Intensive Counseling For Overweight/Obesity and Cardiovascular Risk Factors

Evidence summary from USPSTF

USPSTF rationale

The USPSTF found adequate evidence that intensive behavioral counseling interventions have moderate benefits for CVD risk in overweight or obese adults who are at increased risk for CVD, including decreases in blood pressure, lipid and fasting glucose levels, and body mass index (BMI) and increases in levels of physical activity. The reduction in glucose levels was large enough to decrease the incidence of a diabetes diagnosis. The USPSTF found inadequate direct evidence that intensive behavioral counseling interventions lead to decreases in mortality or CVD rates. The USPSTF concludes with moderate certainty that intensive behavioral counseling interventions to promote a healthful diet and physical activity have a moderate net benefit in overweight or obese adults who are at increased risk for CVD.

Clinical Considerations

Patient Population Under Consideration

This recommendation applies to adults aged 18 years or older in primary care settings who are overweight or obese and have known CVD risk factors (hypertension, dyslipidemia, impaired fasting glucose, or the metabolic syndrome). In the studies reviewed by the USPSTF, the vast majority of participants had a BMI greater than 25 kg/m².

Behavioral Counseling Interventions

Most studies evaluated interventions that combined counseling on a healthful diet and physical activity and were intensive, with multiple contacts (which may have included individual or group counseling sessions) over extended periods. Interventions involved an average of 5 to 16 contacts over 9 to 12 months depending on their intensity (6). Most of the sessions were in-person, and many included additional telephone contacts. Interventions generally focused on behavior change, and all included didactic education plus additional support. Most included audit and feedback, problem-solving skills, and individualized care plans. Some trials also focused on medication adherence. Interventions were delivered by specially trained professionals, including dietitians or nutritionists, physiotherapists or exercise professionals, health educators, and psychologists.

Many types of intensive counseling interventions were effective. However, it was not clear how the magnitude of the effect was related to the format of the intervention (for example, face-to-face, individual, group, or telephone), the person providing the counseling, the duration of the intervention, or the number of sessions because different combinations of components were effective (see the [Implementation section](#) for more information on effective interventions). Because of the intensity and expertise required, most interventions were referred from primary care and delivered outside that setting.

Intensive Counseling For Overweight/Obesity and Cardiovascular Risk Factors

Current Prioritized List status

Line: 325

Condition: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) (See Guideline Notes 1,5,64,65)
 Treatment: INTENSIVE NUTRITIONAL/PHYSICAL ACTIVITY COUNSELING AND BEHAVIORAL INTERVENTIONS
 ICD-10: E66.01-E66.2,E66.8-E66.9
 CPT: 96150-96154,97802-97804,98966-98969,99051,99060,99070,99078,99201-99239,99281-99285,99291-99404,99408-99412,99429-99444,99468-99477,99480,99487-99496,99605-99607
 HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,G0447,S0270-S0274

Line: 594

Condition: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) (See Guideline Notes 8,64,65)
 Treatment: NON-INTENSIVE NUTRITIONAL/PHYSICAL ACTIVITY COUNSELING AND BEHAVIORAL INTERVENTIONS; BARIATRIC SURGERY FOR OBESITY WITH A SIGNIFICANT COMORBIDITY OTHER THAN TYPE II DIABETES & BMI >=35 OR BMI >=40 WITHOUT A SIGNIFICANT COMORBIDITY
 ICD-10: E66.01-E66.2,E66.8-E66.9,Z71.3
 CPT: 43644,43645,43770-43775,43846-43848,98966-98969,99051,99060,99070,99078,99201-99239,99281-99285,99291-99404,99408-99412,99429-99444,99468-99477,99480,99487-99496,99605-99607
 HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,G0447,S0270-S0274

GUIDELINE NOTE 5, OBESITY

Line 325

Medical treatment of obesity is limited to accepted intensive counseling on nutrition and exercise, provided by health care professionals. Intensive counseling is defined as face to face contact more than monthly. Visits are not to exceed more than once per week. Intensive counseling visits (once every 1-2 weeks) are covered for 6 months. Intensive counseling visits may continue for longer than 6 months as long as there is evidence of continued weight loss. Maintenance visits are covered no more than monthly after this intensive counseling period. Pharmacological treatments are not intended to be included as services on this line.

Code	Code Description	Line Description
278.02	Overweight	DMAP Excluded File

Code	Code Description	Line Description
E66.3	Overweight	668 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

Intensive Counseling For Overweight/Obesity and Cardiovascular Risk Factors

HERC Staff Recommendations:

- 1) **Place 278.02 and E66.3 on Lines 325 and 594**
- 2) **Advise DMAP to remove 278.02 from the Excluded File. Remove E66.3 from Line 668**
- 3) **Rename Line 325**
Condition: OBESITY (ADULT BMI \geq 30, CHILDHOOD BMI \geq 95 PERCENTILE) [and OVERWEIGHT IN ADULTS \(BMI >25\) WITH CARDIOVASCULAR RISK FACTORS](#) (See Guideline Notes 1,5,64,65)
Treatment: INTENSIVE NUTRITIONAL/PHYSICAL ACTIVITY COUNSELING AND BEHAVIORAL INTERVENTIONS
- 4) **Rename Line 594**
Condition: OBESITY (ADULT BMI \geq 30, CHILDHOOD BMI \geq 95 PERCENTILE) [and OVERWEIGHT IN ADULTS \(BMI >25\)](#) (See Guideline Notes 8,64,65)
Treatment: NON-INTENSIVE NUTRITIONAL/PHYSICAL ACTIVITY COUNSELING AND BEHAVIORAL INTERVENTIONS; BARIATRIC SURGERY FOR OBESITY WITH A SIGNIFICANT COMORBIDITY OTHER THAN TYPE II DIABETES & BMI \geq 35 OR BMI \geq 40 WITHOUT A SIGNIFICANT COMORBIDITY
- 5) **Modify Guideline Note 5 as follows:**

GUIDELINE NOTE 5, OBESITY [AND OVERWEIGHT](#)

Line 325

Medical treatment of [overweight \(with known cardiovascular risk factors\) and obesity](#) is limited to accepted intensive counseling on nutrition and ~~exercise~~ [physical activity](#), provided by health care professionals. Intensive counseling is defined as face to face contact more than monthly. Visits are not to exceed more than once per week. Intensive counseling visits (once every 1-2 weeks) are covered for 6 months. Intensive counseling visits may continue for longer than 6 months as long as there is evidence of continued weight loss or [improvement in cardiovascular risk factors based on the intervention](#). Maintenance visits are covered no more than monthly after this intensive counseling period.

[Known cardiovascular risk factors in overweight persons for which this therapy is effective include: hypertension, dyslipidemia, impaired fasting glucose, or the metabolic syndrome.](#)

Pharmacological treatments are not intended to be included as services on this line.

Intensive Counseling For Overweight/Obesity and Cardiovascular Risk Factors

- 6) Remove pharmacist drug management codes from Line 325

Code	Description
99605	Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, new patient
99606	Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, established patient
99607	Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; each additional 15 minutes (List separately in addition to code for primary service)

- 7) Remove 99356 and 99357 from Line 325

Code	Description
99356	Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour (List separately in addition to code for inpatient Evaluation and Management service)
99357	Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; each additional 30 minutes (List separately in addition to code for prolonged service)

VbBS Issue Summary

PET Scan and Fever of Unknown Origin

Question: should PET scans be a covered service for investigation of fever of unknown origin (FUO)?

Question source: CareOregon

Issue: The current PET scan guideline was last reviewed in 2011. It does not include fever of unknown origin (FUO) as an indication. CareOregon is requesting that PET scan be reviewed for FUO. The particular concern is the clinical scenario where there is a low pretest probability of infection, but still a need to rule out occult infection focus.

Fever of unknown origin (FUO) is defined as a persistent body temperature of greater than or equal to 101 F (38.3 C) for 3 weeks or longer without discovering the cause despite extensive investigation for at least one week. The four subgroups of the differential diagnosis of FUO are infections, malignancies, autoimmune conditions, and miscellaneous. A thorough history, physical examination, and standard laboratory testing remain the basis of the initial evaluation of the patient with FUO. Newer diagnostic modalities, including updated serology, viral cultures, computed tomography, and magnetic resonance imaging, have important roles in the assessment of these patients.

GUIDELINE NOTE 19, PET SCAN GUIDELINES

Lines 120,137,139,161,162,167,178,203,204,214,233,263,266,279,292,319

PET Scans are covered for diagnosis of the following cancers only:

- Solitary pulmonary nodules and non-small cell lung cancer
- Evaluation of cervical lymph node metastases when CT or MRI do not demonstrate an obvious primary tumor.

For diagnosis, PET is covered only when it will avoid an invasive diagnostic procedure, or will assist in determining the optimal anatomic location to perform an invasive diagnostic procedure.

PET scans are covered for the initial staging of the following cancers:

- Cervical cancer only when initial MRI or CT is negative for extra-pelvic metastasis
- Head and neck cancer when initial MRI or CT is equivocal
- Colon cancer
- Esophageal cancer
- Solitary pulmonary nodule
- Non-small cell lung cancer
- Lymphoma
- Melanoma

For staging, PET is covered when clinical management of the patient will differ depending on the stage of the cancer identified and either:

- A) the stage of the cancer remains in doubt after standard diagnostic work up, OR
- B) PET replaces one or more conventional imaging studies when they are insufficient for clinical management of the patient.

Restaging is covered only for cancers for which staging is covered and for thyroid cancer if recurrence is suspected and I131 scintigraphy is negative. For restaging, PET is covered after completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence or to determine the extent of a known recurrence. PET is not covered to monitor tumor response during the planned course of therapy. PET scans are NOT indicated for routine follow up of cancer treatment or routine surveillance in asymptomatic patients.

PET scans are also indicated for preoperative evaluation of the brain in patients who have intractable seizures and are candidates for focal surgery. PET scans are NOT indicated for cardiac evaluation.

PET Scan and Fever of Unknown Origin

Evidence

- 1) **Hao 2013**, meta-analysis of fluorodeoxyglucose-PET in the evaluation of fever of unknown origin
 - a. N=15 studies (595 patients)
 - b. The pooled sensitivity of 18F-FDG PET/CT in detecting the cause of FUO was 85% (95% confidence interval 81–88%) on a per-patient-based analysis.
 - c. Conclusion 18F-FDG PET/CT demonstrated high sensitivity for the diagnosis of patients with FUO. 18F-FDG PET/CT is an accurate technique in this setting, but the possibility of false-positive results should be kept in mind.
- 2) **Dong 2011**, meta-analysis of fluorodeoxyglucose-PET/PET-CT in the evaluation of fever of unknown origin
 - a. N=9 studies (388 patients), with overall good methodological quality.
 - b. PET was “helpful” in 15-89% of patients
 - c. Pooled sensitivity and specificity of FDG-PET for the detection of FUO were 0.826 (95% CI; 0.729–0.899) and 0.578 (95% CI; 0.488–0.665), respectively
 - d. Pooled sensitivity and specificity of FDG-PET/CT were 0.982 (95% CI; 0.936–0.998) and 0.859 (95% CI; 0.750–0.934), respectively
 - e. Conclusions: Although the FDG-PET studies that we examined were heterogeneous, FDG-PET appears to be a sensitive and promising diagnostic tool for the detection of the causes of FUO. FDG-PET/CT should be considered among the first diagnostic tools for patients with FUO in whom conventional diagnostics have been unsuccessful.
- 3) **Qiu 2012**, review of fluorodeoxyglucose-PET/PET-CT in the evaluation of fever of unknown origin
 - a. N=7 studies (286 patients)
 - i. Sensitivity 50-100%
 - ii. Specificity 46-90%
 - iii. PPV: 30-92%
 - iv. NPV: 50-100%
 - b. Conclusions: 18F-FDG PET or PET/CT are sensitive techniques for the evaluation of FUO. However, it is still not a routine procedure in the workup of FUO due to its high cost and limited availability. PET/CT scanning can detect at least one non-physiologic focal accumulation of 18F-FDG in most patients presenting with FUO. Compared with 67Ga-citrate scintigraphy and 111In labeled leukocyte scanning, the diagnosis of a wider spectrum of diseases can be obtained much earlier. Although the results of previous 18F-FDG FDG/PET studies are promising, prospective studies using PET/CT on larger populations of patients with FUO are limited. More data are needed to determine the diagnostic utility.

Other policies

- 1) **Aetna 2014**
 - a. PET use in FUO work up is experimental
- 2) **Texas Medicaid 2011**
 - a. PET is not indicated in the work-up of patients with FUO.

PET Scan and Fever of Unknown Origin

Summary: PET scans appear to be a promising new technology for evaluation of FUO. However, while PET may have high sensitivity, the specificity of this type of testing is quite low, allowing for many false positive results. High false positive rates would likely increase the number of follow up tests that would be required, thereby increasing costs.

HERC staff recommendation:

- 1) Do not add FUO as an indication for PET scanning in our current PET guideline
 - a. Experimental

VbBS Issue Summaries 1/8/2015

Catheter-Directed Thrombolysis for Pulmonary Embolism

Question: Should catheter-directed thrombolysis procedures be added to the pulmonary embolism line?

Question source: DMAP

Issue: No catheter-directed thrombolysis CPT codes (CPT 37211-37214) are on line 217 ACUTE PULMONARY HEART DISEASE AND PULMONARY EMBOLI. The only treatment codes on this line are pulmonary artery embolectomy codes (CPT 33910-33916), which are used for mechanical thrombolysis. Venous and arterial thrombolysis CPT codes are found on various lines. DMAP requested that HERC consider adding catheter-directed thrombolysis to the PE line.

Pulmonary embolism (PE) is a condition in which a blood clot lodges in the pulmonary arteries and causes ischemia of the lung tissue. PE is a life-threatening condition that is accompanied by significant morbidity and mortality. PE is treated with 1) systemic anticoagulation with heparin or similar medications, 2) mechanical thrombolysis, in which a clot is physically removed by an interventional radiologist using a catheter, 3) systemic thrombolysis with medications such as streptokinase or urokinase which breaks up the fibrin in clots, and 4) thrombolysis with medications delivered directly to the site of the clot via catheter (catheter-directed thrombolysis). The first treatments developed for this condition were systemic anticoagulation. Over time, the agents used for anticoagulation have been improved. Mechanical thrombolysis has been previously reviewed by the HSC and found to have evidence of effectiveness. Systemic thrombolysis is a controversial procedure, which carries an estimated 20% risk of major hemorrhage, including a 3%–5% risk of hemorrhagic stroke. Most guidelines limit its use to patients with such severe PE that they are hemodynamically unstable. In an attempt to reduce the risk of systemic thrombolysis, catheter-directed thrombolysis has been developed in recent years. This therapy attempts to deliver the thrombolysis medications directly to the area of the clot.

Current Prioritized List placement

CPT code	Code description	Current line(s)
37211	Transcatheter therapy, arterial infusion for thrombolysis other than coronary	257 ARTERIAL EMBOLISM/THROMBOSIS: ABDOMINAL AORTA, THORACIC AORTA 322 STROKE 352 NON-LIMB THREATENING PERIPHERAL VASCULAR DISEASE 452 ATHEROSCLEROSIS, AORTIC AND RENAL
37212	Transcatheter therapy, venous infusion for thrombolysis other than coronary	83 PHLEBITIS AND THROMBOPHLEBITIS, DEEP 285 BUDD-CHIARI SYNDROME, AND OTHER VENOUS EMBOLISM AND THROMBOSIS
37213	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary	83,257,285,322,352,452
37214	cessation of thrombolysis including removal of catheter and vessel closure by any method	83,257,285,322,352,452

Catheter-Directed Thrombolysis for Pulmonary Embolism

Evidence summary

- 1) **Dong 2009**, Cochrane review of thrombolytic therapy for PE
 - a. N=8 trials
 - i. No trial used catheter-directed thrombolytic therapy
- 2) **Kuo 2009**, meta-analysis of catheter-directed therapy for the treatment of massive pulmonary embolism
 - a. N=35 studies (594 patients)
 - i. 6 prospective studies, 29 retrospective
 1. No controlled studies
 2. Most studies were small (N=3-26 patients); one study included 164 patients
 - ii. Utilized “modern techniques” defined as the use of low-profile devices (<10 F), mechanical fragmentation and/or aspiration of emboli including rheolytic thrombectomy, and intraclot thrombolytic injection if a local drug was infused
 - iii. Clinical success was defined as stabilization of hemodynamics, resolution of hypoxia, and survival to hospital discharge.
 - b. The pooled clinical success rate from catheter directed therapy (CDT) was 86.5% (95% confidence interval [CI]: 82.1%, 90.2%).
 - c. Pooled risks of minor and major procedural complications were 7.9% (95% CI: 5.0%, 11.3%) and 2.4% (95% CI: 1.9%, 4.3%), respectively.
 - d. No comparisons were made to other treatment types
 - e. **CONCLUSIONS:** Modern CDT is a relatively safe and effective treatment for acute massive PE. At experienced centers, CDT should be considered as a first-line treatment for patients with massive PE.
- 3) **Skaf 2007**, systematic review of catheter treatments for PE
 - a. N=33 studies (210 patients undergoing catheter thrombectomy with local lytics or systemic and local lytics)
 - b. Pooled data, success defined as clinical improvement in hemodynamic parameters immediately after procedure
 - i. Greenfield successful in 10 of 10 patients (100%) when used in combination with local or local + systemic thrombolytic agents.
 - ii. Clinical success with standard angiographic catheters occurred in 139 of 151 patients (92%) when used with local infusions of thrombolytic agents or local + systemic infusions.
 - iii. Clinical success when used in combination with thrombolytic agents occurred in 6 of 6 patients (100%) with the Amplatz catheter, in 20 of 23 patients (87%) with the Angiojet catheter, and in 19 of 20 patients (95%) with the Hydrolyser catheter.
 - c. Complications
 - i. Minor bleeding at the insertion site among all patients, with and without thrombolytic agents, occurred in 29 of 348 patients (8%), and major bleeding at the insertion site occurred in 8 of 348 patients (2%). One patient experienced perforation of the right ventricle with the Greenfield catheter.

Catheter-Directed Thrombolysis for Pulmonary Embolism

Guidelines for treatment of PE

- 1) **NICE 2012**, guidance on venous thromboembolic disease
 - a. Recommends catheter-directed thrombolytic therapy for deep venous thrombosis (DVT) in certain clinical situations
 - b. Recommends low molecular weight heparin (LMWH) or fondaparinux or unfractionated heparin for treatment of PE depending on the clinical scenario
 - c. Recommends consideration of IV fibrinolytic therapy for patients with PE and haemodynamic instability
 - d. Does not specifically address use of catheter-directed thrombolytic therapy for PE
- 2) **SIGN 2013**, guidance on use of antithrombotics
 - a. Recommends catheter-directed thrombolytic therapy for deep venous thrombosis (DVT)
 - i. When compared with systemic intravenous thrombolysis, catheter-directed intra-arterial (CDIA) thrombolytic therapy is more effective for limb salvage (80% versus 45%) and is associated with fewer major haemorrhagic adverse events (5-8% versus 20%). When compared with surgical treatment, CDIA thrombolytic therapy is equally effective for limb salvage but is associated with higher rates of stroke (1.3% versus 0%) and major haemorrhagic adverse events (8.8% versus 3.8%).
 - b. Recommends heparin (low molecular weight or unfractionated), Rivaroxaban for treatment of pulmonary embolism
 - c. Does not specifically address use of catheter-directed thrombolytic therapy for PE
- 3) **Jaff 2011**, AHA guidelines for treatment of thromboembolism
 - a. Patients with objectively confirmed PE and no contraindications should receive prompt and appropriate anticoagulant therapy with subcutaneous lowmolecular-weight heparin (LMWH), intravenous or subcutaneous unfractionated heparin (UFH) with monitoring, unmonitored weight-based subcutaneous UFH, or subcutaneous fondaparinux. For patients with suspected or confirmed heparin-induced thrombocytopenia, a non-heparin-based anticoagulant, such as danaparoid (not available in the United States), lepirudin, argatroban, or bivalirudin, should be used
 - b. Systemic fibrinolysis is reasonable for patients with massive acute PE and acceptable risk of bleeding complications (*Class IIa; Level of Evidence B*).
 - c. Systemic fibrinolysis may be considered for patients with submassive acute PE judged to have clinical evidence of adverse prognosis (new hemodynamic instability, worsening respiratory insufficiency, severe RV dysfunction, or major myocardial necrosis) and low risk of bleeding complications (*Class IIb; Level of Evidence C*).
 - d. **Hybrid catheter based therapy that includes both catheter-based clot fragmentation and local thrombolysis is an emerging strategy.**
 - i. Only operators experienced with these techniques should perform catheter-based intervention. Interventionalists must be comfortable

Catheter-Directed Thrombolysis for Pulmonary Embolism

managing cardiogenic shock, bradyarrhythmias, anticoagulation, and cardiac tamponade. Invasive arterial access is recommended for patients with shock or hypotension to help guide vasopressor management. Patients with massive PE who have contraindications to fibrinolytic therapy who present to centers unable to offer catheter or surgical embolectomy should be considered for urgent transfer to a center with these services available so that they can be evaluated for this therapy

Summary:

Catheter-directed thrombolytic therapy is a promising emerging technology for treatment of massive PE or PE with hemodynamic instability. However, no major guideline at this time includes this therapy. This technology appears to be experimental. Current standard therapies (systemic anticoagulation, systemic fibrinolysis, and mechanical embolectomy) are available for treatment of PE on the Prioritized List.

HERC staff recommendation

- 1) Do not add catheter directed thrombolysis to the pulmonary embolism line
 - a. Experimental

Coverage of Tonsillar Hypertrophy

Question: What is the HERC intent for coverage for tonsillar hypertrophy

Question source: Lori Andrews, Referral Coordinator at Treasure Valley Pediatric Clinic in Ontario, Oregon

Issue: Tonsillar hypertrophy [ICD-9 code 474.11 (Hypertrophy of tonsils alone)] is on two lines, one covered and one uncovered (lines 395 STREPTOCOCCAL SORE THROAT AND SCARLET FEVER; VINCENT'S DISEASE; ULCER OF TONSIL; UNILATERAL HYPERTROPHY OF TONSIL, 574 CHRONIC DISEASE OF TONSILS AND ADENOIDS). Similar code 474.10 (Hypertrophy of tonsil with adenoids) only appears on the uncovered line only (line 574). The intention was to cover unilateral tonsillar hypertrophy, which is outlined in GN 36. However, this intent is not clear to health plans and other partners. The ICD-10 equivalent (J35.1) to 474.11 is also on both lines.

From Ms. Andrews:

I have a question about two very similar conditions on the prioritized list. ICD-9 code 474.11 enlarged tonsils alone or tonsillar hypertrophy is a covered code. 474.10 enlarged tonsils and adenoids is below the line. When we make referrals to ENT as PCP, our providers are not able to determine if the adenoids are enlarged as only the tonsils are visualized, and we refer for dx code 474.11 which does not require an EOCCO referral #. ENT typically diagnoses 474.10, and then have to ask for a retroactive referral. Why is there such a difference between these two very similar codes?

GUIDELINE NOTE 36, ADENOTONSILLECTOMY FOR INDICATIONS OTHER THAN OBSTRUCTIVE SLEEP APNEA

Lines 49,84,395,574

Tonsillectomy/adenotonsillectomy is an appropriate treatment for patients with:

- A) Five documented attacks of strep tonsillitis in a year or 3 documented attacks of strep tonsillitis in each of two consecutive years where an attack is considered a positive culture/screen and where an appropriate course of antibiotic therapy has been completed;
- B) Peritonsillar abscess requiring surgical drainage; or,
- C) Unilateral tonsillar hypertrophy in adults; unilateral tonsillar hypertrophy in children with other symptoms suggestive of malignancy.

See Guideline Note 118 for diagnosis and treatment of obstructive sleep apnea in children.

Coverage of Tonsillar Hypertrophy

HERC Staff Recommendations:

- 1) Adopt a new guideline note as shown below
 - a) Not appropriate to modify GN36 as the diagnosis code may be used for consultation and non-surgical treatment as well as for tonsillectomy

GUIDELINE NOTE XXX, UNILATERAL TONSILLAR HYPERTROPHY

Lines 395,574

ICD-9 474.11/ICD-10 J35.1 is included on line 395 only for 1) unilateral tonsillar hypertrophy in adults and 2) unilateral tonsillar hypertrophy in children with other symptoms suggestive of malignancy. Bilateral tonsillar hypertrophy and unilateral tonsillar hypertrophy in children without other symptoms suggestive of malignancy are included only on line 574.

VbBS Issue Summaries 1/8/2019

Hemangiomas

Question: What changes should be made to the new hemangioma line and guideline?

Question source: DMAP Hearings Division and HERC staff

Issue: A new line for hemangiomas was created as part of the ICD-10 review. This change was made in response to the fact that the hemangioma ICD-9 code most often used was Ancillary, and intended for manual review to see if treatment was appropriate. The HERC decided to define when treatment should be undertaken by putting this code on the Prioritized List with a guideline note. This new line and guideline note will first appear on the January, 2015 Prioritized List.

Recently, the DMAP Hearings Division received a request for coverage for treatment of a hemangioma diagnosis code (ICD-9 228.09) which is still present on the Ancillary List. HERC staff determined that this code was more appropriate for the Prioritized List and the equivalent ICD-10 code was on a line on this list. HERC staff also determined that further definition of when treatment of a hemangioma is NOT covered is required.

January 1, 2015 Prioritized List:

Line: 326

Condition: DERMATOLOGIC HEMANGIOMAS, COMPLICATED (See Guideline Note 13)

Treatment: MEDICAL THERAPY

ICD-9: 228.01

ICD-10: D18.01

CPT: 11300-11446,12031,12032,13100-13151,17106-17108,21011-21014,21552,21554,21931-21933,22901-22903,23071,23073,24071,24073,25071,25073,26111,26113,27043,27045,27337,27339,27632,27634,28039,28041,40500-40530,40810-40816,40820,41116,41826,42104-42107,42160,42808,69145,98966-98969,99051,99060,99070,99078,99201-99215,99281-99285,99341-99355,99358-99378,99381-99404,99408-99412,99429-99449,99487-99496,99605-99607

HCPCS: G0396,G0397,G0463

GUIDELINE NOTE 13, HEMANGIOMAS, COMPLICATED

Line 326

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

Hemangiomas

ICD-9 Code	Code Description	Current Placement
228.00	Hemangioma of unspecified site	636 BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES
228.01	Hemangioma of skin and subcutaneous tissue	326 DERMATOLOGIC HEMANGIOMAS, COMPLICATED 636
228.02	Hemangioma of intracranial structures	130 BENIGN NEOPLASM OF THE BRAIN AND SPINAL CORD
228.03	Hemangioma of retina	100 DIABETIC AND OTHER RETINOPATHY
228.04	Hemangioma of intra-abdominal structures	130 BENIGN NEOPLASM OF THE BRAIN AND SPINAL CORD
228.09	Hemangioma of other sites	636

HERC staff recommendations:

- 1) Remove 228.04 (Hemangioma of intra-abdominal structures) from line 130 and add to line 647 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
 - a. Inappropriate placement; used to code for hemangiomas of the liver and GI tract, peritoneum and retroperitoneum
 - b. ICD-10 equivalent code D18.03 is on line 647
- 2) Make the changes shown below to GN13

GUIDELINE NOTE 13, HEMANGIOMAS, COMPLICATED

Line 326, 636

Dermatologic Hemangiomas (ICD-9 228.01) are ~~covered~~ included on ~~this~~ line 326 when they are ulcerated, infected, recurrently hemorrhaging, or function-threatening (e.g. eyelid hemangioma). Otherwise, they are included on line 636.

Stereotactic Body Radiation Therapy (SBRT)

Question: Stereotactic Body Radiation Therapy (SBRT)

Question source: Amit Shah, CareOregon

Issue:

The HSC/HERC reviewed stereotactic body radiation therapy in December of 2012. Based on no evidence of effectiveness, they decided to not cover these therapies.

The HTAS started work on the topic of Stereotactic Body Radiation Therapy (SBRT) in late 2013 and reviewed the evidence from trusted sources. Ultimately they felt that the evidence source was too disparate from other guidelines such as Medicare and decided to drop the topic. There is still interest from stakeholders in the VbBS reviewing and making coverage determination.

Prioritized List Status

Cranial stereotactic radiosurgery is covered on 4-6 Lines, depending on the code

130	BENIGN NEOPLASM OF THE BRAIN AND SPINAL CORD	MEDICAL AND SURGICAL TREATMENT, WHICH INCLUDES CHEMOTHERAPY AND RADIATION THERAPY
199	SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	BURR HOLES, CRANIECTOMY/CRANIOTOMY
204	Cancer of Bones (<i>for spinal lesions</i>)	MEDICAL AND SURGICAL TREATMENT, WHICH INCLUDES CHEMOTHERAPY AND RADIATION THERAPY
299	CANCER OF BRAIN AND NERVOUS SYSTEM	LINEAR ACCELERATOR, MEDICAL AND SURGICAL TREATMENT, WHICH INCLUDES CHEMOTHERAPY AND RADIATION THERAPY
322	STROKE	MEDICAL THERAPY
446	TRIGEMINAL AND OTHER NERVE DISORDERS	MEDICAL AND SURGICAL TREATMENT, WHICH INCLUDES RADIATION THERAPY

SBRT is Excluded from coverage

CPT code	Description	Line placement
77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions	DMAP Excluded File
77435	Stereotactic body radiation therapy, tx management, per tx course, to 1 or more lesions, w/ image guidance, max 5 fractions	DMAP Excluded File

Stereotactic Body Radiation Therapy (SBRT)

Evidence summary from the Draft Coverage Guidance

Clinical Background

SBRT has been developed to improve external beam radiation therapy (EBRT) as a treatment modality for certain cancers. The goal of these newer techniques is two-fold: to improve the targeting of radiation to the tumor to minimize damage to normal tissue and increase the dose of radiation delivered to the tumor.

Evidence Review

Core Evidence Source:

Gerrity, M., Thielke, A., Leof, A.W., Ryan, K., Little, A., Kriz, H., & King, V. (2012). *Stereotactic radiosurgery and stereotactic body radiation therapy*. Olympia, WA: Washington State Health Care Authority Health Technology Assessment Program. Retrieved July 30, 2013, from http://www.hta.hca.wa.gov/stereotactic_radiation.html

Evidence was identified that evaluated SRS and SBRT for cancers in the following anatomic locations: abdomen (anus/rectum/colon, liver, pancreas, and adrenal glands), central nervous system (astrocytoma, brain metastases, ependymoma, glioblastoma, glioma, meningioma, neurocytoma, pituitary adenoma, schwannoma), head and neck (glomus jugulare, head and neck, ocular melanoma), lung, prostate, and spine. A total of 3,034 citations were screened, of which 253 studies met criteria for inclusion in this review. Except for six randomized controlled trials (RCTs) of SRS for brain metastases and one for glioblastoma, the evidence for SRS and SBRT is based on cohort and case series studies that have substantial methodological limitations. Almost all of these studies are non-comparative, and only two focus solely on children. Thus, the risk of bias is high and estimates of the relative benefits and harms of SRS/SBRT compared to conventional EBRT are highly uncertain for most of the tumors covered in this review. Because surgery is generally not considered an option in patients undergoing SRS/SBRT, comparative evidence is limited to EBRT.

The findings from comparative studies addressing efficacy (e.g., overall survival, quality of life) and harms are summarized below by tumor. For the remainder of the tumors, the overall strength of evidence was very low and often heterogeneous. Evidence was limited either to case series or no more than one poor quality cohort study. Therefore, no general conclusions can be drawn for these tumors. In addition, even though the overall strength of evidence is low or very low, harms for a few tumors will be described because of their frequency or severity. For the remaining tumors, in addition to fatigue and general malaise, harms were mostly regional toxicities based on the location of the malignancy (e.g., radiation pneumonitis for lung, headaches or radionecrosis with brain edema for brain, erectile dysfunction for prostate) and commonly included acute and

Stereotactic Body Radiation Therapy (SBRT)

late toxicities¹ Information on cost was identified for brain metastases, lung cancer, pancreatic cancer, meningioma and tumors of the spine, and is presented in those respective sections.

Brain Metastases

For SRS + whole brain radiation therapy (WBRT) compared to WBRT alone, the overall strength of evidence is moderate for survival and tumor control. Although local tumor control is probably better, SRS+WBRT compared to WBRT alone likely has no significant difference in overall survival. Subgroup analyses from one RCT (n=333), which provides low overall strength of evidence, suggest that median survival in patients with single metastases (6.5 vs. 4.9 months, SRS+WBRT vs. WBRT, respectively, p=0.039) and patients who are recursive partitioning analysis (RPA)² Class 1 (11.6 vs. 9.6 months, SRS+WBRT vs. WBRT, respectively, p=0.045) may be better with SRS+WBRT compared to WBRT alone. Acute and late toxicities are probably not significantly different for SRS+WBRT compared to WBRT alone, based on moderate strength of evidence. Approximately 2% to 5% of patients may experience severe (Grade 3 or 4) acute and late toxicities

For SRS+WBRT compared to SRS alone, the overall strength of evidence is moderate for the outcome of overall survival and tumor control. Although local and distant tumor control is probably better, SRS+WBRT compared to SRS alone probably has no significant difference in overall survival. An overall low strength of evidence exists to suggest there is no difference in functional independence, time to worsened performance status or quality of life for SRS+WBRT compared to SRS alone. The overall strength of evidence is low for harms and indicates that severe (Grade 3 or 4) acute and late toxicities may be similar for SRS+WBRT compared to SRS alone and occur in approximately 2% to 5% of patients.

For SRS alone compared to WBRT alone, the overall strength of evidence is very low based on six cohort studies, two with historical controls, and two additional small poor quality cohort studies. These studies suggest that overall survival may be better for patients receiving SRS alone compared to WBRT alone, but the poor quality of the

¹ Toxicities are graded as follows: *Grade 1*: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated. *Grade 2*: Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living (ADL) (e.g., preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.). *Grade 3*: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL (e.g., bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden). *Grade 4*: Life-threatening consequences; urgent intervention indicated. *Grade 5*: Death related to adverse events.

² RPA is classification system related to patient prognosis. *Class 1*: Karnofsky performance status (KPS) \geq 70, age < 65, controlled primary disease with no extracranial mets. *Class 2*: not meeting criteria for class 1 or 3. *Class 3*: KPS < 70. KPS = 70 indicates patients can take care of themselves, are out of bed more than 50% of the time, but are unable to do normal work and activities.

Stereotactic Body Radiation Therapy (SBRT)

studies and the heterogeneity across studies limit any conclusions. For harms, toxicity rates appear to be similar for SRS alone compared to WBRT alone. For cost, the strength of evidence is very low that SRS alone is more cost-effective than WBRT alone or SRS plus WBRT based on poor quality economic evaluations.

Glioblastoma

The overall strength of the evidence is low based on one fair quality RCT that conflicts with two poor quality cohort studies. The addition of SRS to EBRT and carmustine (chemotherapy) may not affect survival in patients with newly diagnosed glioblastoma based on the results from the RCT. However, adding SRS to other treatments for glioblastoma may increase the risk of symptomatic radionecrosis requiring a second surgery, based on low overall strength of evidence.

Pituitary Adenoma

Based on one fair quality (n=125) and one poor quality (n=72) cohort study, there is a low overall quality of evidence suggesting there may be no difference in overall survival or local tumor control in patients treated with SRS instead of EBRT, but there is uncertainty regarding this conclusion. New onset hypopituitarism was lower in the SRS groups in both studies, although this was not statistically significant. For hormone secreting tumors, the median time to remission was shorter in the SRS groups in both studies (statistically significant in one). Thirteen case series added additional information on harms. Radiation induced pituitary deficiencies ranged from 9% to 30%. Additional harms include transient cranial nerve palsy, visual deficits, temporal lobe necrosis, internal carotid artery stenosis, unilateral blindness, seizures and memory loss.

Glioma

Based on one poor quality cohort study and eight case series, the overall strength of evidence is very low for prolonged survival with salvage SRS in patients with recurrent gliomas and for harms in patients with primary and recurrent malignant gliomas. Although there is uncertainty, these studies raise concerns about radiation necrosis leading to a mass effect requiring surgery or potentially stimulating recurrence.

Meningioma

No studies addressed effectiveness. Based on 28 case series, the overall strength of evidence is very low for harms. Erythema, alopecia and post-radiation edema are common adverse effects, and those treated with gamma knife radiosurgery (GKRS) had an overall complication rate of 13% and permanent morbidity of 7%. One poor quality cost analysis compared microsurgery, linear accelerator and GKRS in the Netherlands and found microsurgery slightly more costly than the other comparators, but the poor quality of the study prevents conclusions.

Schwannoma

The overall strength of evidence for harms from SRS for schwannomas is very low, based on two poor quality cohort studies. However, about 1% of patients may develop

Stereotactic Body Radiation Therapy (SBRT)

hydrocephalus requiring a shunt (although one study suggests this is as high as 12%), 1% to 2% may develop a new malignancy, and up to 36% may develop new facial nerve dysfunction. There were no studies that compared SRS to EBRT, so relative harms are uncertain.

Ocular melanoma

The overall strength of evidence for harms from SRS for choroidal and uveal melanoma is very low. However, enucleation due to treatment side effects such as painful neovascular glaucoma may occur in 4% to 13% of patients.

Early Stage Non-Small Cell Lung Cancer

The overall strength of evidence is very low for efficacy outcomes. SBRT for non-operable Stage I non-small cell lung cancer (NSCLC) may result in 3-year overall survival rates of 50% to 60% and local control rates of 80% to 100%. The overall strength of evidence regarding harms is very low. There is uncertainty about the rate of acute and late toxicities, especially as they compared to EBRT. However, rates of greater than or equal to Grade 3 late toxicities may range 2% to 10%. In addition, the placement of fiducial markers, when used, to help target the radiation to the tumor may cause a pneumothorax requiring chest tube placement or hospitalization in approximately 9% to 28% of patients. There is very low strength of evidence based on three poor quality economic analyses pertaining to costs. The costs of EBRT may be \$50,000 to \$61,000 and the costs for SBRT may be \$41,000 to \$57,000, with an incremental cost effectiveness ratio of \$6,000 per quality adjusted life year, although there is significant uncertainty in these estimates.

Spine Tumors

The overall strength of evidence is very low based on 40 case series. Some of these studies included patients who were EBRT treatment failures. Local tumor control rates may range from 76% to 96%, and median survival may range from 11 to 22 months. Rates of pain control may range from 80% to 90%, with improvement in quality of life. However, comparative rates for EBRT are not reported. Adverse events may include fatigue, nausea, esophagitis, dysphagia, spinal fracture, paresis and myelopathy. One poor quality cost study suggests that costs/patient for SBRT may be \$8,424 and the costs of EBRT may be as low as \$4,999, but the overall strength of evidence is very low.

Subgroups, Cost and Cost-effectiveness

Few, if any, studies addressed patient subgroups or costs of SRS/SBRT. Except as noted above for brain metastases, there was insufficient evidence to address outcomes and harms for any subgroup for any of the tumors in this report. The cost studies done, as described above, were low quality with significant risk of bias in their estimates of effectiveness and costs. Study limitations make drawing any conclusions about cost or cost-effectiveness difficult.

Guidelines

Stereotactic Body Radiation Therapy (SBRT)

A total of 16 guidelines and 11 ACR Appropriateness Criteria^{®3} were identified that address the use of SRS and SBRT. Appropriateness Criteria[®] issued by ACR are considered to be a clinical decision making aid rather than a broadly applied guideline. All guidelines and Appropriateness Criteria[®] are summarized in the table below.

Summary of Guidelines and ACR Appropriateness Criteria[®] by Tumor Location

Malignancy	Guideline (Year) Quality	Usually Not Appropriate / Not Recommended	May be Appropriate	Usually Appropriate / Recommended
Abdomen				
Recurrent rectal cancer	Konski [ACR] 2011b Fair	In four case variants of recurrent rectal cancer presented, SBRT therapy was considered “usually not appropriate” in all cases.		
Hepatocellular carcinoma	NCCN 2012c Poor		All tumors irrespective of location may be amenable to SBRT or external-beam conformal radiation. SBRT is often used for 1-3 tumors with a cumulative diameter under 6 cm. SBRT could be considered for larger lesions, if there is at least 800 cc of uninvolved liver and liver radiation tolerance can be respected.	
Rectal cancer	NCCN 2012h Poor	In patients with a limited number of liver or lung metastases,		

³ In the ACR Appropriateness Criteria[®] scale, a score of 1 to 3 is considered “usually not appropriate”, 4 to 6 is considered “may be appropriate”, and 7 to 9 is considered “usually appropriate.”

Stereotactic Body Radiation Therapy (SBRT)

Malignancy	Guideline (Year) Quality	Usually Not Appropriate / Not Recommended	May be Appropriate	Usually Appropriate / Recommended
		radiotherapy can be considered in highly selected cases or in the setting of a clinical trial. Radiotherapy should not be used in the place of surgical resection.		
Colon cancer	NCCN 2012b Poor	In patients with a limited number of liver or lung metastases, radiotherapy can be considered in highly selected cases or in the setting of a clinical trial. Radiotherapy should not be used in the place of surgical resection.		
Pancreatic adenocarcinoma	NCCN 2012g Poor	No standard dose or dose per fraction has been established for SBRT; therefore, it should preferably be utilized as part of a clinical trial.		
Brain and CNS				
Melanoma	ACN 2008 Good		To improve survival, patients with limited or no extracranial disease and with favorable prognosis brain metastases can be considered for surgical	

Stereotactic Body Radiation Therapy (SBRT)

Malignancy	Guideline (Year) Quality	Usually Not Appropriate / Not Recommended	May be Appropriate	Usually Appropriate / Recommended
			resection and if unresectable, for stereotactic radiosurgery	
Brain metastases	Patel [ACR] 2011 Fair		Radiosurgery for recurrent brain metastases is a viable option if size and number permit.	
Brain metastases	Videtic [ACR] 2009 Fair	Given the finding that SRS does not increase survival of patients with two or more brain metastases, clinicians need to practice careful selection of patients for this intervention.		
Brain metastases	Suh [ACR] 2010 Fair		Since much controversy exists regarding optimal treatment for a patient with a single brain metastasis, patient participation in clinical trials is important to evaluate best treatment. For those patients who do not participate in clinical trials, the roles of surgery and SRS in improving outcomes for patients with a single lesion are evident.	
Brain metastases	American Thyroid		EBRT (including stereotactic	

Stereotactic Body Radiation Therapy (SBRT)

Malignancy	Guideline (Year) Quality	Usually Not Appropriate / Not Recommended	May be Appropriate	Usually Appropriate / Recommended
from thyroid cancer	Association 2009 Poor		radiosurgery) may be indicated for brain metastases not amenable to surgery	
Brain metastases	Ammirati 2010 Poor		Re-irradiation (either WBRT and/or SRS), surgical excision or, to a lesser extent, chemotherapy, can be recommended depending on a patient's specific condition and based on the judgment of the patient's treating physician.	
Brain metastases	Tsao [ASTRO] 2012 Fair		If patient has good prognosis and brain metastasis \leq 3-4 cm. For multiple brain metastases, patients with good prognosis and all metastases \leq 3-4cm.	
Brain metastases	IRSA 2008 Poor			The available data indicate that SRS and open surgical resection (where feasible) are both excellent treatment options for patients with solitary brain metastases.

Stereotactic Body Radiation Therapy (SBRT)

Malignancy	Guideline (Year) Quality	Usually Not Appropriate / Not Recommended	May be Appropriate	Usually Appropriate / Recommended
				Stereotactic radiosurgery is an effective treatment for patients with multiple brain metastases
Low grade glioma	NCCN 2012a Poor	SRS has not been established to have a role in the management of low grade gliomas. Phase I trials using SRS do not support its role as initial treatment.		
Meningioma	NCCN 2012a Poor		WHO grade 1 meningiomas may also be treated with stereotactic radiosurgery doses of 12-14 Gy in a single fraction when appropriate.	
Brain metastases	NCCN 2012a Poor			Recommended maximum marginal doses of 24, 18, or 15 Gy according to tumor volume is recommended.
Metastatic Spine	NCCN 2012a Poor		Doses to vertebral body metastases will depend on patient's performance status and primary histology. In selected cases, or	

Stereotactic Body Radiation Therapy (SBRT)

Malignancy	Guideline (Year) Quality	Usually Not Appropriate / Not Recommended	May be Appropriate	Usually Appropriate / Recommended
			recurrences after previous radiation, stereotactic radiotherapy is appropriate.	
Brain metastases from thyroid cancer	NCCN 2012j Poor			For solitary CNS lesions, either neurosurgical resection or stereotactic radiosurgery is preferred.
Head and Neck				
Recurrent head and neck	McDonal d[ACR] 2010 Fair		SBRT therapy “may be appropriate” in one of five cases. SBRT was not considered in the treatment for the remaining four cases.	
Lung				
Stage I/II NSCLC	Scott [ACCP] 2007 Fair		Other local therapies such as stereotactic radiation or radiofrequency ablation may be appropriate for patients who are medically inoperable . The use of these techniques in patients who are surgical candidates should not occur outside of the context of a clinical research study.	
Stage I NSCLC	Gewanter [ACR]		Emerging institutional data suggest that	

Stereotactic Body Radiation Therapy (SBRT)

Malignancy	Guideline (Year) Quality	Usually Not Appropriate / Not Recommended	May be Appropriate	Usually Appropriate / Recommended
	2010 Fair		central early-stage lung lesions can be treated safely with lower doses per fraction	
Stage I NSLCL	Rosenzweig [ACR] 2008 Fair	Currently extracranial stereotactic body radiotherapy (SBRT) is being examined as an alternative to conventionally fractionated radiotherapy in patients with inoperable stage I disease		
Stage I	NCCN 2012f Poor		Recommended for patients who are medically inoperable and is also an appropriate option for many older patients	
Prostate				
	Morgan [ACR] 2011 Fair	The use of hypofractionation in general and a stereotactic approach looks very promising, but more robust studies with longer follow-up clearly are needed.		
Other Cancers/ Multiple Sites				
Bone metastases	Janjan [ACR] 2008 Fair	SBRT therapy was considered to be “usually not appropriate” in seven		

Stereotactic Body Radiation Therapy (SBRT)

Malignancy	Guideline (Year) Quality	Usually Not Appropriate / Not Recommended	May be Appropriate	Usually Appropriate / Recommended
		of 8 cases. SBRT was not considered in the treatment for the remaining case.		
Non-spine bone metastases	Lutz [ACR] 2011 Fair	SBRT therapy was considered to be “usually not appropriate” in four of five cases. SBRT was not considered in the treatment for the remaining case.		
Soft tissue sarcoma	NCCN 2012i Poor		Patients can also receive stereotactic radiosurgery or chemotherapy as an alternate method for control of metastatic lesions. Many different issues are factored into this decision (e.g., patient performance status, patient preferences, specific clinical problems from the metastases, treatment availability), and specific details are best left to clinical judgment.	

[\[Evidence Source\]](#)

MED Report Evidence Summary

In patients with brain metastases, there is a moderate level of evidence for SRS+WBRT compared to WBRT alone for survival and tumor control. Local tumor control is probably better for SRS+WBRT compared to WBRT alone, but likely has no significant difference in overall survival. One RCT (low strength of evidence) suggests longer median survival

Stereotactic Body Radiation Therapy (SBRT)

in patients with single metastases and patients who are RPA Class 1 (a prognostic measure based on age, performance status and tumor control). There is a moderate level of evidence for SRS+WBRT compared to SRS alone for the outcome of overall survival and tumor control. Although local and distant tumor control is probably better, SRS+WBRT compared to SRS alone probably has no significant difference in overall survival. There is a low level of evidence that there is no difference in overall survival or local tumor control in patients with pituitary adenoma treated with SRS instead of EBRT. Similarly, there is a low level of evidence that in patients with newly diagnosed glioblastoma, the addition of SRS to EBRT and chemotherapy does not affect survival. There is an insufficient level of evidence for all other tumors and comparisons.

California Technology Assessment Forum, 2011

1. Technology assessment of SBRT for non small cell lung cancer
2. Recommendations: It is recommended that stereotactic body radiation therapy for the treatment of early stage non small cell lung cancer in medically inoperable patients with peripheral lesions meets CTAF criteria 2-5 for safety, effectiveness and improvement in outcomes. It is recommended that stereotactic body radiation therapy for the treatment of early stage non small cell lung cancer in medically inoperable patients with central lesions and medically operable patients does not meet CTAF TA criteria 2-5, for safety, effectiveness, and improvement in outcomes.

Other payers

Medicare Coverage

Medicare has not issued a national coverage determination for SRS/SBRT. Coverage decisions are therefore issued by regional Medicare contractors through Local Coverage Determinations (LCDs). Two Medicare LCDs that cover Washington were reported in the source report: one addressing SBRT (L28366 [2011]), and another addressing SRS and stereotactic radiotherapy⁴ (SRT) (L30318 [2011]) (CMS 2011b, 2011c). The Medicare LCDs identify coverage of SBRT for the following indications.

SBRT: LCD 28366 (2011) states that SBRT is covered for primary and metastatic tumors of the lung, liver, kidney or pancreas when the following criteria are met:

- Patient's medical condition justified aggressive treatment;
- Other forms of radiotherapy or focal therapy (including but not limited to EBRT and IMRT) cannot be as safely or effectively utilized;
- The tumor can be completely targeted with acceptable risk to surrounding critical structures;
- For germ cell or lymphoma, effective chemotherapy regimens have been exhausted or are not otherwise feasible; and
- When other forms of focal therapy cannot be as safely or effectively used.

⁴ In stereotactic radiotherapy, radiation is delivered in multiple fractions (2-5) at a somewhat lower dose than SRS, to a larger area

Stereotactic Body Radiation Therapy (SBRT)

Coverage is possible for other lesions with documented necessity. Coverage for SBRT is not covered for the following conditions and circumstances:

- Treatment is unlikely to result in clinical cancer control and/or functional improvement;
- When there is wide-spread cerebral or extra-cranial metastases; or
- Patient has poor performance status.

For prostate cancer, SBRT is covered as monotherapy for low and intermediate risk prostate cancer when:

- Patient's medical condition justified aggressive treatment;
- Other forms of radiotherapy or focal therapy (including but not limited to EBRT and IMRT) cannot be as safely or effectively utilized; and
- The tumor can be completely targeted with acceptable risk to surrounding critical structures;

Lesions of other sites (bone, breast, uterus, ovary, and other internal organs) are generally not covered, but may be in cases of recurrence after conventional radiation modalities.

Aetna

Coverage for SBRT is limited to localized malignant conditions where highly precise application is required. This includes lung or liver metastases not amenable to surgery, medically inoperable early stage lung cancer, primary liver cancer not amenable to surgery, spinal and para-spinal tumors, though this is not an exhaustive list.

HERC Staff Assessment

Stereotactic brain radiation therapy is already covered. Stereotactic body radiation therapy is not currently covered. There is insufficient evidence to support its use. HTAS was potentially interested in adopting Medicare criteria before they stopped reviewing the topic. Medicare criteria may be difficult to implement according to a CCO Medical Director and we have not done an extensive comparison to other available coverage criteria. The California Technology Assessment Forum found sufficient evidence to cover SBRT for non-small cell lung cancer in medically inoperable patients.

HERC Staff Recommendations:

OPTION 1: Make no change to the Prioritized List

Continue to leave SBRT on the "Recommended for Noncoverage Table"

32701	Thoracic target(s) delineation for stereotactic body radiation therapy (SRS/SBRT), (photon or particle beam), entire course of treatment
77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions
77435	Stereotactic body radiation therapy, tx

Stereotactic Body Radiation Therapy (SBRT)

	management, per tx course, to 1 or more lesions, w/ image guidance, max 5 fractions
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OPTION 2:

A. Add SBRT codes 32701, 77373, 77435 to either the lung cancer line alone OR several selected cancer lines.

a. Add to lung cancer line with a guideline:

GUIDELINE NOTE XXX Stereotactic body radiation therapy
Stereotactic body radiation therapy is included on Line 266 only for early stage non-small cell lung cancer in medically inoperable patients with peripheral lesions.

OR

b. Selected cancer lines without a guideline

Line	Condition
204	CANCER OF BONES
218	CANCER OF KIDNEY AND OTHER URINARY ORGANS
266	CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS
320	CANCER OF LIVER
321	CANCER OF PANCREAS
333	CANCER OF PROSTATE GLAND

Cochlear Implant Guidelines

Question: Should the cochlear implant guideline be modified for children over age 5?

Question source: Dr. Frank Warren, ENT with Portland Clinic

Issue: Dr. Warren has requested that the HERC review our current guideline criteria for placement of cochlear implants in children older than age 5. A cochlear implant is an implanted electronic hearing device, designed to produce useful hearing sensations to a person with severe to profound nerve deafness by electrically stimulating nerves inside the inner ear.

Excerpts from letter from Dr. Warren (see packet for full letter):

The current OHP criteria for children from birth to age five are in agreement with the current clinical practice across the nation. However, there is a statement in the criteria regarding children that are over age 5, which are very strict and fall outside the current accepted criteria. Several times a year we run into a situation where the medical reviewers for OHP deny cochlear implantation based on these guidelines that eventually gets overturned on appeal, but delays implantation for children during a very critical time in their auditory development. We believe that this ought to be reviewed and revised in order to better care for the children that fall victim to this statement every year.

We propose that the criteria be changed to reflect more current criteria (consistent with the current FDA criteria) and read "children over 12 months must have bilateral sensorineural severe to profound hearing loss (>70dB average of 500, 1000, 2000 Hz), have limited benefit from hearing aids with a speech discrimination score of <30% on age appropriate testing".

Cochlear implants were first added to the Prioritized List in 1996. In 2004, a guideline which was adopted which was based on the OHSU guideline at the time and was very similar to the CMS guideline then in place. There has been no review of the cochlear implant guideline in the past 10 years.

Current FDA approval for cochlear implantation limits use to persons age 2 years and older with severe-to-profound deafness (i.e., pure tone average thresholds of 70 dB HL or greater), and to children 12 to 23 months of age with profound deafness (i.e., pure tone average thresholds of 90 dB HL or greater). Whenever possible, outcomes from word and sentence recognition testing are also used to determine candidacy. Current FDA approval permit implantation in adults with open-set sentence recognition scores of approximately 50% to 60% words correct.

Current List status:

Cochlear implant CPT codes are located on lines 283 SENSORINEURAL HEARING LOSS - AGE 5 OR UNDER and line 423 SENSORINEURAL HEARING LOSS - OVER AGE OF FIVE. Cochlear implants for children age 5 and under are governed by GN31; for children over age 5 and for adults by GN 49.

GUIDELINE NOTE 31, COCHLEAR IMPLANTATION, AGE 5 AND UNDER

Line 283

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

Cochlear Implant Guidelines

- A) Profound sensorineural hearing loss in both ears (defined as 91dB hearing loss or greater at 500, 1000 and 2000 Hz)
- B) Child has reached the age of 1
- C) Receive little or no useful benefit from hearing aids
- D) No medical contraindications
- E) High motivation and appropriate expectations (both child, when appropriate, and family)

Bilateral cochlear implants are covered. Simultaneous implantation appears to be more cost-effective than sequential implantation.

GUIDELINE NOTE 49, COCHLEAR IMPLANTS, OVER AGE 5

Line 423

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

- 1) Profound sensorineural hearing loss in both ears (defined as 91dB hearing loss or greater at 500, 1000 and 2000 Hz)
- 2) Receive little or no useful benefit from hearing aids
- 3) No medical contraindications
- 4) High motivation and appropriate expectations (both child, when appropriate, and family)

Postlinguistic adults will be considered candidates for cochlear implants if the following criteria are met:

- 1) Severe to profound sensorineural hearing loss in both ears (defined as 71dB (decibels) hearing loss or greater at 500 Hz (hertz), 1000 Hz and 2000 Hz)
- 2) Hearing loss acquired after learning oral speech and language development (postlinguistic hearing loss)
- 3) Receive limited benefit from appropriately fit hearing aids; i.e., scores of 40% or less on sentence recognition test in the best-aided listening condition
- 4) No medical contraindications

Prelinguistic adults will be considered candidates for cochlear implants if the following criteria are met:

- 1) Profound sensorineural hearing loss in both ears (defined as 91dB (decibels) hearing loss or greater at 500 Hz (hertz), 1000 Hz and 2000 Hz)
- 2) Hearing loss acquired before learning oral speech and language development (prelinguistic hearing loss)
- 3) Receive no benefit from hearing aids
- 4) No medical contraindications
- 5) A desire to be a part of the hearing world

Bilateral cochlear implants are covered. Simultaneous implantation appears to be more cost-effective than sequential implantation.

Cochlear Implant Guidelines

Evidence

- 1) **NICE 2009**; systematic review
 - a) 33 studies, of which 13 involved adults and 20 involved children. Meta-analysis of the data was not possible because of heterogeneity between the studies
 - b) Children: unilateral cochlear implantation
 - i) Eight studies compared a unilateral cochlear implant with non- technological support (that is, without acoustic hearing aids, but permitting lip reading or sign language), and six studies compared unilateral cochlear implants with acoustic hearing aids. In ten of the studies children acted as their own controls and in four of the studies there was a separate non-randomised control group. The studies reported benefits from cochlear implants in auditory, speech perception and speech production outcomes. In the four studies that reported statistical significance, the benefits were statistically significant.
 - c) Children: bilateral cochlear implantation
 - i) Three studies compared bilateral cochlear implants with a unilateral cochlear implant, and three studies compared bilateral cochlear implants with a unilateral cochlear implant and a contralateral hearing aid. In four studies the children acted as their own controls, whereas the other two studies included a non-randomised control group. Benefits were reported for auditory and speech perception outcomes with bilateral cochlear implantation. In the five studies that reported levels of statistical significance, three reported statistically significant improvements in the ability to identify the direction from which a sound is coming with bilateral cochlear implants. In addition, two studies reported statistically significant improvements in speech perception in noisy conditions with bilateral cochlear implants. However, differences for speech perception outcomes in quiet conditions were statistically significant for only two out of seven outcome measures.
 - d) Children: quality of life and education outcomes
 - i) None of the studies in the Assessment Group's systematic review reported either quality of life or educational outcomes. Further searches identified four studies that measured quality of life and seven studies that measured educational outcomes. Studies assessing quality of life suggest that a cochlear implant can improve a child's quality of life and their quality of life as perceived by their parents.
 - ii) The studies of educational outcomes suggest that children who are profoundly deaf and have a cochlear implant may be more likely to be educated within a mainstream school than children with a similar level of deafness but without a cochlear implant. The studies also suggest that children who are profoundly deaf and have a cochlear implant may have a higher level of academic performance than those who are profoundly deaf but have no cochlear implant.
 - e) Adults: unilateral cochlear implantation
 - i) Four studies compared a unilateral cochlear implant with non-technological support (for example, without acoustic hearing aids, but permitting lip reading or sign language), and four studies compared a unilateral cochlear implant with an acoustic hearing aid. In seven studies participants acted as their own controls; the eighth study included a non-randomised control group. The studies measured speech perception outcomes. Four also measured quality of life and one measured an auditory outcome. The studies suggested that there were benefits from the use of cochlear implants in all the outcomes

Cochlear Implant Guidelines

measured. When statistical significance levels were reported, these benefits were statistically significant, except for the auditory outcome.

- f) Adults: bilateral cochlear implantation
 - i) Five studies compared unilateral cochlear implants with bilateral cochlear implants. The Assessment Group did not identify any studies of adults that compared bilateral cochlear implants with a unilateral cochlear implant and a contralateral hearing aid. Two studies were randomised controlled trials and in the other three, participants acted as their own controls. There was some overlap in the participants included in three of the studies. The studies measured auditory, speech perception and quality of life outcomes. Auditory outcomes were statistically significantly better for bilateral cochlear implants than for a unilateral implant. However, the results for speech perception and quality of life were more mixed, with some outcomes suggesting a negative impact of bilateral implantation owing to worsening of tinnitus after the second implantation
- g) Adults: quality of life
 - i) Three studies that measured quality of life were included in the systematic review. However, because of the importance of this outcome, further searches were completed to identify other studies that measured quality of life. Six further studies were identified, all of which reported benefits in quality of life associated with cochlear implants. Four studies reported levels of statistical significance, and three of these reported statistically significant benefits for quality of life after cochlear implantation.
- h) Cost-effectiveness
 - i) The ICER for unilateral implantation in children who are prelingually deaf and receive an implant at the age of 1 year was £13,400 per QALY gained. The corresponding ICERs for simultaneous and sequential bilateral implantation compared with unilateral implantation were £40,400 and £54,100 per QALY gained, respectively.
 - ii) The ICER for unilateral implantation in adults who are postlingually deaf was £14,200 per QALY gained. The corresponding ICERs for simultaneous and sequential bilateral implantation compared with unilateral implantation were £49,600 and £60,300 per QALY gained, respectively.

Other guidances/guidelines

- 1) **NICE 2009**
 - a) Unilateral cochlear implantation is recommended as an option for people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids
 - i) severe to profound deafness is defined as hearing only sounds that are louder than 90 dB HL at frequencies of 2 and 4 kHz without acoustic hearing aids
 - ii) Adequate benefit from acoustic hearing aids is defined as:
 - (a) for adults, a score of 50% or greater on Bamford–Kowal–Bench (BKB) sentence testing at a sound intensity of 70 dB SPL
 - (b) for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability.

Cochlear Implant Guidelines

- b) Simultaneous bilateral cochlear implantation is recommended as an option for the following groups of people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids:
 - i) Children
 - ii) adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness.
- c) Sequential bilateral cochlear implantation is not recommended as an option for people with severe to profound deafness

Other policies

1) **CMS 2005**

- a) Effective for services performed on or after April 4, 2005, cochlear implantation may be covered for treatment of bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition. Medicare coverage is provided only for those patients who meet all of the following selection guidelines.
 - i) Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
 - ii) Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
 - iii) Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;
 - iv) No contraindications to surgery; and
 - v) The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.
- d) Effective for services performed on or after April 4, 2005, cochlear implantation may be covered for individuals meeting the selection guidelines above and with hearing test scores of greater than 40%

2) **Aetna 2014**

- a) Aetna considers uniaural (monaural) or binaural (bilateral) cochlear implantation a medically necessary prosthetic for adults aged 18 years and older with bilateral, pre- or post-linguistic, sensorineural, moderate-to-profound hearing impairment who meet *both* of the following criteria:
 - i) Member has bilateral severe to profound sensorineural hearing loss determined by a pure tone average of 70 dB or greater at 500 Hz, 1000 Hz, and 2000 Hz; *and*
 - ii) Member has limited benefit from appropriately fitted binaural hearing aids. Limited benefit from amplification is defined by test scores of 40 % correct or less in best-aided listening condition on open-set sentence cognition (e.g., Central Institute for the Deaf (CID) sentences, Hearing in Noise Test sentences (HINT), and consonant-nucleus-consonant (CNC) test.
- b) Aetna considers uniaural (monaural) or binaural (bilateral) cochlear implantation a medically necessary prosthetic for infants and children with bilateral sensorineural hearing impairment who meet *all* of the following criteria:

Cochlear Implant Guidelines

- i) Child has profound, bilateral sensorineural hearing loss determined by a pure tone average of 90 dB or greater at 500, 1000 and 2000 Hz; *and*
 - ii) Child has limited benefit from appropriately fitted binaural hearing aids. For children 4 years of age or younger, limited benefit is defined as failure to reach developmentally appropriate auditory milestones measured using the Infant-Toddler Meaningful Auditory Integration Scale, the Meaningful Auditory Integration Scale, or the Early Speech Perception test, or less than 20 % correct on open-set word recognition test (Multisyllabic Lexical Neighborhood Test) in conjunction with appropriate amplification and participation in intensive aural habilitation over a 3 to 6 month period. For children older than 4 years of age, limited benefit is defined as less than 12 % correct on the Phonetically Balanced-Kindergarten Test, or less than 30 % correct on the Hearing in Noise Test for children, the open-set Multi-syllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending on the child's cognitive ability and linguistic skills; *and*
 - iii) A 3- to 6-month hearing aid trial has been undertaken by a child without previous experience with hearing aids. Note: When there is radiological evidence of cochlear ossification, this requirement may be waived at Aetna's discretion.
- c) The following additional medical necessity criteria must also be met for uniaural (monaural) or binaural (bilateral) cochlear implantation in adults and children:
- i) The member must be enrolled in an educational program that supports listening and speaking with aided hearing; *and*
 - ii) The member must have had an assessment by an audiologist and from an otolaryngologist experienced in this procedure indicating the likelihood of success with this device; *and*
 - iii) The member must have no medical contraindications to cochlear implantation (e.g., cochlear aplasia, active middle ear infection); *and*
 - iv) The member must have arrangements for appropriate follow-up care including the long-term speech therapy required to take full advantage of this device.

Cochlear Implant Guidelines

HERC staff recommendation

- 1) No change to current GN31
 - a. Current guideline consistent with NICE guidance and major medical plan coverage
 - b. May consider defining “little or no useful benefit” from hearing aids
- 2) Revise GN49 as shown below
 - a. Changes consistent with the NICE guidance from 2009
 - i. No differentiation by pre- or post-lingual adult
 - ii. Allow slightly higher scores on sentence recognition tests

GUIDELINE NOTE 31, COCHLEAR IMPLANTATION, AGE 5 AND UNDER

Line 283

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

- F) Profound sensorineural hearing loss in both ears (defined as 91dB hearing loss or greater at 500, 1000 and 2000 Hz)
- G) Child has reached the age of 1
- H) Receive little or no useful benefit from hearing aids
- I) No medical contraindications
- J) High motivation and appropriate expectations (both child, when appropriate, and family)

Bilateral cochlear implants are covered. Simultaneous implantation appears to be more cost-effective than sequential implantation.

GUIDELINE NOTE 49, COCHLEAR IMPLANTS, OVER AGE 5

Line 423

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

- 1) Profound sensorineural hearing loss in both ears (defined as 91dB hearing loss or greater at 500, 1000 and 2000 Hz)
- 2) Receive little or no useful benefit from hearing aids
- 3) No medical contraindications
- 4) High motivation and appropriate expectations (both child, when appropriate, and family)

Postlinguistic-a Adults will be considered candidates for cochlear implants if the following criteria are met:

- 1) Severe to profound sensorineural hearing loss in both ears (defined as ~~74dB~~ 91 dB (decibels) hearing loss or greater at 500 Hz (hertz), 1000 Hz and 2000 Hz)
- ~~2) Hearing loss acquired after learning oral speech and language development (postlinguistic hearing loss)~~
- 3) Receive limited benefit from appropriately fit hearing aids; i.e., scores of ~~40~~ 50% or less on sentence recognition test in the best-aided listening condition
- 4) No medical contraindications

~~Prelinguistic adults will be considered candidates for cochlear implants if the following criteria are met:~~

- ~~1) Profound sensorineural hearing loss in both ears (defined as 91dB (decibels) hearing loss or greater at 500 Hz (hertz), 1000 Hz and 2000 Hz)~~
- ~~2) Hearing loss acquired before learning oral speech and language development (prelinguistic hearing loss)~~
- ~~3) Receive no benefit from hearing aids~~

Cochlear Implant Guidelines

- ~~4) No medical contraindications~~
- ~~5) A desire to be a part of the hearing world~~

Bilateral cochlear implants are covered. Simultaneous implantation appears to be more cost-effective than sequential implantation.

VbBS Issue Summaries 1/8/2015

Retained tympanostomy tubes removal for ICD-10

Question: How should the retained tympanostomy tube guideline be modified for the ICD-10 Prioritized List?

Question source: Holly Jo Hodges, Trillium CCO; HERC Staff

Issue: In August 2014 HERC approved a new guideline note for retained tympanostomy tubes.

Guideline Note XXX Retained tympanostomy tubes

Lines 178, 308, 405, 418, 502

Removal of retained tympanostomy tubes under anesthesia, if indicated (cpt code 69424 *Ventilating tube removal requiring general anesthesia*) or as part of an office visit, are intended to be covered for Line 502 diagnoses with the Line 405 icd-9 code 385.83 *Retained foreign body of middle ear*.

This needs to be applied to the ICD-10 list, however, it does not translate well.

The equivalent Line on the ICD-10 List is 379 CHOLESTEATOMA; INFECTIONS OF THE PINNA but does not have a comparable code to retained foreign body of middle ear. The code it translates to is: *H74.8Xx Other specified disorders of middle ear and mastoid, unspecified ear*

ICD-10 Prioritized List Status

Cpt code 69424 *Ventilating tube removal requiring general anesthesia* is located on the following lines:

Line	Condition	Treatment
174	ACUTE MASTOIDITIS	MASTOIDECTOMY, MEDICAL THERAPY
290	COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	MEDICAL AND SURGICAL TREATMENT
317	HEARING LOSS - AGE 5 OR UNDER	MEDICAL THERAPY INCLUDING HEARING AIDS
379	CHOLESTEATOMA; INFECTIONS OF THE PINNA	MEDICAL AND SURGICAL TREATMENT
394	ACUTE OTITIS MEDIA	MEDICAL AND SURGICAL TREATMENT
481	CHRONIC OTITIS MEDIA	PE TUBES/ADENOIDECTOMY/TYMPAN OPLASTY, MEDICAL THERAPY

ICD-10 Code	Code Description	Line
H74.8x1	Other specified disorders of right middle ear and mastoid	481 CHRONIC OTITIS MEDIA
H74.8x2	Other specified disorders of left middle ear and mastoid	481 CHRONIC

Retained tympanostomy tubes removal for ICD-10

ICD-10 Code	Code Description	Line
		OTITIS MEDIA
H74.8x3	Other specified disorders of middle ear and mastoid, bilateral	481 CHRONIC OTITIS MEDIA
H74.8x9	Other specified disorders of middle ear and mastoid, unspecified ear	481 CHRONIC OTITIS MEDIA

GUIDELINE NOTE 29, TYMPANOSTOMY TUBES IN ACUTE OTITIS MEDIA

Line 394

Tympanostomy tubes (69436) are only included on this line as treatment for 1) recurrent acute otitis media (three or more episodes in six months or four or more episodes in one year) that fail appropriate medical management, 2) for patients who fail medical treatment secondary to multiple drug allergies or who fail two or more consecutive courses of antibiotics, or 3) 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, 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).

GUIDELINE NOTE 51, CHRONIC OTITIS MEDIA WITH EFFUSION

Line 481

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

There should be a 3 to 6 month watchful waiting period after diagnosis of otitis media with effusion, and if documented hearing loss is greater than or equal to 25dB in the better hearing ear, tympanostomy surgery may be indicated given short but not long-term improvement in hearing. Formal audiometry is indicated for 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 or developmental delay should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

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

Adenoidectomy is not indicated at the time of first pressure equalization tube insertion. It may be indicated in children over 3 years who are having their second set of tubes.

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

HERC Staff Assessment

H74.8xX could be added to Line 379 to be consistent. However, this would be adding a new diagnosis to a currently unrelated line. More simply, retained tympanostomy tubes can just be viewed as a complication, since these usually fall out on their own. Removal of tubes is currently on the Complications ALWAYS requiring treatment line (290) which generally has much higher acuity issues on it. So, placing retained tympanostomy tubes

Retained tympanostomy tubes removal for ICD-10

and removal of these tubes to the Complications USUALLY Requiring Treatment line is logical.

HERC Staff Recommendations:

- 1) Remove 69424 *Ventilating tube removal requiring general anesthesia* from all lines. Place only on Line 427 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
- 2) For ICD-9 code 385.83 RETAINED FOREIGN BODY OF MIDDLE EAR
 - a. Remove from line 379 CHOLESTEATOMA; INFECTIONS OF THE PINNA
 - b. Add to Line 427
- 3) For ICD-10 code H74.8xX *Other specified disorders of middle ear and mastoid*
Add to Line 427
- 4) Delete the guideline note on RETAINED TYMPANOSTOMY TUBES approved at the August meeting and instead modify guideline notes 29 and 51 as follows:

GUIDELINE NOTE 29, TYMPANOSTOMY TUBES IN ACUTE OTITIS MEDIA

Line 394

Tympanostomy tubes (69436) are only included on this line as treatment for 1) recurrent acute otitis media (three or more episodes in six months or four or more episodes in one year) that fail appropriate medical management, 2) for patients who fail medical treatment secondary to multiple drug allergies or who fail two or more consecutive courses of antibiotics, or 3) 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, 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 51, CHRONIC OTITIS MEDIA WITH EFFUSION

Line 481

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).

Retained tympanostomy tubes removal for ICD-10

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 or developmental delay should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

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

Adenoidectomy is not indicated at the time of first pressure equalization tube insertion. It may be indicated in children over 3 years who are having their second set of tubes.

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

[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.](#)

VbBS Issue Summaries 18/2015

Intraocular Steroid Implants

Issue: various coding and guideline note changes were made regarding intraocular steroid implants at the November, 2014 VbBS meeting. However, Allergan has contacted HERC staff and identified several errors and omissions in these changes that were not the VbBS/HERC intent.

CPT 67027 (Implantation of intravitreal drug delivery system) and 67028 (Intravitreal injection of a pharmacologic agent) are found on 4 and 6 lines, respectively, on the January 1, 2015 Prioritized List. As part of the biennial review, old line 106 DIABETIC AND OTHER RETINOPATHY was divided into 2 lines, line 100 DIABETIC AND OTHER RETINOPATHY and 363 CHORIORETINAL INFLAMMATION. CPT 67027 and 67028 were found on previous line 100 with a guideline restricting their use for steroid implants to only diagnoses now found on line 363 (uveitis and similar diagnoses). CPT 67027 and 67028 were not included on either line created from line 106. This was an error for line 363, as the guideline note for this line clearly specifies that these codes are on this line. This error was corrected as an administrative change by HERC staff. However, Allergan is questioning the removal of these codes from line 100, as they can be used for more than steroid implants (antibiotic injections, ganciclovir implants, anti-VEGF injections, etc.).

Allergan also requested pairing of these codes with steroid injections for treatment of diabetic macular edema. This was discussed at the November 2015 meeting, but tabled for further research by HERC staff. This research has not yet been completed.

HERC staff recommendations:

- 1) Add CPT 67027 (Implantation of intravitreal drug delivery system) and 67028 (Intravitreal injection of a pharmacologic agent) to line 100 DIABETIC AND OTHER RETINOPATHY
 - a. Addition to line 100 will be governed by the guideline note changes below.
Adding back to line will return to previous coverage
- 2) Modify GN 116 as shown below
 - a. Allows use for diabetic retinopathy diagnoses for non-steroid injection indications

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

Line [100.363](#)

Intraocular steroid implants (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.

[CPT codes 67027 and 67028 are included on line 100 only for non-intraocular steroid implant treatments.](#)

Wearable Cardiac Defibrillator Vests

Question: Should wearable cardiac defibrillator vests be included on the Prioritized List?

Question source: Tracy Muday, MD; Medical Director of Western Oregon Advanced Health CCO

Issue: Wearable cardiac defibrillator vests were reviewed at the August, 2014 VBBS meeting. At that time, the VBBS members requested additional information regarding how often these vests successfully detect and shock ventricular fibrillation (VF) and ventricular tachycardia (VT). HERC staff were directed to review the studies included in the meta-analyses seen at the August meeting. Reviewed at the last meeting were the 2014 MED report, and the 2009 CTAF report.

As reviewed at the August meeting, wearable cardiac defibrillator vests are used by patients at high risk for sudden cardiac death due to arrhythmia to attempt to prevent sudden cardiac death (SCD). The most frequent requests received by the CCOs for these vests are for patients who have had an MI and are in the recommended waiting period after MI before an implantable defibrillator is placed or with cardiomyopathy and EF <35% but still undergoing optimization of medical therapy. Waiting periods required in current Medicare coverage criteria include the following (CMS 2005): 40 days after acute MI, 3 months after CABG or PCI or NICM.

The only WCD device on the market, the LifeVest®, was approved by the US Food and Drug Administration (US FDA) in 2002.

Based on the meta-analyses reviewed, HERC staff concluded in their August, 2014 topic summary that there is no evidence that wearable cardiac defibrillators (WCDs) reduce mortality based on the current peer reviewed literature. There is no evidence that they improve outcomes when used during the waiting period for implantable cardiac defibrillator (ICD) placement or in other situations in which an ICD is not indicated.

Cost

The Medicare allowable is \$2704.94/month, and these are frequently used for about 3 months.

Wearable Cardiac Defibrillator Vests

Current List Status

Code	Code Description	Placement
K0606	Automatic external defibrillator, with integrated electrocardiogram analysis, garment type	Ancillary
K0607	Replacement battery for automated external defibrillator, garment type only, each	Ancillary
K0608	Replacement garment for use with automated external defibrillator, each	Ancillary
K0609	Replacement electrodes for use with automated external defibrillator, garment type only, each	Ancillary
93745	Initial set-up and programming by a physician or other qualified health care professional of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events	Ancillary

Lines including ICD placement (October 1, 2014/January 1, 2015 Prioritized Lists)

76/73 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION
 109/103 CARDIOMYOPATHY, HYPERTROPHIC MUSCLE
 (122)/115 CONGENITAL HEART BLOCK; OTHER OBSTRUCTIVE ANOMALIES OF HEART [note: not on line 122 for October 1, 2014]
 195/193 CHRONIC ISCHEMIC HEART DISEASE
 304/286 LIFE-THREATENING CARDIAC ARRHYTHMIAS
 376/350 CARDIAC ARRHYTHMIAS

Wearable Cardiac Defibrillator Vests

Evidence summary

Note: studies included are those in the 2014 MED report, and the 2009 CTAF report and any studies published after these report periods as identified by HERC staff

Studies cited in MED report not included in this review due to only including ICD patients

- Bigger 1997
- Steinbeck 2009
- Hohnloser 2004

Controlled environment, proof-of-concept studies

1) Auricchio 1998

- a. N=15 patients
- b. Patients undergoing routine electrophysiologic study or ICD testing had VF or VT (10 patients) electrically induced
- c. The device correctly identified and classified 9 of 10 induced arrhythmias. In 1 patient the induced episode of VT was not detected by the device because the sensing electrodes were erroneously disconnected at the time of the induction
- d. The WCD device immediately restored sinus rhythm from an induced VF with relatively low energy (delivered energy, 230 J).

2) Reek 2003

- a. N=12 patients, undergoing electrophysiological testing for ventricular tachyarrhythmias, had VF induced
- b. In all 22 episodes (100%), induced VF was promptly terminated by the first 70 J (n =12) or 100 J (n = 10) biphasic shocks.

"Real world experience"

1) TANAWUTTIWAT 2014, retrospective study

- a. N=97 patients
 - i. underwent ICD removal due to cardiac device infections
- b. The median daily WCD use was 20 hours/day and the median length of use was 21 days
- c. 3 patients received shocks
 - i. 1 patient had 3 episodes of VT, successfully terminated by the WCD.
 1. 2 episodes occurred while in a health care facility (dialysis)
 2. Approximately 45 days after the 3rd shock, the patient died of sepsis after a leg amputation
 - ii. 1 patient had 1 episode of VT, successfully terminated by the WCD.
 1. Episode occurred during a hospitalization, while the patient was pressing her alarm button
 2. The patient died suddenly at home while not wearing the WCD, presumably from ventricular arrhythmias.
 - iii. A third patient experienced two inappropriate treatments due to oversensitivity of the signal artifact.

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- d. 8 total deaths occurred during the study period. Three patients experienced sudden death outside the hospital while not wearing the device. Five patients died while hospitalized.
 - e. no deaths occurred while wearing the WCD.
- 2) **Van 2014**, retrospective cohort study of WCD effectiveness in dialysis patients
- a. N=75 hemodialysis patients
 - b. 66 VT/VF events (unable to determine number of individual patients)
 - c. WCD delivered a total of 136 shocks
 - i. No breakdown in inappropriate shocks (70 inappropriate shocks?)
 - d. The first shock conversion was 63 of 66 (95.5%).
- 3) **Mitrani 2013**, prospective cohort study
- a. N=134 patients
 - b. Patients wore the WD for a mean of 14.1 ± 8.1 hours per day for a mean of 72 ± 55 days
 - c. There were no shocks and no detected episodes of VT during vest follow-up. There were no deaths during the time patients were wearing the WD and 3 deaths of unknown cause after the WD was returned
- 4) **Zoshiri 2013**, retrospective cohort study (LifeVest registry)
- a. 4149 no WCD patients, 809 WCD patients
 - b. 18 appropriate defibrillations occurred in 11 WCD patients (1.3% of the WCD group) for VT/VF. Defibrillations were successful in 12 to 18 shocks. One patient required 8 shocks for 2 separate VT episodes.
 - c. 13 inappropriate shocks (42% of total therapies)
 - d. 5 WCD deaths reported
 - i. 3 WCD patients had asystolic events (2 fatal), 1 had a fatal bradyarrhythmia
 - ii. 1 WCD patient died of VT which was below the rate threshold for shock
- a. In the entire cohort, 1480 of 4958 subjects (30%) died (followup, 3.2 ± 2.3 years; median, 2.8 years). In the No WCD group, 1399 of 4149 subjects (34%) died; 81 of 809 (10%) died in the WCD group. In the PCI cohorts, 763 of 1951 (39%) No WCD and 31 of 288 (11%) WCD patients died. In the CABG cohorts, 636 of 2198 (29%) No WCD and 19 of 226 (8.4%) WCD patients died.
- a. HERC staff note: only 11 patients received shocks in this study, which would increase the death rate to approximately 11% if all WCD patients who received shocks would otherwise have died. Therefore, WCD use cannot explain the difference in survival rate
 - b. WCD use was associated with adjusted lower risks of long-term mortality in the total cohort (39%, $P < 0.0001$) and both post-coronary artery bypass graft surgery (38%, $P = 0.048$) and post-PCI (57%, $P < 0.0001$) cohorts (mean follow-up, 3.2 years). In propensity-matched analyses, WCD use remained associated with lower mortality (58% post-coronary artery bypass graft surgery, $P = 0.002$; 67% post-PCI, $P < 0.0001$). Mortality differences were not attributable solely to therapies for ventricular arrhythmia. Only 1.3% of the WCD group had a documented appropriate therapy.
 - c. No survival benefit found with WCD after 90 days
- 5) **Kao 2012**, prospective cohort study
- a. N=82 patients at 10 centers

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- b. The average daily device use was 19.5 ± 4.6 hr/day (median: 21.8; range: 3.7-23.7) over an average of 75.1 ± 57.7 days (median: 64; range: 7-277).
 - c. There were no SCA events or deaths during the study, and 90-day survival after WCD fitting was 100%.
 - d. There were no adverse events or inappropriate shocks by the WCD.
 - e. No therapeutic shocks reported
- 6) **Saltzberg 2012**, prospective cohort study
- a. N=266 women (107 patients with post-partum cardiomyopathy [PPCM] and 159 patients with nonischemic dilated cardiomyopathy [NICDM])
 - b. The average use duration of the WCD was 124 ± 123 days (median 86.5 days) for the PPCM patients, and 96 ± 83 days (median 76.0 days) for the NIDCM patients.
 - c. The average mean daily WCD wear time was 18.3 ± 5.3 hours for the PPCM patients (median 20.4 hours), and 17.0 ± 6.2 hours for the NIDCM patients (median = 19.3 hours)
 - d. WCD use was discontinued because of nonadherence or device discomfort among 15 (14%) of the PPCM patients and 13 (8%) of the NIDCM patients.
 - e. None of the PPCM patients experienced an arrhythmia that required defibrillation, and none of the patients experienced an inappropriate shock because of artifact.
 - f. None of the PPCM patients died during WCD use. Three (2.8%) died after WCD use for unknown reasons.
 - g. One NIDCM patient received 2 separate appropriate and successful shocks for VT/VF. None of the NIDCM patients experienced an inappropriate shock from artifact.
 - h. Eleven (7%) of the NIDCM patients died during WCD usage; 7 of these were reported as cardiac-related, whereas the causes among the remaining 4 are unknown. Ten patients were not wearing the WCD at the time of death, and details of use in the remaining patient are not available because of the system not being returned.
- 7) **Chung 2010**, retrospective cohort study (LifeVest registry)
- a. N=3,679 patients
 - b. Median daily use was 21.7 h (91% of time available).
 - c. Of 2,169 patients with recorded data, 307 (14.2%) stopped wearing the WCD prematurely because of comfort issues or adverse reactions,
 - d. During the time that the WCD was worn, 80 sustained VT/VF events occurred in 59 patients (1.7% of the total number of patients)
 - i. First-shock success was 79 of 80 (99%). The single failure to halt VT/VF on the first attempt occurred when a conscious patient with sustained VT allowed himself to be shocked after 10 min of using the WCD response buttons to delay the shock
 - ii. Of the 59 patients with 80 VT/VF events, all converted initially; 8 later died (4 of recurrent VT/VF presumably while not wearing the vest, 1 of spouse preventing the vest from shocking, 2 from ECG signal disruption from a fall, 1 from unipolar pacemaker inhibiting detection)
 - e. 3 additional patients died while wearing the vest (2 from pulseless electrical activity, 1 from respiratory arrest)
 - f. 17 deaths from asystole while wearing vest

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- g. During WCD use, 3,541 of 3,569 patients (99.2%) survived overall. Survival occurred in 72 of 80 (90%) VT/VF events and 78 of 106 (73.6%) for all events. Survival was comparable to that of ICD patients.
- h. Inappropriate shocks (not occurring on sustained VT or VF) occurred in 67 of 3,569 (1.9%) patients during 4,788 months of use (1.4% per month).
- 8) **Dillon 2010**, retrospective cohort study (LifeVest registry)
 - a. N=2105 patients
 - b. The median length of use was 36 (range of 3-365) days, and the median daily use was 21.3 (range of 0-23.9) hours per day.
 - c. 54 shocks delivered for VF/VT
 - i. No information on survival or later outcomes given
 - d. 34 inappropriate shocks delivered
 - e. One patient died after a unipolar pacemaker interference with the WCD prevented treatment
- 9) **Klein 2010**, retrospective cohort study
 - a. N=354 patients in Germany
 - b. The mean wearing time of the WCD was 106 days per patient. The mean daily wearing time per patient was 21.3 hours.
 - c. 27 patients (7.6%) experienced arrhythmic episodes when wearing the WCD
 - i. Treatment of VT/VF was necessary for 21 VT/VF episodes in 11 patients. In 20 of the 21 VT/VF events, the first discharge of the WCD was successful (95% success). Two discharges for the same VF episode were necessary in one of the 21 VT/VF events.
- 10) **Feldman 2004**, WEARIT and BIROAD studies of wearable defibrillators
 - a. N=289 patients in 2 studies
 - i. N=117, WEARIT study
 - 1. Patients with symptomatic heart failure and an ejection fraction of <0.30
 - ii. N=112, BIROAD study
 - 1. patients having complications associated with high risk for sudden death after a myocardial infarction or bypass surgery not receiving an ICD for up to 4 months
 - b. 6 (75%) of 8 defibrillation attempts were successful.
 - i. 2 successful defibrillations occurred in the WEARIT patients (both in the same patient, 6 days apart)
 - ii. 4 successful defibrillations were seen in BIROAD patients (two of the four were in the same patient, 9 days apart)
 - iii. Of the two unsuccessful defibrillations, both occurred in patients who had incorrectly placed the therapy electrodes (i.e., the defibrillating pads were reversed and not directed to the skin). One of the events was nonfatal as the patient received a successful external defibrillation. One event was fatal
 - a. 6 inappropriate shock episodes occurred during 901 months of patient use (0.67% unnecessary shocks per month of use).
 - b. Twelve deaths occurred during the study
 - a. 6 were not sudden death
 - b. 6 sudden deaths: 5 not wearing and 1 incorrectly wearing the device (see b iii above)
 - i. Note: no longer able to incorrectly wear device without triggering device alarm

Wearable Cardiac Defibrillator Vests

- a. Most patients tolerated the device although 68 patients (24%) quit due to comfort issues or adverse reactions.

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Wearable Cardiac Defibrillator Vests

Study	Patients	Indication(s)	Appropriate shocks (Events/# patients)	First shock success rate	Inappropriate shocks	Mortality No. (%) All causes	Reasons for stopping WCD
Feldman 2004	289	1) CHF with EF<30% 2) 4 month wait after MI or CABG for ICD	Successful: 2/1 (group 1) 4/3 (group 2) Unsuccessful: 2/2 (group not indicated)	75%	6	12 (4.2%)	1)16% heart transplant, 20% ICD placement 2)42% no longer needed, 23% ICD placement
Dillon 2010*	2,105	21% acute MI 10% old MI 28% cardiomyopathy 21% ICD removal 12% cardiac arrest/ VF/VT 3% other 5% missing	54/?	--	34	--	
Klein 2010	354	39% early post-MI 25% post-CABG 18% risk stratification (cardiomyopathy or conduction problem) 6% cardiac transplant wait list 10% ICD removal 2% delay/refusal of ICD	21/11 5% post MI 7% post-CABG 8% ICD explant 11% pre-transplant 13% risk stratification	95%	3	5%	43% ICD placement 42% medical management 5% died
Chung 2010*	3,679	23% ICD removal 16% VF/VT 12.5% post-MI 9% post-CABG 28% cardiomyopathy	80/59 ICD removal 49/33 VF/VT 9/6 Post-MI 12/10 Post-CABG 2/2	99%	--	28 (0.8%)	

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		4% EF<35% 7% misc or unknown	Cardiomyopathy 4/4 Misc 4/4				
Kao 2012	82	CHF listed for transplant or EF<40% or receiving inotropes	0	NA	0	--	41% no longer needed 34% ICD implant 16% unknown or refused to wear
Saltzberg 2012	266	107 Peripartum cardiomyopathy (PPCM) 159 cardiomyopathy (NIDCM)	2/1	100%	0	11 (4.1%)	PPCM: 26% EF improved, 20% ICD NIDCM: 40% ICD, 13% EF improved
Mitrani 2013	134	89 Cardiomyopathy 45 post-CABG	0	NA	0	3 (2.2%)	38% EF improved 33% ICD implant
Zoshiri 2013	809	Post-CABG or stenting	18/11	--	13	5 (0.6%)	32% CABG and 30% PCI had ICD implant
Tanawuttiwat 2014	97	ICD removal	5/3	100%	2	8 (8.2%)	
Van 2014	75	Sudden cardiac arrest	--	95.5%	--	22 (29.3%)	

* Lifevest registry study, possible patient overlap

Wearable Cardiac Defibrillator Vests

Expert input

Eric Stecker, cardiologist at OHSU

I do not feel evidence supports WCD use within 40 days after AMI. Two large NEJM-published randomized trials of ICDs in that setting were negative. Saved lives from arrhythmia but risk of non-arrhythmic death increases and counterbalances it

HERC Staff Assessment

Wearable cardiac defibrillator vests have a high success rate in detecting and successfully shocking sustained VF and VT in both controlled and “real world” settings. Patient compliance with wearing vest is high in all studies. The total number of patients receiving shocks is very low across all studies. Inappropriate shock rates are low.

No study has identified a survival advantage from WCDs compared to no WCD. Lack of demonstrated mortality benefit may be due in part to study design: 1) the very low rate of events (sustained VF/VT and appropriate shocks) seen across studies (0.7%-5.9%, with most studies about 2.5% of patients), 2) the severe underlying disease burden of the patients requiring WCD placement results in a high overall mortality rate, and 3) most studies were cohort studies rather than RCTs designed to look at mortality differentials. However, survival benefit may not exist; WCDs are typically used during intervals when ICDs have not been shown to have a survival benefit and therefore WCDs, which are generally a less effective technology than ICDs (cannot pace bradyarrhythmias, etc.), reasonably may not be expected to show benefit. Studies that followed individual patients receiving therapeutic shocks found that many eventually died despite the WCD. The studies that found that WCD patients had a lower death rate than non-WCD patients did not have shock rates which would explain the survival difference (i.e. survival was from some other factor).

Wearable Cardiac Defibrillator Vests

Other policies/guidelines

Medicare 2013

Automatic EXTERNAL DEFIBRILLATORS are covered for beneficiaries at high risk for sudden cardiac death (SCD) due to one of the conditions described under I or II. It is expected the ordering physician be experienced in the management of beneficiaries at risk for SCD.

- I. A wearable defibrillator (K0606) is covered for beneficiaries if they meet one of the criteria (1-4), described below:
 1. A documented episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia. These dysrhythmias may be either spontaneous or induced during an electrophysiologic (EP) study, but may not be due to a transient or reversible cause and not occur during the first 48 hours of an acute myocardial infarction; or
 2. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy; or
 3. Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 0.35; or
 4. A previously implanted defibrillator now requires explantation
- II. A nonwearable automatic defibrillator (E0617) is covered for beneficiaries in two circumstances. They meet either (1) both criteria A and B or (2) criteria C, described below:
 - A. The beneficiary has one of the following conditions (1-8):
 1. A documented episode of cardiac arrest due to ventricular fibrillation, not due to a transient or reversible cause
 2. A sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia, either spontaneous or induced during an electrophysiologic (EP) study, not associated with acute myocardial infarction, and not due to a transient or reversible cause
 3. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy
 4. Coronary artery disease with a documented prior myocardial infarction with a measured left ventricular ejection fraction less than or equal to 0.35, and inducible, sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) during an EP study. To meet this criterion;
 - a. The myocardial infarction must have occurred more than 4 weeks prior to the external defibrillator prescription; and,
 - b. The EP test must have been performed more than 4 weeks after the qualifying myocardial infarction.
 5. Documented prior myocardial infarction and a measured left ventricular ejection fraction less than or equal to 0.30.Beneficiaries must not have:
 - a. Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; or,

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- b. Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past 3 months; or,
 - c. Had an enzyme-positive MI within past month; or,
 - d. Clinical symptoms or findings that would make them a candidate for coronary revascularization; or,
 - e. Irreversible brain damage from preexisting cerebral disease; or,
 - f. Any disease, other than cardiac disease (e.g. cancer, uremia, liver failure), associated with a likelihood of survival less than one year.
- 6. Beneficiaries with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction (LVEF) $\leq 35\%$.
 - 7. Beneficiaries with nonischemic dilated cardiomyopathy (NIDCM) > 3 months, NYHA Class II and III heart failure, and measured LVEF $\leq 35\%$
 - 8. Beneficiaries who meet one of the previous criteria (1-7) and have NYHA Class IV heart failure
- B. Implantation surgery is contraindicated
 - C. A previously implanted defibrillator now requires explantation

Other policies

1) BCBS 2014

- a. Medically Necessary: The wearable cardioverter defibrillator (WCD) is considered medically necessary for individuals at high-risk of sudden cardiac arrest, who meet the following criteria:
 - i. Individuals must meet the medical necessity criteria for an implantable cardioverter defibrillator (ICD); AND
 - ii. Individuals must have ONE of the following documented medical contraindications to ICD implantation:
 - 1. Those awaiting a heart transplantation - on waiting list and meet medical necessity criteria for heart transplantation; or
 - 2. Those with a previously implanted ICD that requires explantation due to infection with waiting period before ICD reinsertion; or
 - 3. Those with an infectious process or other temporary condition that precludes initial implantation of an ICD.

2) Aetna 2014

- a. Aetna considers wearable cardioverter-defibrillators (WCDs) (automatic external cardioverter-defibrillators that are worn under the member's clothing) medically necessary durable medical equipment (DME) only for members who meet any of the following criteria:
 - i. A documented episode of VF or a sustained, lasting 30 seconds or longer, VT (these dysrhythmias may be either spontaneous or induced during an electrophysiologic (EP) study, but may not be due to a transient or reversible cause and not occur during the first 48 hours of an AMI); or
 - ii. A previously implanted defibrillator now requires explantation; or

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- iii. Either documented prior myocardial infarction or dilated cardiomyopathy and a measured LVEF less than or equal to 35 %; *or*
 - iv. Familial or inherited conditions with a high risk of life-threatening VT such as long QT syndrome or hypertrophic cardiomyopathy.
- b. Aetna considers WCDs experimental and investigational for other indications because its safety and effectiveness has not been established.

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Wearable Cardiac Defibrillator Vests

HERC Staff Recommendations (October 1, 2014 PL/January 1, 2015 PL):

- 1) Add CPT 93745 (Initial set-up and programming by a physician or other qualified health care professional of wearable cardioverter-defibrillator includes initial programming of system, establishing baseline electronic ECG, transmission of data to data repository, patient instruction in wearing system and patient reporting of problems or events) and HCPCS K0606-K0609 (DME items for wearable cardioverter-defibrillator) to lines with implantable cardiac defibrillators
 - a. 73 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION
 - b. 103 CARDIOMYOPATHY, HYPERTROPHIC MUSCLE
 - c. 115 CONGENITAL HEART BLOCK; OTHER OBSTRUCTIVE ANOMALIES OF HEART
 - d. 193 CHRONIC ISCHEMIC HEART DISEASE
 - e. 286 LIFE-THREATENING CARDIAC ARRHYTHMIAS
 - f. 350 CARDIAC ARRHYTHMIAS
- 2) Advise DMAP to remove CPT 93745 and HCPCS K0606-K0609 from the Ancillary List
- 3) Adopt a new guideline regarding wearable cardiac defibrillators
 - a. Option 1: Adopt wording based on Medicare criteria
 - b. Option 2: Adopt wording based on best available evidence of effectiveness (HERC staff preferred)

Option 1

GUIDELINE NOTE XXX WEARABLE CARDIAC DEFIBRILLATORS

Lines 73,103,115,193,286,350

Wearable cardiac defibrillators (CPT 93745, HCPCS E0617, K0606-K0609) are included on these lines for patients at high risk for sudden cardiac death due to

- 1) A documented episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia, not be due to a transient or reversible cause and not occurring during the first 48 hours of an acute myocardial infarction; or
- 2) Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy; or
- 3) Either documented prior myocardial infarction (MI) when the patient is more than 40 days from the MI event or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 0.35; or
- 4) A previously implanted defibrillator now requires explantation

Option 2

GUIDELINE NOTE XXX WEARABLE CARDIAC DEFIBRILLATORS

Lines 73,103,115,193,286,350

Wearable cardiac defibrillators (WCDs; CPT 93745, HCPCS E0617, K0606-K0609) are included on these lines for patients at high risk for sudden cardiac death who meet the medical necessity criteria for an implantable cardioverter defibrillator (ICD) but are unable to have an ICD implanted due to medical condition (e.g. ICD explanted due to infection with waiting period before ICD reinsertion or current medical condition contraindicates surgery). WCDs are not included on this line for use during the waiting period for ICD implantation after myocardial infarction, coronary bypass surgery, coronary artery stenting, or other situations when ICDs are not indicated.

Section 4.0

Coverage Guidances

Ablation for Atrial Fibrillation

Ablation for Atrial Fibrillation

Primary evidence sources:

Al-Khatib, S.M., Allen Lapointe, N., Chatterjee, R., Crowley, M.J., Dupre, M.E., Kong, D.F., et al. (2013). *Treatment of atrial fibrillation. Comparative Effectiveness Review 119*. (Prepared by the Duke Evidence-based Practice Center under Contract No. 290-2007-10066-I.) AHRQ Publication No.13-EHC095-EF. Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from www.effectivehealthcare.ahrq.gov/reports/final.cfm

Chen, H.S., Wen, J.M., Wu, S.N., & Liu, J.P. (2012). Catheter ablation for paroxysmal and persistent atrial fibrillation. *Cochrane Database of Systematic Reviews, Issue 4*. Art. No.: CD007101. DOI: 10.1002/14651858.CD007101.pub2. Retrieved from

Hashimoto, R.E., Raich, A., Junge, M., & Skelly, A. (2013). Catheter ablation procedures for supraventricular tachyarrhythmia, including atrial flutter & atrial fibrillation. Olympia, WA: Washington State Health Care Authority Health Technology Assessment Program. Retrieved from http://www.hca.wa.gov/hta/Pages/Forms/HTA_Findings.aspx

One additional source:

- 1 guideline - AHA/ACC/HRS

Ablation for Atrial Fibrillation

Evidence Summary

- Ablation of the AV node or bundle of His in patients with AF results in lower heart rate at 12 months than pharmacologic treatment (moderate SOE), although there is no difference in mortality or exercise capacity (low SOE)

Ablation for Atrial Fibrillation Evidence Summary

- Pulmonary vein isolation (PVI) results in a greater likelihood of maintaining sinus rhythm at 12 months than pharmacologic treatment (high SOE)
 - Most of the evidence for this finding is in patients with AF who have failed at least one AAD

Ablation for Atrial Fibrillation

Evidence Summary

- PVI also results in lower risk of hospitalization over 12 months (moderate SOE) and improved QOL (moderate SOE), but the evidence is insufficient to assess the impact of PVI on mortality

Ablation for Atrial Fibrillation Evidence Summary

- The surgical Maze procedure, when done at the time of other cardiac surgery, results in a higher likelihood of maintaining sinus rhythm than not performing the Maze (moderate SOE)
- PVI done at the time of other cardiac surgery results in a higher likelihood of maintaining sinus rhythm than not performing PVI (high SOE), and no apparent difference in all-cause mortality or stroke (low SOE)

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: ABLATION FOR ATRIAL FIBRILLATION

DRAFT for HERC meeting materials 1/8/2015

HERC COVERAGE GUIDANCE

AV node ablation is recommended for coverage only in persons with inadequate ventricular rate control resulting in symptoms, left ventricular systolic dysfunction or substantial risk of left ventricular systolic dysfunction. Coverage is recommended only when pharmacological therapy for rate control is ineffective or not tolerated (*weak recommendation*)

Transcatheter pulmonary vein isolation is recommended for coverage for those who remain symptomatic from atrial fibrillation despite rate control medications and antiarrhythmic medications (*strong recommendation*)

Surgical ablation (pulmonary vein isolation or Maze procedure) for atrial fibrillation is recommended for coverage at the time of other cardiac surgery for patients who remain symptomatic despite rate control medications (*weak recommendation*).

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

Al-Khatib, S.M., Allen Lapointe, N., Chatterjee, R., Crowley, M.J., Dupre, M.E., Kong, D.F., et al. (2013). *Treatment of atrial fibrillation. Comparative Effectiveness*

Review 119. (Prepared by the Duke Evidence-based Practice Center under Contract No. 290-2007-10066-I.) AHRQ Publication No.13-EHC095-EF. Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from www.effectivehealthcare.ahrq.gov/reports/final.cfm

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January, C.T., Wann, L.S., Alpert, J.S., Calkins, H., Cleveland, Jr, J.C., Cigarroa, J.E., et al. (2014). 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *Circulation, 129*. doi:10.1161/CIR.0000000000000041. Retrieved from <http://circ.ahajournals.org/content/early/2014/03/27/CIR.0000000000000041.citation>

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

SUMMARY OF EVIDENCE

Clinical Background

Atrial fibrillation (AF) is a supraventricular tachyarrhythmia characterized by uncoordinated atrial activation with consequent deterioration of mechanical function. Different systems have been proposed to classify AF. Although the type of AF can change over time, it is often helpful to characterize it at a given moment, as this may guide treatment. Types of AF include first-detected, paroxysmal (arrhythmia terminates spontaneously within 7 days), persistent (arrhythmia is sustained beyond 7 days), longstanding persistent (patients who have been in AF for any period longer than 1 year when attempts at achieving sinus rhythm are planned or are in progress), and permanent AF (in which cardioversion has failed or has not been attempted).

It is estimated that more than 2.3 million Americans have AF. The prevalence of AF increases with age and approaches 8 percent in patients older than 80 years of age. AF is the most common sustained arrhythmia seen in clinical practice. The impact of AF is

compounded by its known association with significant mortality, morbidity, and health care costs. Not only is the risk of death in patients with AF twice that of patients without AF, but AF can result in myocardial ischemia or even infarction, heart failure exacerbation, and tachycardia-induced cardiomyopathy if the ventricular rate is not well controlled. The most dreaded complication of AF is thromboembolism, especially stroke. Importantly, when ischemic stroke occurs in patients with AF, it is either fatal or of moderate to high severity in the majority of patients. The management of AF and its complications is responsible for almost \$16 billion in costs to the U.S. health care system each year.

Treatment Strategies

Management of AF involves three distinct areas: rate control (treatments to slow the heart rate to a normal range), rhythm control (treatments to revert the heart rhythm back to normal), and prevention of thromboembolic events. Whether or not a rhythm-control strategy is adopted, current treatment guidelines suggest that adequate rate control should be achieved in all patients with AF to prevent myocardial infarction (if significant coronary artery disease is present), exacerbation of heart failure, and tachycardia-induced cardiomyopathy; to alleviate symptoms; and to improve exercise tolerance and quality of life.

Rate Control

If pharmacological therapy is insufficient for rate control and symptom management or is associated with side effects, the 2006 ACC/AHA/ESC Guidelines recommend ablation of the atrioventricular node (AVN) in conjunction with permanent pacemaker implantation to control heart rate. As the latter involves implantation of an indwelling device that is not reversible, it is considered a treatment of last resort for patients for whom initial pharmacotherapy was ineffective.

Another clinical dilemma is whether patients with AF do better with strict or lenient rate control. In theory, strict control could reduce symptoms and prevent complications. However, stricter control requires more intensive use of medications, which carry their own side effects. The 2011 Focused Update on the Management of Patients With Atrial Fibrillation by the American College of Cardiology Foundation (ACCF), the AHA, and the Heart Rhythm Society (HRS) addressed the issue of strict versus lenient rate control in patients with AF. Specifically, these guidelines emphasized the following Class III recommendation (evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful): "Treatment to achieve strict rate control of heart rate (<80 bpm at rest or <110 bpm during a 6-minute walk) is not beneficial compared with achieving a resting heart rate <110 bpm in patients with persistent AF who have stable ventricular function (left ventricular ejection fraction >0.40) and no or acceptable symptoms related to the arrhythmia."

Rhythm Control

If patients with AF continue to have significant symptoms despite adequate rate control through either pharmacological therapy or AVN ablation, then a rhythm-control strategy (either pharmacological or electrical) is currently recommended. For pharmacological cardioversion of AF, the 2014 ACC/AHA/ESC Guidelines recommend flecainide, dofetilide, propafenone, and ibutilide as Class I recommendations, and amiodarone as a Class IIa recommendation (weight of evidence/opinion is in favor of usefulness/efficacy). To enhance direct-current cardioversion, the 2014 ACC/AHA/ESC Guidelines recommend pretreatment with amiodarone, flecainide, ibutilide, propafenone, or sotalol. For maintenance of sinus rhythm after cardioversion, the 2014 ACC/AHA/ESC Guidelines list different antiarrhythmic medications for different clinical settings.

In addition to pharmacological and direct-current cardioversion, a number of surgical interventions are used for rhythm control. Catheter ablation for the treatment of AF, with pulmonary vein isolation (PVI) being the most commonly used ablation, has evolved rapidly from a highly experimental procedure to its current status as a commonly performed procedure that is widely regarded as a clinically useful treatment option for symptomatic patients with AF in whom medications are not effective or not tolerated.

Several other procedures for the treatment of AF have been investigated. One such procedure is the surgical Maze procedure, which appears to confer some benefit to selected patients with AF. Although several studies of rate- and rhythm-control strategies exist, to date no study has shown that maintaining patients with AF in sinus rhythm provides a long-term survival benefit. It is also unknown whether the risks and benefits of different therapies vary by AF type.

Evidence Review

Rate-Control Procedures Versus Drugs or Versus Other Procedures in Patients for Whom Initial Pharmacotherapy Was Ineffective

Al-Khatib 2013 reports on four RCTs (one good, two fair, and one poor quality) involving a total of 211 patients that compared the effectiveness of a procedural intervention versus a primarily pharmacological intervention for rate control of AF. All four studies recruited patients with permanent AF, (referred to as “resistant chronic” AF in one study). All studies included at least one treatment arm with radiofrequency ablation of either the AVN or His bundle in conjunction with pacemaker placement. The comparison arms included a pharmacological intervention whose main purpose was to control ventricular heart rate rather than converting the underlying rhythm of AF.

Based on three studies reported in Al-Khatib 2013 (one good, one fair, one poor quality) involving 211 patients, patients undergoing a procedural intervention had a significantly lower heart rate at 12 months than those receiving a primarily pharmacological intervention. This was measured differently in all three studies. In one, the mean heart rate in the intervention group was 71 ± 6 bpm compared to 83 ± 8 bpm in the medication group ($p < 0.01$). In this study, maximum heart rate did not differ between groups. In the second study, those in the ablation group had higher minimum (70 ± 9 vs. 39 ± 9 bpm; $p < 0.05$) and mean (76 ± 7 vs. 71 ± 11 bpm; $p < 0.05$) heart rates than the medication group, but lower maximum heart rates (117 ± 16 bpm vs. 152 ± 37 bpm; $p < 0.05$). The third study reported the percent of each group who had either a normal or uncontrolled ventricular rate; in the ablation group, 100% had a normal ventricular rate (50-90 bpm) compared to 58% in the medication group. Similarly, none of the ablation group had an uncontrolled heart rate (>90 bpm at rest or > 130 bpm on exertion), while 42% of the medication group did. There was no difference by treatment arm in all-cause mortality (two studies [one good, one fair quality], 201 patients); cardiovascular mortality (one study [good quality], 102 patients); or exercise capacity (two studies [one good, one fair quality], 135 patients) (all low strength of evidence). There was insufficient strength of evidence to support findings for other outcomes, including quality of life.

Rhythm-Control Procedures and Drugs for Maintenance of Sinus Rhythm

Al-Khatib 2013 included 65 studies enrolling 6,739 patients that evaluated procedures for rhythm control. Of those that specified type of AF, eleven included only patients with longstanding persistent AF, 17 studies included only patients with paroxysmal AF, and 4 studies included only patients with persistent AF.

Transcatheter PVI versus antiarrhythmic drugs

Al-Khatib 2013 concluded, based on eight RCTs (five good, three fair quality) involving 921 patients, that transcatheter PVI is superior to antiarrhythmic drugs for **maintenance of sinus rhythm** over 12 months of follow up in patients with AF (one RCT reported 48 months of follow up). All trials had statistically significant results, as did meta-analysis of all eight trials (OR 6.51, 95% CI 3.22 to 13.16). This evidence is strongest in younger patients with little to no structural heart disease and with mild or no enlargement of the left atrium. Only one trial was limited to patients receiving ablation as first line therapy (Wazni 2005), while five specifically required failure of at least one AAD to be included in the study. The Wazni trial included 70 patients who experienced monthly episodes of symptomatic AF for at least three months, and found that at one year follow up, 63% of those treated with AADs had at least one recurrence of AF, compared to 13% of those

who received PVI. Another trial included only in Hashimoto 2013 included only patients with persistent AF (MacDonald 2011), and reported that at final follow up (6 months), 50% of patients in the PVI group were in sinus rhythm while none of the control group were (no statistical testing done). This latter trial was limited to patients with advanced heart failure. (Note: This outcome is reported as freedom from recurrence in Hashimoto 2013, but results are similar.)

Al-Khatib 2013 concluded, based on two RCTs (Pappone 2006, Forleo 2009, both good quality) involving 268 patients, that transcatheter PVI is superior to antiarrhythmic medications in **reducing cardiovascular hospitalizations** (moderate strength of evidence). Both of these trials were also included in Hashimoto 2013. A third study, Stabile 2006, reported only in Hashimoto 2013, found a lower number of hospitalizations in the PVI group which did not reach statistical significance. A fourth RCT, Wazni 2005, reported only in Al-Khatib 2013, found the rate of hospitalization specifically for AF was higher in the AAD arm (15 of 35) than the PVI arm (3 of 32, $p < 0.001$) in the first 12 months of follow up.

Chen 2012 reported that only one trial (Stabile 2006) reported all-cause **mortality**. There were no statistically significant differences between groups for this outcome. In this trial, the one death that occurred in the PVI group was from a stroke that occurred during the procedure and was followed by a brain hemorrhage 9 months later. There were two deaths in the AAD group (diagnosis not specified).

Al-Khatib 2013 also reported only one study for the outcome of all-cause mortality, however, it was a different study than was reported by Chen. This study (Oral 2006) reported one death in the PVI arm at 12 months compared to none in the AAD arm; no statistical testing was done.

Hashimoto 2013 reported that four RCTs (Jais 2008, Wilbur 2010, Stabile 2006, Oral 2006) reported overall mortality rates (not procedure related) at 9 to 12 months of follow up. Mortality rate in the PVI arm ranged from 1% to 3%, while in the AAD arm a rate of 3% was reported in two studies. According to Hashimoto, Stabile 2006 was the only RCT to report mortality in both arms. Two cohort studies included in Hashimoto 2013 did report an increased risk of death in the AAD group at follow up times ranging from 1 to 3 years (Pappone 2003: 6.5% in the PVI group vs. 14.3% in the AAD group, $p < 0.001$) or at a mean follow up of 69 months (Sonne 2009: 2.1% in the PVI group vs. 16.5% in the AAD group, $p = 0.001$).

Eight studies evaluated **quality of life (QOL) or functional status**, three RCTs reported in all three source reports, two additional RCTs reported in both Hashimoto 2013 and Al-Khatib 2013, two additional RCTs in Hashimoto 2013 only and one cohort study reported in Al-Khatib 2013 only. In general, there was greater improvement from

baseline in these scores in patients randomized to the PVI arm, compared to the AAD arm, and in most of these studies, results were statistically significant for at least some measures.

Harms were reported in eight RCTs, but for the most part, were not statistically analyzed. Complications reported in each study are summarized in the Table below:

Author	N	PVI Arm	AAD Arm
Krittayaphong	30	1 stroke, 1 groin hematoma	AE in 7 patients (47%): GI AE in 6 pts, corneal deposits in 2 pts, hypothyroidism in 2 pts, abnormal LFTs in 2 pts, hyperthyroidism in 1 pt, sinus node dysfunction in 1 pt
Wazni	70	No TE events, no bradycardia, 1 asymptomatic PV stenosis	No TE events, 8.6% bradycardia
Pappone	198	No serious AE	Sig AE leading to drug withdrawal in 23 pts,
Oral	146	None	None
Stabile	137	4.4% major complications (stroke, phrenic paralysis, pericardial effusion)	1 TIA, 2 cancer, 1 sudden death
Jais	112	2 cardiac tamponade, 2 groin hematomas, 1 PV stenosis requiring stent	1 hyperthyroidism, 2 deaths (unrelated)
Forleo	70	1 groin hematoma	17% sig drug AE (bradycardia, atrial flutter, sinus node dysfunction)
Wilber	167	5 major AE (pericardial effusion, pulmonary edema, pneumonia, vascular complication, heart failure)	5 major AE (2 life-threatening arrhythmias, 3 disabling drug intolerance requiring discontinuation)

TE = thromboembolic; PV = pulmonary vein

Cryoablation PVI vs. AAD

One RCT reported in Hashimoto 2013 found that patients randomized to receive cryoablation had significantly greater freedom from recurrence compared with those patients randomized to receive AADs alone (69.9% versus 7%, respectively; $P < .001$). There was one death (0.6%) in the cryoablation PVI group and none in the AAD group at 12 months, which was not statistically significant.

Surgical Maze versus standard of care (mitral valve surgery)

Al-Khatib 2013 included seven RCTs (one good, six fair quality) involving 361 patients for this comparison. Surgical Maze at the time of other cardiac surgery (specifically mitral valve surgery) is superior to mitral valve surgery alone for **maintenance of sinus rhythm** over at least 12 months of followup in patients with persistent AF (OR 5.80, 95% CI 1.79 to 18.81). Six studies reported on all cause mortality; meta-analysis found an OR of 1.97 (95% CI 0.81 to 4.80) suggesting an increased risk of death with the Maze procedure, but this did not reach statistical significance.

PVI done at the time of cardiac surgery versus cardiac surgery alone or cardiac surgery in combination with antiarrhythmic drugs (AADs) or catheter ablation

Al-Khatib 2013 included eight RCTs (five good, three fair quality) involving 532 patients for this comparison. Pulmonary vein isolation done at the time of cardiac surgery is superior to cardiac surgery alone or cardiac surgery in combination with AADs or catheter ablation for **maintenance of sinus rhythm** over 12 months of followup in patients with persistent AF (OR 3.91, 95% CI 1.54 to 9.91). Two studies reported no difference between groups in all-cause mortality or stroke.

There are insufficient data on the effect of rhythm control with PVI or surgical Maze on final outcomes, such as all-cause mortality, stroke, heart failure, and left ventricular ejection fraction, and on the safety and durability of the effectiveness of these procedures beyond 12 months.

Other comparisons

There are a variety of other comparisons included in Al-Khatib 2013 and Chen 2012, most of which had a limited number of studies and were considered outside the scope of this guidance document. These include the following:

- Circumferential PVI versus Segmental PVI
- Transcatheter PVI with complex fractionated atrial electrogram (CFAE) ablation versus transcatheter PVI without CFAE ablation
- Transcatheter PVI using different types of ablation catheters
- Transcatheter PVI with Cavotricuspid isthmus (CTI) ablation vs. transcatheter PVI without CTI ablation
- Transcatheter PVI vs transcatheter PVI with ablation sites other than CTI and CFAE and transcatheter PVI involving all four PVs vs transcatheter PVI involving arrhythmogenic PVs only

- Transcatheter PVI Alone vs transcatheter PVI plus postablation antiarrhythmic drugs
- Left atrial ablation vs. bi-atrial ablation
- PVI, circumferential PVI or left atrium ablation vs. ablation plus additional linear ablation
- PV-left atrium junction ablation vs. PV-left atrium junction ablation combined with CTI ablation
- Circumferential PV ablation vs. circumferential PV ablation plus PVI
- Superior PV ablation vs. four-PV ablation
- Small area isolation vs. large area isolation around PVs in circumferential PV ablation
- CFAE plus PV atrium isolation vs. PV atrium isolation alone
- Circumferential PV ablation vs. modified circumferential PV ablation
- Arrhythmogenic PVI vs all PVI

[Evidence Source]

Evidence Summary

Ablation of the AV node or bundle of His in patients with AF results in lower heart rate at 12 months than pharmacologic treatment (moderate SOE), although there is no difference in mortality or exercise capacity (low SOE). Pulmonary vein isolation (PVI) results in a greater likelihood of maintaining sinus rhythm at 12 months than pharmacologic treatment (high SOE); most of the evidence for this finding is in patients with AF who have failed at least one AAD. This procedure (PVI) also results in lower risk of hospitalization over 12 months (moderate SOE) and improved QOL (moderate SOE), but the evidence is insufficient to assess the impact of PVI on mortality.

The surgical Maze procedure, when done at the time of other cardiac surgery, results in a higher likelihood of maintaining sinus rhythm than not performing the Maze (moderate SOE). Similarly, PVI done at the time of other cardiac surgery results in a higher likelihood of maintaining sinus rhythm than not performing PVI (high SOE), and no apparent difference in all-cause mortality or stroke (low SOE).

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
Ablation of AV node/bundle of His compared to rate control medications in patients for whom initial pharmacotherapy was ineffective	Lower heart rate, no difference in mortality/exercise capacity	Moderate/Low based on 1 to 3 poor to good quality studies, depending on the outcome	High	High	AV node ablation is recommended for coverage only in symptomatic persons when pharmacological therapy for rate control is ineffective or not tolerated. (<i>weak recommendation</i>)	Studies show mixed clinical significance of a lower heart rate. In those with persistently uncontrolled heart rate despite AADs, AV node ablation is a reasonable alternative to prevent the negative consequences of an uncontrolled rate such as MI, exacerbation of CHF or cardiomyopathy.
Transcatheter PVI vs. AAD	Better maintenance of SR, fewer	High/Moderate, based on 1 to	High	Moderate	Transcatheter PVI is recommended for	Transcatheter PVI produces

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
	hospitalizations, better QOL, possibly lower mortality	8 fair to good quality studies, depending on the outcome			coverage when a rhythm control strategy is desired (<i>strong recommendation</i>)	superior clinical outcomes to antiarrhythmic drugs alone when a rhythm control strategy is pursued
Maze procedure	Better maintenance of SR; possible (nonsignificant) increase in mortality	Moderate based on 1 good and six fair quality studies	Moderate (concurrent with other cardiac surgery)	Moderate	The Maze procedure is recommended for coverage at the time of other cardiac surgery if the benefits of maintenance of sinus rhythm are thought to outweigh the potential risk of increased mortality (<i>weak recommendation</i>)	Maze may help maintain sinus rhythm but concerning nonsignificant increased risk of mortality
PVI done with other cardiac surgery	Better maintenance of SR	High based on 5 good and 3 fair quality studies	Moderate (concurrent with other cardiac surgery)	Low	PVI is recommended for coverage (<i>weak recommendation</i>)	PVI may help maintain sinus rhythm without significant additional risks

SR = sinus rhythm PVI = pulmonary vein isolation AAD = anti-arrhythmic drugs

*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

Nine quality measures pertaining to atrial fibrillation were identified when searching the [National Quality Measures Clearinghouse](#); however, none of them referenced ablation.

Choosing Wisely[®] is part of a multi-year effort of the ABIM Foundation to help physicians be better stewards of finite health care resources. Originally conceived and piloted by the [National Physicians Alliance](#) through a [Putting the Charter into Practice grant](#), more than 50 medical specialty organizations, along with Consumer Reports, have identified a number of tests or procedures commonly used in their field, whose necessity should be questioned and discussed. Each participating organization was free to determine how to create its own list, provided that it used a clear methodology and adhered to the following set of shared guidelines:

- Each item should be within the specialty's purview and control.
- The tests and/or interventions should be used frequently and/or carry a significant cost.
- Each recommendation should be supported by generally accepted evidence.
- The selection process should be thoroughly documented and publicly available on request.

One of the organizations that chose to participate in the *Choosing Wisely*[®] campaign is the Heart Rhythm Society. The most recent list created by this organization states the following:

“Don't ablate the atrioventricular node in patients with atrial fibrillation when both symptoms and heart rate are acceptably controlled by well-tolerated medical therapy.

Atrioventricular node ablation and pacemaker implantation may provide benefit in some patients when rate and related symptoms cannot be controlled by medication therapy, (Class IIa, indicated) or when there is concern for possible tachycardia-induced cardiomyopathy (Class IIb, may be considered). However, according to current professional society clinical guidelines, the risks of AV node ablation outweigh the benefits among patients with no symptoms and who have appropriate rate control with well-tolerated medical therapy.”

They cite the 2011 publication of the ACCF/AGA guidelines on the management of patient with AF as supporting evidence. These guidelines were recently updated (2014), and are rated fair quality using the MED standard criteria, primarily because study selection criteria was not specified and the quality of included studies was not assessed. These guidelines state the following with regard to AV node ablation for rate control in AF:

Class IIa

3. AV nodal ablation with permanent ventricular pacing is reasonable to control the heart rate when pharmacological therapy is inadequate and rhythm control is not achievable. (Level of Evidence: B)

Class III: Harm

1. AV nodal ablation with permanent ventricular pacing should not be performed to improve rate control without prior attempts to achieve rate control with medications. (Level of Evidence: C)

For catheter ablation for rhythm control (e.g. PVI), the guidelines state the following:

Class I

1. AF catheter ablation is useful for symptomatic paroxysmal AF refractory or intolerant to at least 1 class I or III antiarrhythmic medication when a rhythm control strategy is desired. (Level of Evidence: A)

2. Prior to consideration of AF catheter ablation, assessment of the procedural risks and outcomes relevant to the individual patient is recommended. (Level of Evidence: C)

Class IIa

1. AF catheter ablation is reasonable for selected patients with symptomatic persistent AF refractory or intolerant to at least 1 class I or III antiarrhythmic medication. (Level of Evidence: A)

2. In patients with recurrent symptomatic paroxysmal AF, catheter ablation is a reasonable initial rhythm control strategy prior to therapeutic trials of antiarrhythmic drug therapy, after weighing risks and outcomes of drug and ablation therapy. (Level of Evidence: B)

Class IIb

1. AF catheter ablation may be considered for symptomatic long-standing (>12 months) persistent AF refractory or intolerant to at least 1 class I or III antiarrhythmic medication, when a rhythm control strategy is desired. (Level of Evidence: B)

2. AF catheter ablation may be considered prior to initiation of antiarrhythmic drug therapy with a class I or III antiarrhythmic medication for symptomatic persistent AF, when a rhythm control strategy is desired. (Level of Evidence: C)

Class III: Harm

1. AF catheter ablation should not be performed in patients who cannot be treated with anticoagulant therapy during and following the procedure. (Level of Evidence: C)

2. AF catheter ablation to restore sinus rhythm should not be performed with the sole intent of obviating the need for anticoagulation. (Level of Evidence: C)

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.

DRAFT

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	
427.31	Atrial fibrillation
ICD-10 Diagnosis Codes	
I48.0	Paroxysmal atrial fibrillation
I48.1	Persistent atrial fibrillation
I48.2	Chronic atrial fibrillation
I48.91	Unspecified atrial fibrillation
ICD-9 Volume 3 (Procedure Codes)	
None	
CPT Codes	
33250	Operative ablation of supraventricular arrhythmogenic focus or pathway (eg, Wolff-Parkinson-White, atrioventricular node re-entry), tract(s) and/or focus (foci); without cardiopulmonary bypass (For intraoperative pacing and mapping by a separate provider, use 93631) Codes 33254-33256 are only to be reported when there is no concurrently performed procedure that requires median sternotomy or cardiopulmonary bypass.
33251	...with cardiopulmonary bypass
33254	Operative tissue ablation and reconstruction of atria, limited (eg, modified maze procedure)
33255	Operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure); without cardiopulmonary bypass
33256	...with cardiopulmonary bypass
33257	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), limited (eg, modified maze procedure) (List separately in addition to code for primary procedure)
33258	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (eg, maze procedure), without cardiopulmonary bypass (List separately in addition to code for primary procedure)
33259	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (eg, maze procedure), with cardiopulmonary bypass (List separately in addition to code for primary procedure)
33261	Operative ablation of ventricular arrhythmogenic focus with cardiopulmonary bypass
33265	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (eg, modified maze procedure), without cardiopulmonary bypass
33266	...operative tissue ablation and reconstruction of atria, extensive (eg, modified maze procedure), without cardiopulmonary bypass
93613	Intracardiac electrophysiologic 3-dimensional mapping (List separately in addition to code for primary procedure)
93650	Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement
93653	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment

CODES	DESCRIPTION
	of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry (Do not report 93653 in conjunction with 93600-93603, 93610, 93612, 93618-93620, 93642, 93654)
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure) (Use 93655 in conjunction with 93653, 93654, 93656)
93656	Comprehensive electrophysiologic evaluation including transeptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with atrial recording and pacing, when possible, right ventricular pacing and recording, His bundle recording with intracardiac catheter ablation of arrhythmogenic focus, with treatment of atrial fibrillation by ablation by pulmonary vein isolation
93657	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure)
93799	Unlisted cardiovascular service or procedure
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.

Ablation of AV node/bundle of His vs. rate control medications



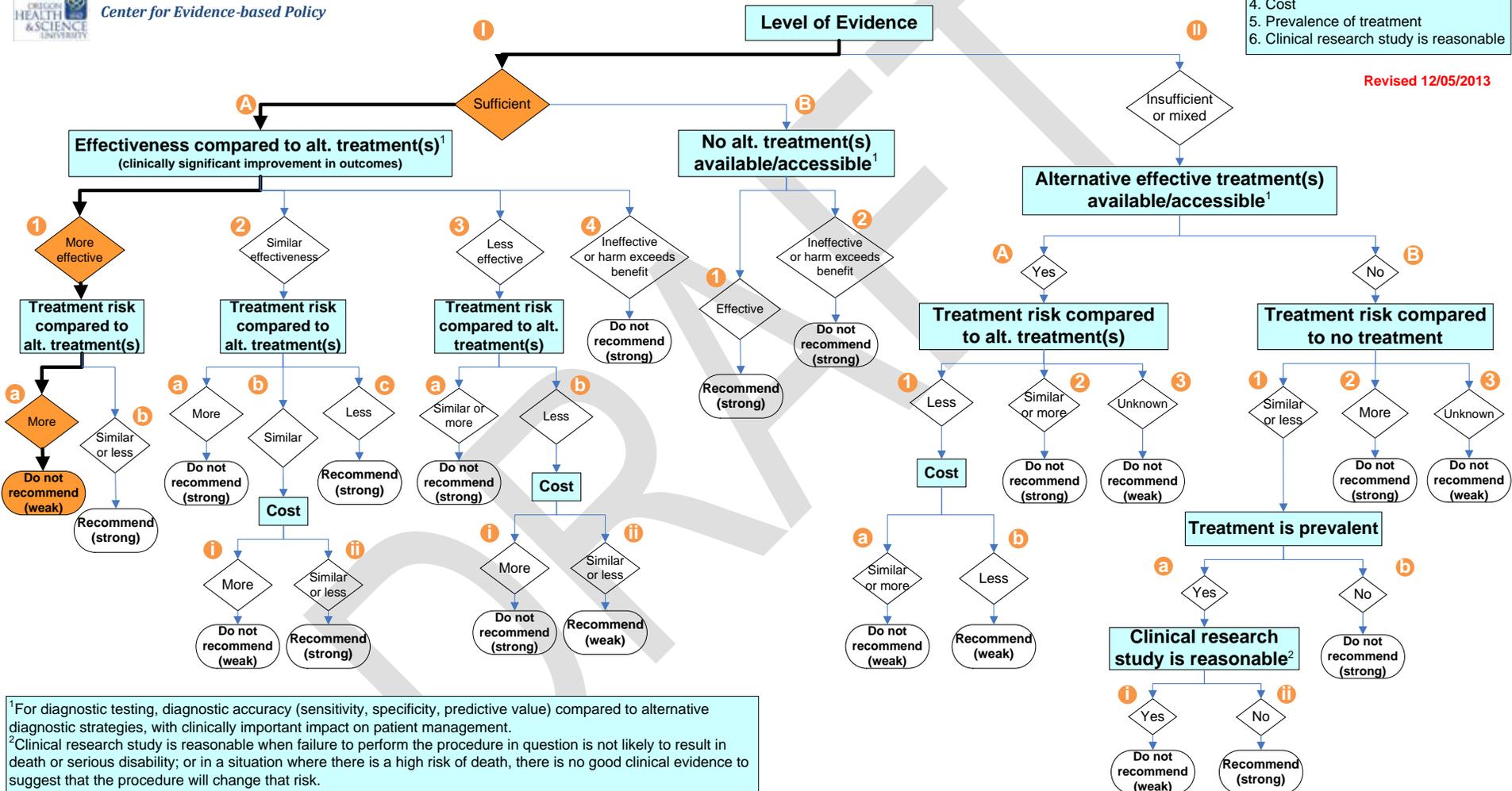
Center for Evidence-based Policy

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.

Transcatheter pulmonary vein isolation (PVI) vs. antiarrhythmic drugs (AAD); Surgical ablation (Maze procedure or PVI done with other cardiac surgery)



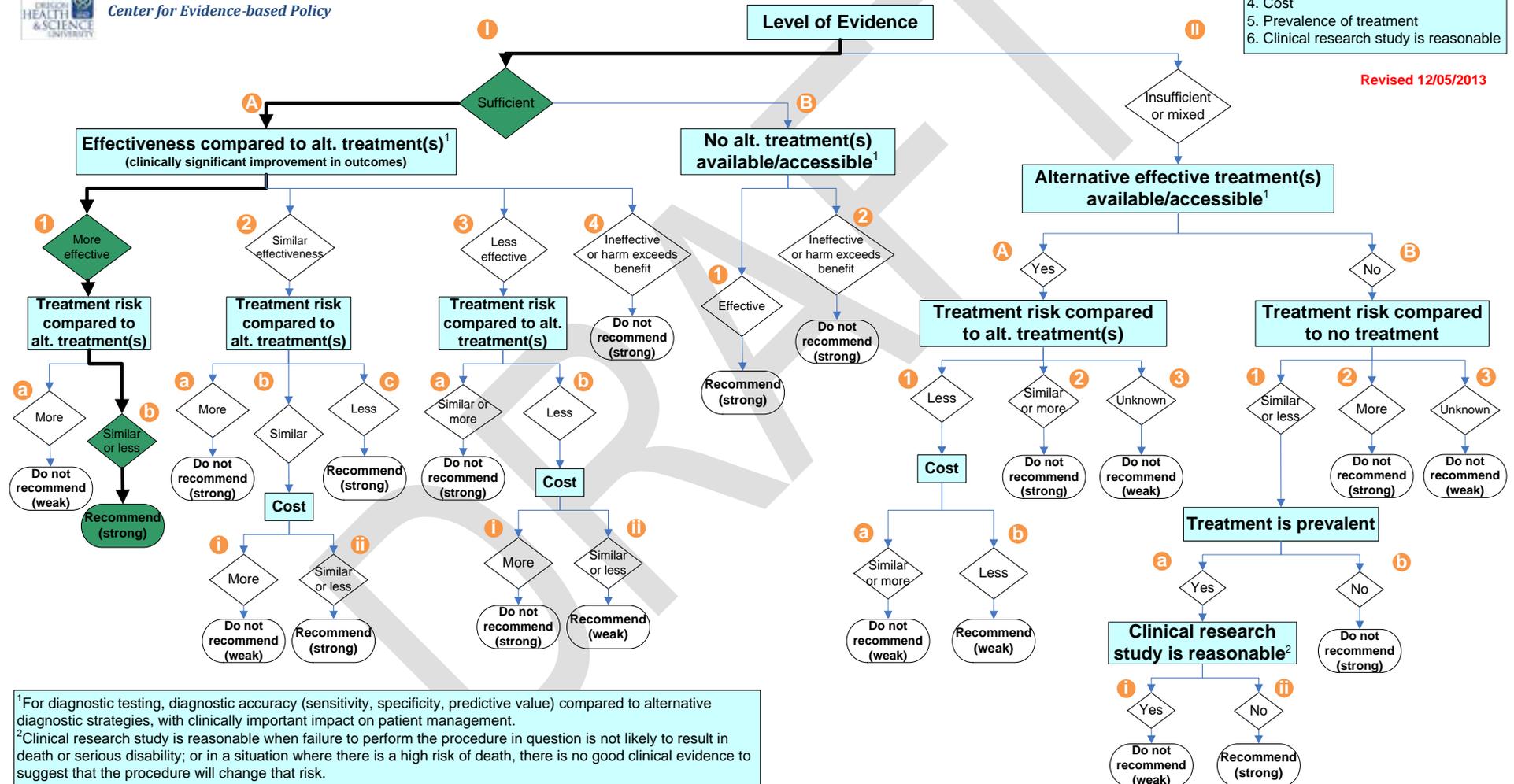
Oregon Health & Science University
Center for Evidence-based Policy

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



COVERAGE GUIDANCE: ABLATION FOR ATRIAL FIBRILLATION

This issue summary was reviewed by VbBS 11/13/2014. The VbBS affirmed the staff recommendations for consideration by HERC.

Question: How should the EGBS Coverage Guidance regarding ablation for atrial fibrillation be applied to the Prioritized List?

Question source: Evidence Based Guideline Subcommittee

Issue: EGBS approved a new Coverage Guidance at their September, 2014 meeting. This CG needs final approval by HERC at the November, 2014 meeting. The summary of the coverage guidance is shown below.

HERC COVERAGE GUIDANCE

AV node ablation is recommended for coverage only in persons with inadequate ventricular rate control resulting in symptoms, left ventricular systolic dysfunction or substantial risk of left ventricular systolic dysfunction. Coverage is recommended only when pharmacological therapy for rate control is ineffective or not tolerated (*weak recommendation*)

Transcatheter pulmonary vein isolation is recommended for coverage for those who remain symptomatic from atrial fibrillation despite rate control medications and antiarrhythmic medications (*strong recommendation*)

Surgical ablation (pulmonary vein isolation or Maze procedure) for atrial fibrillation is recommended for coverage at the time of other cardiac surgery for patients who remain symptomatic despite rate control medications (*weak recommendation*).

Evidence Summary

Ablation of the AV node or bundle of His in patients with AF results in lower heart rate at 12 months than pharmacologic treatment (moderate SOE), although there is no difference in mortality or exercise capacity (low SOE). Pulmonary vein isolation (PVI) results in a greater likelihood of maintaining sinus rhythm at 12 months than pharmacologic treatment (high SOE); most of the evidence for this finding is in patients with AF who have failed at least one AAD. This procedure (PVI) also results in lower risk of hospitalization over 12 months (moderate SOE) and improved QOL (moderate SOE), but the evidence is insufficient to assess the impact of PVI on mortality.

The surgical Maze procedure, when done at the time of other cardiac surgery, results in a higher likelihood of maintaining sinus rhythm than not performing the Maze (moderate SOE). Similarly, PVI done at the time of other cardiac surgery results in a higher likelihood of

maintaining sinus rhythm than not performing PVI (high SOE), and no apparent difference in all-cause mortality or stroke (low SOE).

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
Ablation of AV node/bundle of His compared to rate control medications in patients for whom initial pharmacotherapy was ineffective	Lower heart rate, no difference in mortality/exercise capacity	Moderate/Low based on 1 to 3 poor to good quality studies, depending on the outcome	High	High	AV node ablation is recommended for coverage only in symptomatic persons when pharmacological therapy for rate control is ineffective or not tolerated. (<i>weak recommendation</i>)	Studies show mixed clinical significance of a lower heart rate. In those with persistently uncontrolled heart rate despite AADs, AV node ablation is a reasonable alternative to prevent the negative consequences of an uncontrolled rate such as MI, exacerbation of CHF or cardiomyopathy.
Transcatheter PVI vs. AAD	Better maintenance of SR, fewer hospitalizations, better QOL, possibly lower mortality	High/Moderate, based on 1 to 8 fair to good quality studies, depending on the outcome	High	Moderate	Transcatheter PVI is recommended for coverage when a rhythm control strategy is desired (<i>strong recommendation</i>)	Transcatheter PVI produces superior clinical outcomes to antiarrhythmic drugs alone when a rhythm control strategy is pursued
Maze procedure	Better maintenance of SR; possible (nonsignificant) increase in mortality	Moderate based on 1 good and six fair quality studies	Moderate (concurrent with other cardiac surgery)	Moderate	The Maze procedure is recommended for coverage at the time of other cardiac surgery if the benefits of maintenance of sinus rhythm are thought to	Maze may help maintain sinus rhythm but concerning nonsignificant increased risk of mortality

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
					outweigh the potential risk of increased mortality <i>(weak recommendation)</i>	
PVI done with other cardiac surgery	Better maintenance of SR	High based on 5 good and 3 fair quality studies	Moderate (concurrent with other cardiac surgery)	Low	PVI is recommended for coverage <i>(weak recommendation)</i>	PVI may help maintain sinus rhythm without significant additional risks

Current Prioritized List status

ICD-9 427.31 Atrial fibrillation is on line 350 CARDIAC ARRHYTHMIAS

CPT code	Code description	Current lines	Suggested lines
33250	Operative ablation of supraventricular arrhythmogenic focus or pathway (eg, Wolff-Parkinson-White, atrioventricular node re-entry), tract(s) and/or focus (foci); without cardiopulmonary bypass	286 LIFE-THREATENING CARDIAC ARRHYTHMIAS 350 CARDIAC ARRHYTHMIAS	286, 350
33251	...with cardiopulmonary bypass	286, 350	286, 350
33254	Operative tissue ablation and reconstruction of atria, limited (eg, modified maze procedure)	286, 350	350
33255	Operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure); without cardiopulmonary bypass	286, 350	350
33256	...with cardiopulmonary bypass	286, 350	350
33257	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), limited (eg, modified maze procedure)	286, 350	350
33258	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (eg, maze procedure), without cardiopulmonary bypass	286, 350	350
33259	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (eg, maze procedure), with cardiopulmonary bypass	286, 350	350
33261	Operative ablation of ventricular arrhythmogenic focus with cardiopulmonary bypass	73 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 193 CHRONIC ISCHEMIC HEART DISEASE 286,350	286,350
33265	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (eg, modified maze procedure), without cardiopulmonary bypass	286, 350	350
33266	...operative tissue ablation and reconstruction of atria, extensive (eg, modified maze procedure), without cardiopulmonary bypass	286, 350	350

93613	Intracardiac electrophysiologic 3-dimensional mapping	286, 350	286, 350
93650	Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement	286, 350	286, 350
93653	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry	286, 350	286, 350
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure)	286, 350	286, 350
93656	Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with atrial recording and pacing, when possible, right ventricular pacing and recording, His bundle recording with intracardiac catheter ablation of arrhythmogenic focus, with treatment of atrial fibrillation by ablation by pulmonary vein isolation	286, 350	286, 350
93657	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation	350	350

HERC staff recommendations:

- 1) Remove procedures used solely for ablation of atrial fibrillation from line 286 LIFE-THREATENING CARDIAC ARRHYTHMIAS
 - a. CPT 33254-33259, 33265, 33266
- 2) Remove 33261 (Operative ablation of ventricular arrhythmogenic focus with cardiopulmonary bypass) from lines 73 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION and 193 CHRONIC ISCHEMIC HEART DISEASE
 - a. Arrhythmias being treated by this procedure will be on lines 286 or 350
- 3) Add the following guideline to line 350:

GUIDELINE NOTE XXX ABLATION PROCEDURES FOR ATRIAL FIBRILLATION

Line 350

AV nodal ablation (CPT 33250, 33251, 33261, 93650) pairs with atrial fibrillation (ICD-9 427.31/ICD-10 I48.0, I48.1, I48.2, I48.91) only for patients with inadequate ventricular rate control resulting in symptoms, left ventricular systolic dysfunction or substantial risk of left ventricular systolic dysfunction, when pharmacological therapy for rate control is ineffective or not tolerated

Transcatheter pulmonary vein isolation (93656-93657) pairs with atrial fibrillation (ICD-9 427.31/ICD-10 I48.0, I48.1, I48.2, I48.91) only for patients who remain symptomatic from atrial fibrillation despite rate control medications and antiarrhythmic medications.

Surgical ablation (pulmonary vein isolation or Maze procedure) (CPT 33254-33259, 33265, 33266) only pairs with atrial fibrillation (ICD-9 427.31/ICD-10 I48.0, I48.1, I48.2, I48.91) at the time of other cardiac surgery for patients who remain symptomatic despite rate control medications.

HERC Coverage Guidance – Ablation for Atrial Fibrillation Disposition of Public Comments

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Commenters

Identification	Stakeholder
A	Family Physician, Reedsport, OR [Submitted June 26, 2014]
B	Oregon Chapter of the American College of Cardiology, Portland, OR [Submitted July 22, 2014]
C	Medtronic, Inc., Mounds View, MN [Submitted July 21, 2014]

HERC Coverage Guidance – Ablation for Atrial Fibrillation Disposition of Public Comments

Public Comments

Ident.	#	Comment	Disposition
A	1	Agree with recommendations. They appear to be well-researched. Choosing Wisely recommendation adds weight; these have been researched by others and are endorsed by the specialty society.	Thank you for your comment.
B	1	The Oregon Chapter of the American College of Cardiology appreciates the opportunity to provide comments on the Health Evidence Review Commission’s Coverage Guidance for Ablation for the Treatment of Atrial Fibrillation. We are of the opinion that the coverage guidance is well written and appropriate and agree with the overall conclusions and coverage decisions. However, there are several points worth revising, as detailed below.	Thank you for your comment.
B	2	Page 1: Box labeled “HERC Coverage Guidance”, the third and fourth points are redundant, i.e., PVI at time of other cardiac surgery and surgical MAZE procedure at time of other cardiac surgery are the same. This error is repeated several times in the document. Although Al-Khatib distinguishes these two terms in her paper, these are generally used as synonyms in clinical practice, and thus comparisons between them are not valid. We recommend that the definitions of PVI and MAZE be included in the guidance.	PVI and surgical Maze are discussed separately in the AHRQ review, with different studies informing conclusions. Neither procedure is defined or described in this report. Given that both procedures have similar recommendations, box language changed to the generic term “surgical ablation”.
B	3	Page 2: First paragraph under “clinical background”, the term “permanent afib” is now rarely used and signifies afib that is always present and that no attempts are being made to restore sinus rhythm. We suggest clarifying that if attempts are made, then the afib is referred to as “longstanding persistent”.	Current description of atrial fibrillation varieties is from the AHRQ report, and states the following: “Types of AF include first-detected, paroxysmal (arrhythmia terminates spontaneously within 7 days), persistent (arrhythmia is sustained beyond 7 days), longstanding persistent (usually lasting for more than 1 year <u>when attempts at achieving sinus rhythm are planned or are in progress</u>), and permanent AF (in which cardioversion has failed or has not been attempted).” Suggested clarification made to the text.
B	4	Page 3: Top, “the risk of stroke is up to 8%, depending on other stroke risk factors”. To more appropriately classify this risk, we recommend the statement be revised to state a range, such as 1-8%.	Current language is verbatim from the AHRQ report. No citation provided for the range. AHA guideline reports 5X

HERC Coverage Guidance – Ablation for Atrial Fibrillation Disposition of Public Comments

Ident.	#	Comment	Disposition
			increase in stroke risk, but does not list an actual %. Sentence deleted.
B	5	Page 4: Middle, cardiac resynchronization therapy (CRT) is presented as a potential treatment for afib. CRT can be used in conjunction with AV node ablation, but the goal is not to decrease afib burden, as is currently discussed. Existing practice guidelines and current clinical practice do not include CRT as an appropriate treatment for afib, and we recommend removing it as a treatment option.	Language is from the background section and is verbatim from the AHRQ report; there is no evidence pertaining to CRT in the evidence review section. Sentence deleted.
B	6	Page 5: Top, AV node ablation is always in conjunction with placement of a permanent pacemaker (or previous placement of such). We suggest revision to reflect this.	<p>This language is verbatim from the AHRQ report; four of the six included studies evaluated AV node ablation compared to pharmacologic treatment; all of these included placement of a pacemaker. One of the remaining studies compared two different approaches (anterior and posterior) to “AV junction modification”. In this study, no pacemaker was used, as AV node pacing function remained intact. The sixth study compared right ventricular pacing to biventricular pacing.</p> <p>Text of document revised to eliminate reference to studies that did not compare a primarily pharmacologic intervention to a primarily procedural intervention; this allows deletion as follows: “All studies included at least one treatment arm with radiofrequency ablation of either the AVN or His bundle, most often in conjunction with pacemaker placement.”</p>
B	7	Page 8: There are separate paragraphs dealing with surgical PVI v. MAZE procedure at time of other cardiac surgery. Again, see page 1 comments above.	See comment #B2. Box language changed to surgical ablation. However,

HERC Coverage Guidance – Ablation for Atrial Fibrillation Disposition of Public Comments

Ident.	#	Comment	Disposition
			because these two procedures are addressed discretely in the AHRQ report, with different studies supporting PVI and Maze, text of the document other than the box not revised.
B	8	Page 9: Bottom, again, surgical PVI and MAZE are the same thing.	See comment #B7
C	1	Medtronic appreciates this opportunity to comment on Oregon Health Evidence Review Commission’s (HERC’s) draft coverage guidance on ablation for atrial fibrillation (AF). ¹ Medtronic has extensive clinical expertise and offers innovative products across several areas of cardiovascular care, including AF. We applaud the efforts of HERC to develop evidence-based coverage guidance on treatments for AF. The guidance clearly summarizes and evaluates the robust body of evidence for AF treatment strategies.	Thank you for your comment.
C	2	<p>To ensure alignment with the clinical guidelines and avoid potential confusion, we request clarification of the term “persistently symptomatic” in the draft coverage language for pulmonary vein isolation (PVI). The coverage guidance currently states:</p> <p style="padding-left: 40px;"><i>“Transcatheter pulmonary vein isolation is recommended for coverage for those who are persistently symptomatic despite rate control medications and antiarrhythmic medications (strong recommendation).”</i></p> <p>This language may suggest coverage is limited to patients with <i>persistent</i> AF and does not include patients with <i>paroxysmal</i> AF. We believe this may not be HERC’s intention as such language would be counter to the prevailing clinical guidelines and clinical trial evidence cited in the coverage guidance document. The 2014 AHA/ACC/HRS Atrial Fibrillation Guideline (referenced on page 13 of the coverage guidance document) strongly recommends PVI for patients with symptomatic paroxysmal or symptomatic persistent AF who are refractory or intolerant to at least 1 class I or III antiarrhythmic medication (January 2014). We propose the following revised coverage language:</p> <p style="padding-left: 40px;"><i>Transcatheter pulmonary vein isolation is recommended for coverage for those who are symptomatic (paroxysmal AF or persistent AF) despite rate control medications or antiarrhythmic medications (strong recommendation).</i></p>	<p>EbGS agrees that the recommendation as written can be confusing and has modified the language to clarify:</p> <p>Transcatheter pulmonary vein isolation is recommended for coverage for those who are persistently remain symptomatic from atrial fibrillation despite rate control medications and antiarrhythmic medications (strong recommendation)</p>
C	3	This revised language will help to ensure alignment with current clinical practice guidelines and that the appropriate patients have access to the right treatment strategies.	EbGS agrees.

HERC Coverage Guidance – Ablation for Atrial Fibrillation Disposition of Public Comments

References Provided by Commenters

Commenter	References
C	(1) January, C. T., Calkins, H., Murray, K. T., Cigarroa, J. E., & Stevenson, W. G. (2014). 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation. <i>Circulation</i> , 129, 000-00.

DRAFT

Percutaneous Interventions for Cervical Pain

Percutaneous Interventions for Cervical Pain

Primary evidence sources:

Hashimoto, R., Raich, A., Ecker, E., Henrikson, N., Wallace, L., Dettori, J., & Chou, R. (2011). *Spinal injections*. Olympia, WA: Washington Health Technology Assessment Program. Retrieved from http://www.hta.hca.wa.gov/spinal_injections.html

Hashimoto, R., Holmer, H., Sherry, N., & Skelly, A. (2014). *Facet neurotomy*. Olympia, WA: Washington Health Technology Assessment Program. Retrieved from <http://www.hca.wa.gov/hta/Pages/neurotomy.aspx>

Two additional sources:

- 1 systematic review
- 1 retrospective cohort study

Percutaneous Interventions for Cervical Pain

Evidence Summary

- There is no evidence of benefit of epidural steroid injections compared with placebo injections for neck pain in patients either with or without disc herniation and radiculitis, post-surgery syndrome or cervical spinal stenosis
- Epidural injections appear to be superior to intramuscular injections in patients with disc compression and radiculitis

Percutaneous Interventions for Cervical Pain

Evidence Summary

- Conclusions regarding the efficacy of ESI from other sources are mixed, but suggest if they are effective, it is likely only short-term
- One study suggests that ESI may result in a decreased risk of cervical surgery

Percutaneous Interventions for Cervical Pain

Evidence Summary

- There is no apparent difference in efficacy based on differing approaches for administering cervical epidural steroids
- There is limited evidence of benefit of RF neurotomy in patients with confirmed facet joint pain

Percutaneous Interventions for Cervical Pain

Evidence Summary

- Major complications are rare following injections into the cervical spine but can include
 - A life-threatening generalized anaphylactic reaction
 - Grand-mal seizure
 - Dural and subarachnoid puncture
 - Paralysis
 - Death

Percutaneous Interventions for Cervical Pain Evidence Summary

- Expert opinion in one review notes multiple reports of potentially catastrophic complications using a transforaminal injection approach and recommends against their use, despite similar or better efficacy compared to intralaminar approaches

Percutaneous Interventions for Cervical Pain Evidence Summary

- An outbreak in fungal infections and deaths that resulted from the use of contaminated steroid preparations when delivering epidural steroid injections occurred in 2012
- Minor complications are more common but are generally transient in nature
- No major complications of RF neurotomy have been reported

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: PERCUTANEOUS INTERVENTIONS FOR CERVICAL SPINE PAIN

DRAFT for 1/8/2015 VbBS/HERC Meeting Materials

HERC COVERAGE GUIDANCE

Therapeutic cervical spinal epidural injections are recommended for coverage for cervical spine pain with radiculopathy of six weeks duration (*weak recommendation*) only when all of the following criteria are met:

- documented neuroforaminal stenosis (without infection or neoplasia)
- radicular pain in a corresponding dermatomal distribution,
- pain is intractable and conservative therapy has failed,
- fluoroscopic guidance or CT guidance is utilized,
- interlaminar approach is utilized,
- no more than two injections without clinically meaningful improvement in pain and function, and
- maximum of three injections in six months.

Epidural steroid injections of the cervical spine are not recommended for coverage (*strong recommendation*) for other types of neck pain or for headache.

Therapeutic cervical intraarticular facet joint injections and therapeutic cervical medial branch blocks are not recommended for coverage for facet joint pain (*strong recommendation*).

Facet joint radiofrequency neurotomy is recommended for coverage (*weak recommendation*) only when all the following criteria are met:

- at least 3 months of moderate to severe pain with functional impairment,
- pain is predominantly axial and not associated with radiculopathy,
- conservative therapy has failed, and
- complete or nearly complete pain relief (80% or greater) following fluoroscopically guided, low-volume local anesthetic blocks of the medial branch nerves, performed on two separate occasions using two commonly-used agents with different anticipated durations of action.

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

Hashimoto, R., Raich, A., Ecker, E., Henrikson, N., Wallace, L., Dettori, J., & Chou, R. (2011). *Spinal injections*. Olympia, WA: Washington Health Technology Assessment Program. Retrieved from http://www.hta.hca.wa.gov/spinal_injections.html

Little, A., Pettinari, C., Vandegriff, S., Leof, A., Rahman, B., Zoller, E., Kriz, H., Gerrity, M., & King, V. (2013). *Spinal injections: Update to the March 2011 WA HTA report*. Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

Hashimoto, R., Holmer, H., Sherry, N., & Skelly, A. (2014). *Facet neurotomy*. Olympia, WA: Washington Health Technology Assessment Program. Retrieved from <http://www.hca.wa.gov/hta/Pages/neurotomy.aspx>

Additional Sources

Cohen, S.P., Bicket, M.C., Jamison, D., Wilkinson, I., & Rathmell, J.P. (2013). Epidural steroids: A comprehensive, evidence-based review. *Regional Anesthesia and Pain Medicine*, 38(3), 175-200. doi: 10.1097/AAP.0b013e31828ea086.

Lee, S.H., Kim, K.T., Kim, D.H., Lee, B.J., Son, E.S., & Kwack, Y.H. (2012). Clinical outcomes of cervical radiculopathy following epidural steroid injection: a prospective study with follow-up for more than 2 years. *Spine (Phila Pa 1976)*, 37(12), 1041-1047. doi: 10.1097/BRS.0b013e31823b4d1f.

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

SUMMARY OF EVIDENCE

Clinical Background

Chronic neck pain (defined as neck pain that persists more than three months) is common. Risk factors for spinal pain, including neck pain, include increasing age, spinal or disc degeneration, poor posture, anxiety, depression, and injuries. It can be attributed to a number of pathologic changes in the spine, including the following:

- Degenerative disc disease
- Herniated nucleus pulposus
- Spinal stenosis
- Facet joint syndrome
- Whiplash

Medical treatments available for chronic neck pain include non-invasive interventions such as physical therapy, pharmacologic therapy, psychological therapy, exercise, and spinal manipulation. For those patients with inadequate response to those treatments, spinal injections may be considered. Spinal injections involve the injection of an anti-inflammatory agent such as a steroid and/or an anesthetic agent into the spaces in and around the spinal nerves and joints. Types of spinal injection include epidural and facet joint injections and medial branch blocks. The latter two are generally used for pain believed to originate in the facet joint. It has been estimated that the point prevalences of facet joint pain are 10-15% in the low back and 45-55% in the neck. The primary symptom suggestive of facet joint pain is paraspinal tenderness at the affected facet joints, although other symptoms may be present as well. Diagnosis of facet joint pain cannot be accurately made by physical exam or imaging studies alone and diagnostic nerve blocks (medial branch blocks) may be the most accurate assessment method. Epidural injections deliver medication into the epidural space of the spine to decrease inflammation of the nerve root. Two approaches are possible in the neck. The interlaminar approach involves placement of the needle between the lamina of the vertebrae, delivering medication to both the right and left sides of the inflamed area. The transforaminal approach involves placement of the needle in the neural foramen, treating one side at a time.

Facet joint injections deliver the medications (anesthetic with or without a corticosteroid) into the facet joints and include several approaches. Medial branch blocks involve injection of the medication into the area of the medial branch of the posterior primary

ramus. Prior to steroid injections, controlled diagnostic blocks (medial branch blocks) of the joint or the nerves that supply the joint are often performed using local anesthetic. A positive block indicates that pain is eliminated and the affected nerve has been identified as the source of pain.

Once the facet joint is determined to be the source of pain as indicated by a positive diagnostic block, then prolonged pain relief may be achieved with destruction of the nerves to the affected joint in a procedure called facet neurotomy. Neurotomy does not cure the source of pain, but instead cuts off the pain signal from the brain by damaging the nerve. Different types of facet neurotomy are available, but the most common type employs radiofrequency needles to destroy the nerve tissue with heat generated by an electric current. During this procedure, the skin is anesthetized with a local anesthetic and the radiofrequency needles are advanced using guidance to confirm that the needles are properly positioned at the affected nerves. Then a radiofrequency current is applied to disrupt the ability of the nerves to transmit pain signals to the brain.

There are three types of radiofrequency (RF) neurotomy: standard, pulsed and cooled. Pulsed RF neurotomy delivers short bursts of radiofrequency current rather than the continuous flow utilized in non-pulsed RF neurotomy. Pulsed neurotomy allows the nerve tissue to cool between bursts, and is reported to reduce the destruction of neighboring tissue. Some other names used for this procedure include percutaneous radiofrequency denervation, nerve ablation, neurolysis, medial branch neurotomy, medial branch rhizotomy, and articular rhizolysis. Other types of facet neurotomy involve chemical ablation (application of ethyl alcohol, phenol, or sodium morrhuate; cryoablation (application of extreme cold); or laser ablation (application of laser beams) of the medial branch nerves to destroy the nerves and reduce or eliminate pain.

Evidence Review

Trusted Sources

These reports include studies of adults with sub-acute or chronic neck pain due to conditions including (but not limited to) degenerative disc disease, radiculopathy, disc herniation, spinal stenosis and facet joint pain. Evaluated treatments included epidural injections, intraarticular facet injections, medial branch blocks and facet neurotomy. Studies reporting on diagnostic injections (selective nerve root blocks), extraspinal injections (except as a comparator), chemonucleolysis, intradiscal electrothermal therapy and coblation nucleoplasty were excluded. Comparators included any placebo injection (water, saline, local anaesthetic) or non-placebo controls. For efficacy, only randomized controlled trials (RCTs) were included.

A total of seven RCTs were identified that reported on efficacy. Studies were limited to the following populations:

- Chronic neck pain without disc herniation or radiculitis (one study)
- Chronic neck pain with disc herniation or radiculitis (one study)
- Chronic neck pain with resistant cervicobrachialgia (one study)
- Chronic neck pain of facet origin (two studies)
- Cervical post-surgery syndrome (one study)
- Cervical spinal stenosis (one study)

Most of the included studies evaluated one injection technique (interlaminar epidural, facet joint or medial branch block) and compared steroid plus local anaesthetic injection to local anaesthetic alone. However, the trial of patients with resistant cervicobrachialgia compared epidural steroid plus local anaesthetic injection to posterior neck muscle injection with the same substances. The one trial that evaluated facet joint injections compared steroid injection (without local anaesthetic) to local anaesthetic injection.

Efficacy/Effectiveness

For trials comparing cervical epidural steroid injections with:

- Placebo injections for neck pain with disc herniation and radiculitis, there is no benefit based on data from one lower-quality RCT (strength of evidence = very low).
- Placebo injections for neck pain without disc herniation and radiculitis, there is no benefit based on data from one lower-quality RCT (strength of evidence = very low).
- Intramuscular injections for neck pain with disc compression and radiculitis, there is evidence that epidural injections were superior based on data from one lower-quality RCT (strength of evidence = very low).
- Placebo injections for post-surgery syndrome, there is no benefit based on data from one fair quality RCT (strength of evidence = very low).
- Placebo injections for cervical spinal stenosis, there is no benefit based on data from one fair quality RCT (strength of evidence = very low).

For trials comparing cervical intraarticular facet joint steroid injections with:

- Placebo injections for confirmed facet joint pain, there is no benefit based on data from one lower-quality RCT (strength of evidence = very low).

For trials comparing cervical medial branch blocks with:

- Placebo injections for confirmed facet joint pain, there is no benefit based on data from one lower-quality RCT (strength of evidence = very low).

For trials comparing different approaches for administering cervical epidural steroids:

- There were no significant differences between anterolateral and posterolateral approaches in estimated change from baseline in pain score or disability index at two weeks or two months. There is no apparent difference in efficacy based on differing approaches for administering cervical epidural steroids (strength of evidence = very low).

For trials comparing RF neurotomy with:

- Sham neurotomy in patients with confirmed facet joint pain (based on 100% response to three medial branch blocks), significantly more patients in the RF neurotomy group had freedom from “accustomed pain” (risk difference, 50% (95% CI, 18% to 82%) (P = 0.0110) based on evidence from one small (N=24) RCT (strength of evidence = very low).

Table 1. Efficacy/Effectiveness

Indication	Population characteristics	Comparator	Strength of Evidence	Conclusions
Cervical Epidural Steroid Injections				
Neck pain with disc herniation and radiculitis	Cervical disc herniation or radiculitis, chronic neck pain > 6 months duration, no spinal stenosis unless accompanied by disc herniation, no prior cervical spine surgery, opioid use stable/controlled	Placebo epidural injection (local anaesthetic)	Very low	No benefit in terms of pain, function, or opioid use at both three and twelve months or on employment at twelve months based on data from one RCT.
Neck pain without disc herniation and radiculitis	Negative diagnosis of facet joint pain (by use of local anaesthetic blocks), absence of disc herniation/ radiculitis or spinal stenosis, chronic neck/arm pain > 6 months duration, opioid use stable/ controlled	Placebo epidural injection (local anaesthetic)	Very low	No benefit in terms of pain, function, or opioid use at both three and twelve months or on employment at twelve months based on data from one RCT.

Indication	Population characteristics	Comparator	Strength of Evidence	Conclusions
Neck pain with disc compression and radiculitis	Chronic resistant cervicobrachialgia, continued pre-study treatments (medications, PT). Full text only available for purchase	Intramuscular injection (saline and local anaesthetic)	Very low	Epidural injections were superior to intramuscular injections in the posterior neck in terms of pain, analgesic use, and employment at one week and twelve months based on data from one RCT.
Post-surgery syndrome	Cervical post-surgery syndrome, surgery > 1 year previously with continued pain for at least 6 months after surgery, opioid use stable/ controlled	Placebo epidural injection (local anaesthetic)	Very low	No benefit in terms of pain or disability at 3, 6 and 12 months based on data from one RCT.
Cervical spinal stenosis	Cervical central spinal stenosis with or w/o foraminal stenosis, age > 30, chronic neck pain of at least 6 on a scale of 1-10, at least 6 months duration, failed to improve with conservative management (PT, chiro, exercise, drugs, bed rest), opioid use stable/ controlled	Placebo epidural injection (local anaesthetic)	Very low	No benefit in terms of pain or disability at 3, 6 and 12 months based on data from one RCT.
Cervical Intraarticular Facet Joint Steroid Injections				
Confirmed facet joint pain	Neck pain lasting > 3 months due to MVA with documented positive response to medial branch block	Placebo facet injection (local anaesthetic)	Very low	No benefit in terms of the length of pain relief based on one RCT. No long-term data was reported.
Cervical Medial Branch Blocks (local anaesthetic + steroid, ± Sarapin*)				
Confirmed facet joint	Non-specific neck pain > 6 months	Placebo injection	Very low	No benefit in terms of pain or function at both three

Indication	Population characteristics	Comparator	Strength of Evidence	Conclusions
pain	duration, confirmed facet joint pain (response to local anaesthetic blocks), no radicular symptoms, failed conservative management (PT, chiro, exercise, drugs, bed rest), opioid use not heavy, continued previous interventions	(local anaesthetic ± Sarapin)		and twelve months or on opioid use or employment at twelve months based on one RCT.
Facet Neurotomy				
Confirmed facet joint pain	Failed conservative management (mean duration of pain 34 to 44 months), responded to 3 MBBs (100% pain relief)	Sham RF neurotomy	Very low	Significantly more patients in the RF neurotomy group had freedom from “accustomed pain” (risk difference, 50% (95% CI, 18% to 82%) (P = 0.01)
Cervicogenic headache	Cervicogenic HA of at least 2 years duration, rated at least 50 out of 100 on VAS, considerable pain at least 2 days/wk, no prior neck surgery	Injection of major occipital nerve	Low	No difference between groups in headache relief or a composite measure of success at 2 months
Facet joint pain	Patients with previously successful RF neurotomy	None – 3 case series	Very low	Patients are likely to experience a similar response to subsequent RF neurotomy procedures as they experienced during their first RF neurotomy procedure

*Sarapin is a suspension of powdered sarracenia purpurea (pitcher plant). This study had a total of four patient groups, but outcomes were not reported by use of this product.

Harms

- Major complications are rare following injections into the cervical spine and included a life-threatening generalized anaphylactic reaction, grand-mal seizure, dural puncture, subarachnoid puncture, and local hematoma. There were no cases of death or paralysis in the included studies, although there have been case reports of each in the published literature.
- Multiple publications have addressed the outbreak in fungal infections and deaths that resulted from the use of contaminated steroid preparations when delivering epidural steroid injections. As of December 27, 2012, there had been 620 cases of fungal meningitis, stroke presumed due to fungal meningitis, other central nervous system-related infection or septic arthritis attributed to the contamination, and 39 deaths.
- Other major complications were reported in case series of a mixture of lumbar and cervical spinal injection patients and included chest pain, tachycardia/hypertension, significant transient hypertensive episode, hematoma, dural puncture, and a severe vasovagal reaction.
- Minor complications are more common following lumbar or cervical spinal injections but are generally transient in nature, and include pain at the injection site, increased radicular pain/numbness/weakness, nerve root irritation, superficial infections, sympathetic blockade, facial flushing or rash, vasovagal reactions/fainting, headache, gastric complaints, dizziness, pruritus, irregular periods, and insomnia.
- With proper protective measures, total radiation exposure to the physician was within normal limits following a mean of 923 procedures (range, 100 to 1819) with an average length of radiation exposure of 9.8 seconds/procedure (range, 4.9 to 15.2) in all five case series identified.

Table 2. Harms

Spinal Injections	Strength of Evidence	Conclusions
Major complications	High	Major complications are rare following injections into the cervical spine. There were no cases of death or paralysis in the included studies, although there have been case reports of each in the published literature. In five RCTs, there were reports of subarachnoid puncture in 3/710 injections or patients and no reports of dural puncture or death. In four case series there were reports of life-threatening generalized anaphylactic reaction (1 case), grand-mal seizure (1 case), dural puncture (2 cases), and local hematoma (1 case) in

Spinal Injections	Strength of Evidence	Conclusions
		<p>7240 injections or patients.</p> <p>In three case reports of a mix of lumbar and cervical spinal injection patients, there was one case of each of the following major complications in 6935 injections: chest pain, tachycardia/hypertension, significant transient hypertensive episode, hematoma, dural puncture, and a severe vasovagal reaction.</p>
Minor complications	High	<p>Minor complications are more common but are generally transient in nature. They were rare as reported in 5 RCTs. One non-randomized study reported an overall minor complication rate of 1.64%. Complications included: pain at the injection site, increased usual pain, transient pain/weakness, nerve root irritation, transient global amnesia, superficial infections, sympathetic blockade, vasovagal reactions, facial flushing, headache, nausea.</p>
Vascular puncture	Low	<p>The mean incidence of intravascular puncture following fluoroscopically guided cervical spinal injections was 15.6% (range, 4.0–19.4%) as reported in two studies. These studies evaluated the incidence but not the consequences of intravascular injection.</p> <p>The TruCath Spinal Injection System™ may decrease the incidence of vascular puncture.</p>
Radiation exposure to the physician	Low	<p>With proper protective measures, total radiation exposure was within normal limits following a mean of 923 procedures (range, 100 – 1819) with an average length of radiation exposure of 9.8 seconds/procedure (range, 4.9 – 15.2) in all five case series identified.</p>

For RF neurotomy, the only adverse event reported more frequently for RF neurotomy compared to sham was numbness in the area of the treated nerves. Other adverse events reported were psoriatic rash and pain associated with the procedure, neither of which differed significantly from the sham group. Overall strength of the evidence is low.

Additional Sources

Because of the weak evidence base for ESI, the subcommittee chose to consider additional evidence that was provided by the HERC-appointed expert for this topic. The expert provided a systematic review and a retrospective cohort study, both described below.

Cohen 2013

This review included an extensive search of the literature, and all study types were included. However, details of the search, including number and type of studies, were not provided. Authors state that “recommendations were based on a conglomeration of factors including weighted evidence ..., consensus guidelines when relevant, and perceived bias” (p. 175). No quality assessment of included studies was completed, and there was no explicit link between the evidence and recommendations. The review provides a summary of the literature and recommendations for use of epidural steroids in the spine.

Pertaining to injection approach:

There are two different approaches for delivering epidural steroids in the cervical region, interlaminar (IL) and transforaminal (TF). An interlaminar injection involves passage of the needle through the ligamentum flavum in the posterior midline of the spine. Advantages of this approach are purported to be a higher likelihood that the injected medication will reach adjacent spinal levels and the ability to treat bilateral pain. Disadvantages include the potential for dural puncture and the dorsal deposition of the medication, which is more distant from the site of pathology. The transforaminal approach involves placement of the needle within the neuroforamen. Theoretical advantages are that it is the most target specific, carries a lower risk of dural puncture and is associated with a greater incidence of ventral spread. However, they are associated with a higher risk of catastrophic neurological complications.

Pertaining to the efficacy of ESI in the cervical region:

For interlaminar injections, the authors cite three systematic reviews, one of which was supportive of the efficacy of ESI for a variety of conditions, while the other two reported that ESIs are probably effective in the short-term. One of these stated that definitive evidence was lacking, and that the evidence was stronger for herniated disc and non-osseous central stenosis. The other reported that evidence was lacking for long-term efficacy.

For transforaminal injections, the authors report a single RCT, but multiple nonrandomized studies reporting both short and long term efficacy. They also note multiple reports of potentially catastrophic complications. The authors recommend the following:

“Overall, the literature suggests that although the TF approach may be more efficacious than the IL or caudal approaches, the difference in effect size is small. In the cervical, thoracic, and midlumbar to high lumbar regions, the increased risk

for catastrophic neurological complications should preclude the use of TF ESI as a first-line treatment.” (p. 181)

Lee 2012

Lee (2012) is a retrospective cohort study in which 98 patients who received cervical ESI for cervical radiculopathy without major neurologic deficit were followed for two years, then were analyzed based on whether they received spine surgery or not. Patients must have failed 4 weeks of conservative therapy and not have myelopathy or definite motor weakness. The injection was repeated up to 3 times at 1 to 2 week intervals, if pain relief was insufficient (less than 80% improved). Authors report that patients received an average of 1.8 ESI, and that at the 2-year follow up point, 80.6% of patients had not had surgery.

Analysis of clinical factors associated with proceeding to surgery found that having had a previous episode of cervical radiculopathy, pre-ESI pain score and post-ESI pain score were the only correlated factors. Fifteen percent of patients in the non-surgery group had a previous episode of cervical radiculopathy, compared to 42% in the surgery group ($p=0.02$). Prior to ESI, patients in the non-surgery group had a mean visual analogue scale (VAS) score for arm pain of 6.1, compared to 8.2 in the surgical group. Post ESI, the non-surgical group had a mean VAS pain score of 2.8 compared to 6.9 for the surgical group ($p<0.001$ for both). Factors for which there was no statistically significant difference between groups included gender, age, duration of symptoms, type of symptoms, compensation or number of ESI.

Evidence Summary

There is no evidence of benefit of epidural steroid injections compared with placebo injections for neck pain in patients either with or without disc herniation and radiculitis, post-surgery syndrome or cervical spinal stenosis. On the other hand, epidural injections appear to be superior to intramuscular injections in patients with disc compression and radiculitis. Conclusions regarding the efficacy of ESI from other sources are mixed, but suggest if they are effective, it is likely only short-term. One study suggests that ESI may result in a decreased risk of cervical surgery. There is no evidence of benefit of cervical intraarticular facet joint steroid injections or medial branch blocks compared with placebo injections for confirmed facet joint pain. There is no apparent difference in efficacy based on differing approaches for administering cervical epidural steroids. There is limited evidence of benefit of RF neurotomy in patients with confirmed facet joint pain.

Major complications are rare following injections into the cervical spine but can include a life-threatening generalized anaphylactic reaction, grand-mal seizure, dural and subarachnoid puncture, paralysis and death. Expert opinion in one review notes multiple

reports of potentially catastrophic complications using a transforaminal injection approach and recommends against their use, despite similar or better efficacy compared to intralaminar approaches. An outbreak in fungal infections and deaths that resulted from the use of contaminated steroid preparations when delivering epidural steroid injections occurred in 2012. Minor complications are more common but are generally transient in nature. No major complications of RF neurotomy have been reported.

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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
Epidural steroid injections	Balance may result in some net benefit	Effectiveness evidence: Very low Harms evidence: High	Moderate	Moderate to high, given some may prefer interventional vs. pharmacologic vs. lifestyle or more conservative interventions	Recommended for coverage, only when all the following criteria are met: documented neuroforaminal stenosis (without infection or neoplasia); radicular pain in a corresponding dermatomal distribution; pain is intractable and conservative therapy has failed, fluoroscopic guidance or CT guidance is utilized; interlaminar approach is utilized; no more than two injections without clinically meaningful improvement in pain and function; and maximum of three injections in six months. <i>(weak recommendation)</i>	Though quality of evidence from trusted sources is very low, there is evidence from additional sources, namely a retrospective single cohort study, of some benefit when the recommended criteria are met. Additionally, other payer policies include a similar recommendation, namely Medicare and Washington State's payer policies.
Facet joint injections	No benefit	Effectiveness evidence: Very low Harms evidence:	Moderate	Moderate to high, given some may prefer interventional	Not recommended for coverage <i>(strong recommendation)</i>	No net benefit; some harms

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage Recommendation	Rationale
		High		vs. pharmacologic vs. lifestyle or more conservative interventions		
Therapeutic medial branch blocks	No benefit	Effectiveness evidence: Very low Harms evidence: High	Moderate	Moderate to high, given some may prefer interventional vs. pharmacologic vs. lifestyle or more conservative interventions	Not recommended for coverage <i>(strong recommendation)</i>	No net benefit; not common practice; some harms
RF neurotomy	Some evidence of benefit, minimal harms	Effectiveness evidence: Very low Harms evidence: High	Moderate	Moderate to high, given some may prefer interventional vs. pharmacologic vs. lifestyle or more conservative interventions	Recommended for coverage, only when all of the following criteria are met: at least 3 months of moderate to severe pain with functional impairment; pain is predominantly axial and not associated with radiculopathy; conservative therapy has failed; and at least 80% improvement from initial pain level following fluoroscopically-guided, low- volume local anesthetic blocks of the medial branch nerves, performed on two separate occasions. <i>(weak recommendation)</i>	Though quality of evidence from trusted sources is very low, the evidence shows there is some benefit when the recommended criteria are met. Coverage with these criteria was recommended by appointed expert.

*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

No pertinent quality measures were identified when searching the [National Quality Measures Clearinghouse](#).

Professional Society Guidelines

Guidelines reviewed in the WA HTA Spinal Injections report (Hashimoto, 2011) are included in Appendix D.

Payer Coverage Policies

Coverage policies for selected payers are included here.

Medicare

Two local coverage determinations were identified in the [Medicare Coverage Database](#).

- [L30481 Epidural and Transforaminal Epidural Injections](#)
- [L33842 Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy](#)

Medicare coverage guidance is detailed in Appendix E.

Washington HTA Limitations of Coverage

Therapeutic Epidural Injections in the lumbar or cervical-thoracic spine for chronic pain are a covered benefit when all of the following conditions are met:

- For treatment of radicular pain
- With fluoroscopic guidance or CT guidance
- After failure of conservative therapy
- No more than two without clinically meaningful improvement in pain and function, and
- Maximum of 3 in 6 months

COMMITTEE DELIBERATIONS – VALUE-BASED BENEFITS SUBCOMMITTEE

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

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

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Appendix A. GRADE 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	
720.9	Unspecified inflammatory spondylopathy
721	Spondylosis , various
722	Degeneration/displacement intervertebral disc, various
723	Spinal stenosis, brachial neuritis or radiculitis, various
724	Spinal stenosis, various
738.4	Acquired spondylolisthesis
ICD-10 Diagnosis Codes	
M43.00-3	Spondylolysis
M43.10-3	Spondylolisthesis
M47.10-3	Other spondylosis with myelopathy
M47.20-3	Other spondylosis with radiculopathy
M47.811-3, M47.819	Spondylosis without myelopathy or radiculopathy
M47.891-3	Other spondylosis
M48.00-3	Spinal stenosis
M50	Cervical disc disorders
M54.10-3	Radiculopathy
M54.2	Cervicalgia
ICD-9 Volume 3 (Procedure Codes)	
03.91	Injection of anesthetic into spinal canal for analgesia
03.92	Injection of another agent into spinal canal
CPT Codes	
62310	Inject spine cervical/thoracic
64479	Inj foramen epidural c/t
64480	Inj foramen epidural add-on
64490- 64495	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (flouro or CT), cervical, thoracic, lumbar or sacral; single, second or third level
64633- 64636	Destruction by neurolytic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (flouro or CT), cervical, thoracic, lumbar or sacral; single, second or third level
64479-80	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance; cervical or thoracic, single level and each additional
64490-2	Injection(s), diagnostic or therapeutic agent, paravertebral facet joint (or nerves innervating that joint), with imaging guidance; cervical or thoracic, single level and each additional
0213T– 0218T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical, thoracic, lumbar or sacral; single, second or third level
77003	Fluoroguide for spine injection
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.

Facet Joint Injections, Therapeutic Medial Branch Blocks



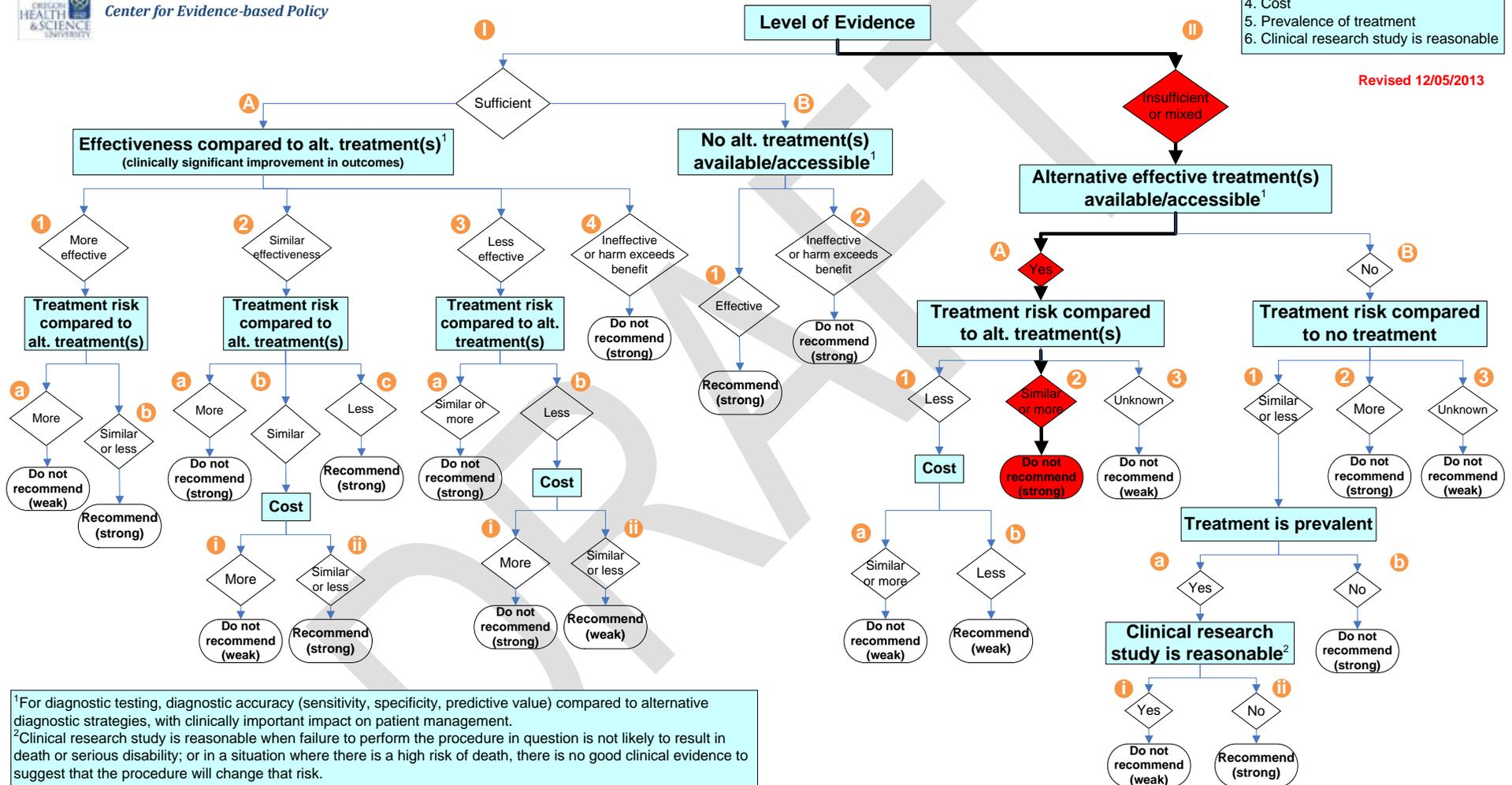
Center for Evidence-based Policy

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



Epidural Steroid Injections, RF Neurotomy

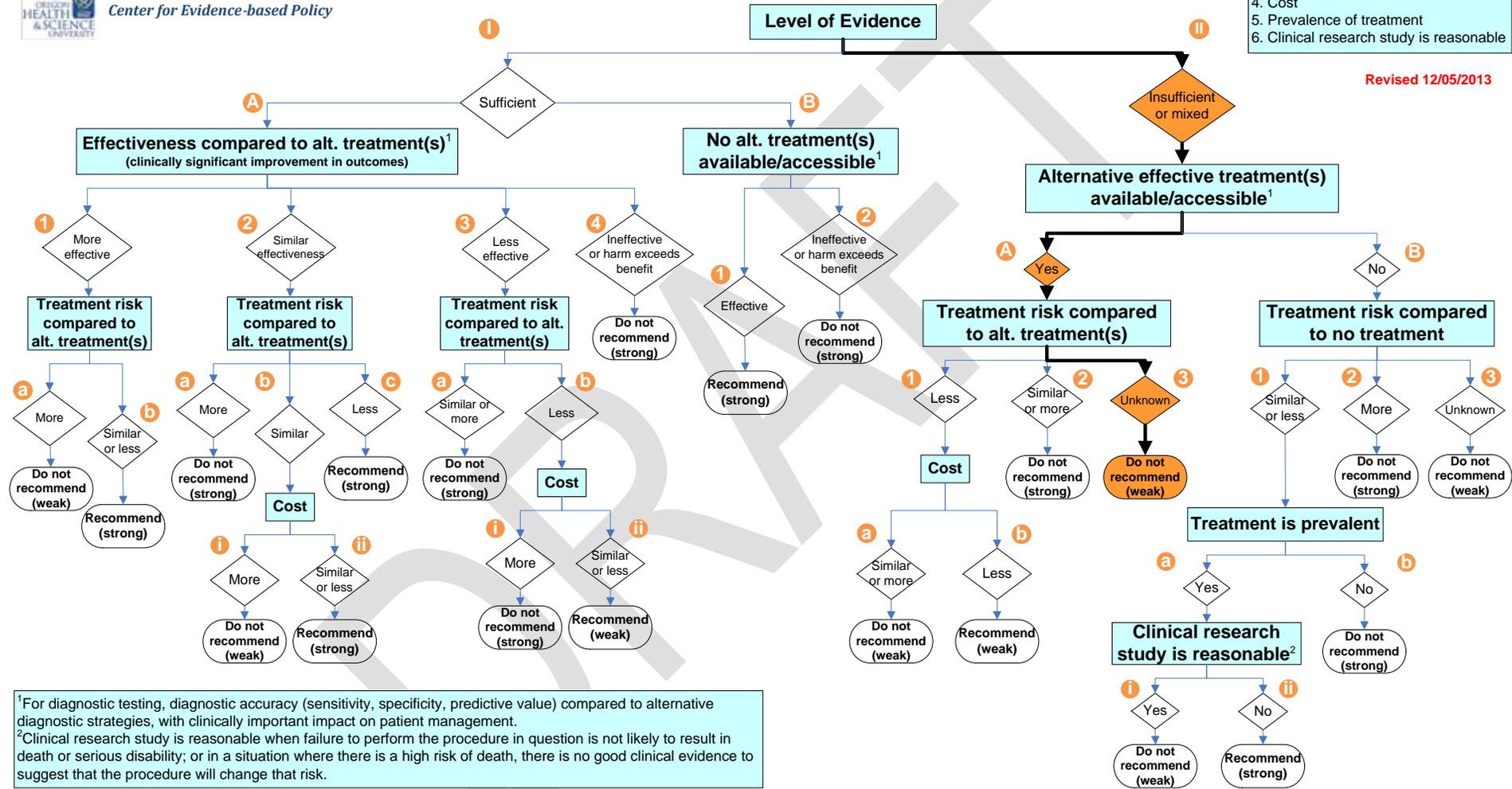


HERC Guidance Development Framework

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.

Appendix D. Guidelines Included in the WA HTA Spinal Injections Report

Hashimoto, R., Raich, A., Ecker, E., Henrikson, N., Wallace, L., Dettori, J., & Chou, R. (2011). *Spinal Injections*. Olympia, WA: Washington Health Technology Assessment Program. Retrieved from http://www.hta.hca.wa.gov/documents/spinal_injection_draft_report.pdf

Fourteen guidelines were reported in this report. Of those, five pertain to cervical pain. One of those addressed chronic pain in general, was from 2008 and could not be retrieved, therefore was not assessed further. At the request of HERC staff, the quality of the other four guidelines was rated using an instrument adapted from the Appraisal of Guidelines Research and Evaluation (AGREE) Collaboration. A summary of the pertinent recommendations and the quality rating of each guideline is presented in the table below:

Guideline	Recommendations	Quality
<p>American Society of Interventional Pain Physicians. (2009) Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain (NGC:007428). [Updated in 2013]. http://asipp.org/Guidelines.htm</p>	<p>Cervical discography is indicated only when a treatment is available to test the diagnostic hypothesis of discogenic pain of the cervical spine in individuals who have been properly selected and screened to eliminate other sources of cervical pain.</p> <p>There is good evidence for disc herniation and fair evidence for axial or discogenic pain, central spinal stenosis, and post cervical surgery syndrome. Cervical interlaminar epidural injections are indicated for these conditions with appropriate indications.</p> <p>Diagnostic cervical facet joint nerve blocks are recommended in patients with somatic or non-radicular neck pain or headache and upper extremity pain, with duration of pain of at least 3 months, without preponderance of evidence of discogenic pain, disc herniation, or evidence of radiculitis.</p> <p>There is fair evidence for conventional radiofrequency neurotomy and therapeutic facet joint nerve blocks with limited evidence for intraarticular injections. Consequently, the recommendation is that therapeutic facet joint nerve blocks or conventional radiofrequency neurotomy may be provided based on the response from controlled diagnostic blocks.</p>	<p>Poor</p>
<p>Institute for Clinical Systems Improvement. (2009). <i>Assessment and management of chronic pain</i> (NGC:007602). [Updated in 2013]. https://www.icsi.org/guidelines_more/ca</p>	<p>Examples of commonly used therapeutic procedures are as follows.</p> <p>Facet joint injection</p> <p>Facet joints are an important source of spinal pain in the cervical and lumbar regions. These joints can be reliably anesthetized by way of fluoroscopically guided joint injections. Generally, a depot corticosteroid is administered concomitantly, which may provide short-term benefit for a subset of patients. However, clinical trials have failed to demonstrate any sustained therapeutic benefits following facet joint corticosteroid injections (<i>Nelemans, 2005 [Systematic Review]</i>).</p>	<p>Poor</p>

Guideline	Recommendations	Quality
atalog_guidelines_and_more/catalog_guidelines/catalog_neurological_guidelines/pain/	<p>Percutaneous radiofrequency neurotomy</p> <p>Percutaneous radiofrequency (RF) neurotomy (sometimes erroneously referred to as facet rhizotomy) is a treatment for neck or back pain generated by facet joints. Properly selected candidates for this procedure should experience complete or nearly complete relief of their pain following fluoroscopically guided, low-volume local anesthetic blocks of the medial branch nerves that innervate the pain-generating joint(s). To minimize false-positive results, an equivalent degree of relief of appropriate pharmacologic duration should be carefully documented on two separate occasions, using two different types of local anesthetic. The radiofrequency procedure is performed by placing an insulated needle electrode with an exposed tip adjacent to and in parallel with the medial branch nerves that supply the target joint(s). Radiofrequency current applied to the electrode then heats the adjacent tissues and coagulates the nerve supply to the joint. For the procedure to be effective, multiple lesions must be performed at each nerve location, using electrodes of sufficient diameter. The nerves do regenerate over time, so pain relief is not permanent, but the procedure can be repeated.</p> <p>Radiofrequency neurotomy can provide pain relief for carefully selected patients, but this procedure should be performed only by an experienced pain medicine physician in the context of a longitudinal and comprehensive care plan. Proper patient selection and appropriate technique in positioning the radiofrequency electrodes are absolutely essential to the success of the procedure (<i>Bogduk, 2008 [Low Quality Evidence]; Nath, 2008 [Moderate Quality Evidence]; Hooten, 2005 [Guideline]</i>). Controversy in the literature regarding the efficacy of lumbar radiofrequency neurotomy has arisen from fundamentally flawed clinical trials that have used inappropriate patient selection criteria, and improper procedural technique.</p> <p>Epidural corticosteroid injections</p> <p>Epidural corticosteroid injections are one of the most commonly performed interventions for treatment of spinal pain with a radicular component. All epidural injections should be performed by an experienced physician, under fluoroscopic guidance, using contrast injection to detect vascular uptake and to demonstrate the injectate spread pattern. There are three approaches to the epidural space, including a transforaminal, intralaminar and a caudal technique. Limited evidence was found to support the efficacy of this procedure (<i>Riew, 2000 [High Quality Evidence]; Carette, 1997 [High Quality Evidence]; Dilke, 1973 [High Quality Evidence]</i>).</p> <p>Transforaminal epidural injection</p> <p>Transforaminal epidural injections can be used to determine the spinal level that is the source of radicular pain. The risks of cervical transforaminal epidural steroid injections have been well documented in case reports (<i>Beckman, 2006 [Low Quality Evidence]; Tiso, 2004</i></p>	

Guideline	Recommendations	Quality
	<p><i>[Low Quality Evidence]; Furman, 2003 [Low Quality Evidence]</i>. Specifically, cervical transforaminal epidural steroid injections have been associated with spinal cord and brain injuries resulting in permanent neurological deficits and/or death. These adverse events have been caused by uptake of particulate corticosteroids into radicular or vertebral arteries, producing embolization, severe vasospasm, and either brain or spinal cord infarction. For cervical procedures, it is recommended that only non-particulate corticosteroids be utilized. These procedures should be performed only by an experienced pain medicine physician with access to and knowledge of the use of appropriate imaging equipment and patient monitoring facilities, and should be performed only in the context of a longitudinal care plan, as directed and coordinated by a pain medicine physician (<i>Bogduk, 2008 [Low Quality Evidence]; Tiso, 2004 [Low Quality Evidence]</i>).</p>	
<p>Work Loss Data Institute. (2008). <i>Neck and upper back (acute & chronic)</i> (NGC:006563). [Updated 2011]. Unable to retrieve full guideline (subscription only). http://www.guideline.gov/content.aspx?id=33185</p>	<p>This guideline was not available without full subscription to the WLDI. Review of the summary on the NGC recommends consideration of ESI on the 4th visit, 3-4 weeks after onset of pain, only in those with neurologic findings, only for those “severe cases hoping to avoid surgery”.</p>	<p>Unable to assess quality without access to full guideline</p>
<p>Work Loss Data Institute. (2008). <i>Pain (chronic)</i> (NGC:006564). [Updated 2011]. Unable to retrieve full guideline (subscription only). http://www.guideline.gov/content.aspx?id=33188</p>	<p>This guideline was not available without full subscription to the WLDI. Review of the summary on the NGC did not specifically address neck pain, but states that epidural steroid injections and facet blocks are recommended. Additional information about indications is not provided in the NGC summary.</p>	<p>Unable to assess quality without access to full guideline</p>

Appendix E. CMS Local Coverage Decisions

L30481 Epidural and Transforaminal Epidural Injections

Original Effective Date: For services performed on or after 04/15/2010

Revision Effective Date: For services performed on or after 02/01/2014

Jurisdiction: Includes Oregon

Coverage Indications, Limitations, and/or Medical Necessity

Epidural injections are used for acute and chronic pain, in addition to cancer pain management. Epidural injections are utilized both for diagnostic and therapeutic purposes.

A multi-disciplinary or collaborative comprehensive evaluation (e.g. orthopedics, neurologist, neurosurgeon, physiatrist, anesthesiologist, pain medicine specialist, and/or attending physician), is recommended prior to initiating a trial of these injections for relief of chronic recurrent pain.

Epidural steroid injections, both interlaminar/translaminar and transforaminal should be used only in the presence of radiculopathy.

Indications for Diagnostic and Therapeutic Epidural Injections

Diagnostic interlaminar/translaminar or caudal epidural steroid injections are seldom used. Although the medication injected can sometimes be confined to a limited area, bilateral effects and spread to adjacent levels often occur.

Therapeutic interlaminar/translaminar or caudal epidural injections and infusions of opioid, local anesthetic, or other medications may be used for the treatment of acute and chronic pain or cancer pain.

Epidural injections (interlaminar/translaminar or caudal) may be used for the following.

- Acute obstetric, post traumatic and postoperative pain
- Advanced cancer pain, primary or metastatic
- Acute/sub acute and chronic pain syndrome including cervical, thoracic and lumbar pain with radiculopathy and intervertebral disc disease (with neuritis or radiculitis) with or without myelopathy that has failed to respond to adequate conservative management.
- Nerve root injuries and neuropathic pain and post traumatic including post laminectomy syndrome (failed back syndrome).
- Spinal cord myelopathy
- Complex regional pain syndrome
- Epidural scarring from prior infection, hemorrhage and/or surgery

- Multiple rib fractures
- Vertebral compression fractures
- Post herpetic neuralgia and herpes zoster
- Phantom limb pain

Indications for Diagnostic and Therapeutic Transforaminal Epidural Injections

Transforaminal epidural injection is a selective injection of the cervical, thoracic, lumbar or sacral nerve roots with proximal spread of contrast or local anesthetic through the neural foramen to the epidural space. With the aid of fluoroscopic or computed tomography (CT) imaging, the needle tip is placed within or adjacent to the lateral margin of the neural foramen and contrast material is injected to obtain a neurogram and visualize spread of the injected solution.

A small volume of local anesthetic is injected (less than or equal to 1.0 ml) in order to perform a diagnostic reproducible blockade of a specific nerve root. The diagnostic usefulness is lost if more than 1.0 ml of local anesthetic is injected (the block becomes unreliable since the spread of anesthetic to adjacent levels and structures likely occurs).

Diagnostic transforaminal epidural injections are appropriate for the following purposes.

- To differentiate the level of radicular nerve root pain.
- To differentiate radicular from non radicular pain
- To evaluate a discrepancy between imaging studies and clinical findings
- To identify the source of pain in the presence of multi-level nerve root compression
- To identify the level of pathology at a previous operative site

It might be necessary to perform injections at two different nerve root levels on the same date of service. When multiple levels of nerve root compression or stenosis is suspected to be responsible for the patient's symptoms, presence of the compression or stenosis on imaging studies should be documented in the medical record.

Therapeutic transforaminal epidural injections are appropriate for the following purposes:

Corticosteroid can be added as a therapeutic measure. Injections for therapeutic reasons can be of greater volume. The transforaminal injection can be performed for diagnostic, therapeutic or both purposes.

- Radicular pain resistant to more conservative measures or when surgery is contraindicated.
- Post-decompressive radiculitis or post surgical scarring

- Monoradicular pain, confirmed by diagnostic block in which a surgically correctible lesion cannot be identified
- Treatment of acute herpes zoster or post herpetic neuralgia

General Indications and Limitations

Epidural (interlaminar/translaminar or caudal) and transforaminal epidural corticosteroid injections should not exceed a series of three, per spinal region, within a six-month period when used as treatment for a pain disorder other than treatment for cancer pain. These may be performed at intervals of one week or greater. With each subsequent injection the medical record should clearly document the interval effects from the prior injection(s). Appropriate reasons for a repeat injection are: (a) significant improvement in the patient's symptoms from the prior injection, even if relapsed, or (b) carefully documented technical reasons that it is appropriate to repeat the procedure even if no prior improvement and (c) patients with persistent pain in whom the imaging findings suggest that the pathology should respond to corticosteroid injection. In the absence of a compelling technical reason, it is not appropriate to repeat a procedure a third time if there has been no improvement from the two preceding.

If corticosteroids are used, consideration should be given to the potential complications of repetitive corticosteroid administration.

Many of these procedures, such as those in the peri-operative period, may not require fluoroscopy.

For treatment of chronic pain, the standard of care is that these procedures be performed under fluoroscopic or CT guided imaging. Therefore injections for chronic pain performed without imaging guidance will be considered not medically necessary.

Fluoroscopic guidance **must** be utilized in the performance of single nerve root/transforaminal injections to ensure the precise placement of the needle and medications injected.

Anti-spasmodic drugs administered intrathecally (e.g., baclofen) to treat chronic intractable spasticity are addressed in the Infusion Pump NCD Pub. 100-3 Sec. 280.14. The CPT description of procedure codes 62310, 62311, 62318 and 62319 include anesthetic, antispasmodic, opioid, steroid, other solution; therefore the spasticity conditions are included in this LCD.

[L33842 Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy](#)

Original Effective Date: For services performed on or after 03/05/2014

Revision Effective Date: For services performed on or after 03/05/2014

Jurisdiction: Oregon

Coverage Indications, Limitations, and/or Medical Necessity

Introduction:

This policy does not address sacral conditions or injections or neurotomies. Sacral injections, identified on the claim by the ICD-9 code 724.6, are not subject to the requirements of this LCD.

Facet joints are paired diarthrodial articulations of the superior and inferior articular processes of adjacent vertebrae. The medial branches (MB) of the dorsal rami of the segmental nerves innervate facet joints and the MB nerves from the two adjacent dorsal rami innervate each joint. [Exceptions to this rule are the C2-3 facet joint, which is innervated by the third occipital nerve; and the L5-S1 facet joint, which is innervated by the L4 MB and the L5 dorsal ramus.]

Facet joint injection techniques are used in the diagnosis and/or treatment of chronic neck and back pain. However, the evidence of clinical efficacy and utility has not been well-established in the medical literature, which is replete with non-comparable and inadequately designed studies. Further, there is a singular dearth of long-term outcomes reports. This is particularly problematic given the steroid dosages administered. These drugs alone may develop the relief experienced by patients but are associated with serious adverse health events and could as well be administered orally. Hence, ongoing coverage requires outcomes reporting as described in this LCD to allow future analysis of clinical efficacy.

Definitions

- A zygapophyseal (aka facet) joint “level” refers to the zygapophyseal joint or the two medial branch (MB) nerves that innervate that zygapophyseal joint.
- A “session” is defined as all injections/blocks/RF procedures performed on one day and includes medial branch blocks (MBB), intraarticular injections (IA), facet cyst ruptures, and RF ablations.
- A “region” is all injections performed in cervical/thoracic or all injections performed in lumbar (not sacral) spinal areas.
- “Diagnosis” of facet-mediated pain requires the establishment of pain relief following dual medial branch blocks (MBBs) performed at different sessions.

Neither physical exam nor imaging has adequate diagnostic power to confidently distinguish the facet joint as the pain source.

Indications

- Patient must have history of at least 3 months of moderate to severe pain with functional impairment and pain is inadequately responsive to conservative care such as NSAIDs, acetaminophen, physical therapy (as tolerated).
- Pain is predominantly axial and not associated with radiculopathy or neurogenic claudication.
- There is no non-facet pathology that could explain the source of the patient's pain, such as fracture, tumor, infection, or significant deformity.
- Clinical assessment implicates the facet joint as the putative source of pain.

General Procedure Requirements:

- Pre-procedural documentation must include a complete initial evaluation including history and an appropriately focused musculoskeletal and neurological physical examination. There should be a summary of pertinent diagnostic tests or procedures justifying the possible presence of facet joint pain.
- A procedure note must be legible and include sufficient detail to allow reconstruction of the procedure. Required elements of the note include a description of the techniques employed, nerves injected and sites(s) of injections, drugs and doses with volumes and concentrations as well as pre and post-procedural pain assessments. With RF neurotomy, electrode position, cannula size, lesion parameters, and electrical stimulation parameters and findings must be specified and documented.
- Facet joint interventions (diagnostic and/or therapeutic) must be performed under fluoroscopic or computed tomographic (CT) guidance. Facet joint interventions performed under ultrasound guidance will not be reimbursed.
- A hard (plain radiograph with conventional film or specialized paper) or digital copy image or images which adequately document the needle position and contrast medium flow (excluding RF ablations and those cases in which using contrast is contra-indicated, such as patients with documented contrast allergies), must be retained and submitted if requested.
- In order to maintain target specificity, total IA injection volume must not exceed 1.0 mL per cervical joint or 2 mL per lumbar joint, including contrast. Larger volumes may be used only when performing a purposeful facet cyst rupture in the lumbar spine.
- Total MBB anesthetic volume shall be limited to a maximum of 0.5 mL per MB nerve for diagnostic purposes and 2ml for therapeutic. For a third occipital nerve block, up to 1.0 mL is allowed for diagnostic and 2ml for therapeutic purposes.

- In total, no more than 100 mg of triamcinolone or methylprednisolone or 15 mg of betamethasone or dexamethasone or equivalents shall be injected during any single injection session.
- Both diagnostic and therapeutic facet joint injections may be acceptably performed without steroids.

Provider Qualifications

Provider Qualifications' requirements must be met. Patient safety and quality of care mandate that healthcare professionals who perform Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy are appropriately experienced and/or trained to provide and manage the services. The CMS Manual System, Pub. 100-8, Program Integrity Manual, Chapter 13, Section 5.1 (<http://www.cms.hhs.gov/manuals/downloads/pim83c13.pdf>) underscores this point and states that "reasonable and necessary" services must be "ordered and/or furnished by qualified personnel." Services will be considered medically reasonable and necessary only if performed by appropriately experienced and/or formally trained providers.

The following training requirement applies only to those providers who have not provided these specific interventional pain management services on a regular basis (at least two times per month) during the ten years prior to the effective date of this LCD as may be established by claims billings. A basic requirement of payment is training and/or credentialing by a formal residency/fellowship program and/or other training program that accredited by a nationally-recognized body and whose core curriculum includes the performance and management of the procedures addressed in this policy. Recognized accrediting bodies include only those whose program accreditation gains the trainee eligibility to sit for a healthcare-related licensing exam or licensing itself, which in turn allows the licensee to perform these procedures. At a minimum, training must cover and develop an understanding of anatomy and drug pharmacodynamics and kinetics, the technical performance of the procedure(s) and utilization of the required associated imaging modalities, and the diagnosis and management of potential complications from the intervention.

The following credentialing requirement applies to all providers of the services addressed in this policy. If the practitioner works in a hospital facility at any time and/or is credentialed by a hospital for any procedure, the practitioner must be credentialed to perform the same procedure in the outpatient setting.

Diagnostic Facet Joint Injections

- Dual MBBs are necessary to diagnose facet pain due to the unacceptably high false positive rate of single MBB injections.

- A second confirmatory MBB is allowed if documentation indicates the first MBB produced $\geq 80\%$ relief of primary (index) pain and duration of relief is consistent with the agent employed.
- Intraarticular facet block will not be reimbursed as a diagnostic test unless medial branch blocks cannot be performed due to specific documented anatomic restrictions.

Therapeutic Injections

- Medial Branch Blocks may provide temporary or long-lasting or permanent relief of facet-mediated pain. Injections may be repeated if the first MBB results in significant pain relief ($> 50\%$) for at least 3 months. (See Limitations section for total number of injections that may be performed in one year.)
- Intraarticular injections may be covered for treatment of defined facet pain a) above or below a posterior spinal fusion when technical performance of MBBs is precluded, and/or b) when thermal RF neurotomy is precluded due to an implantable spinal cord stimulator or cardiac pacemaker or c) for rupture of symptomatic synovial cyst. Injections for these conditions and for axial pain with an arthritic joint may be repeated if the first intraarticular injection results in significant pain relief ($> 50\%$) for at least 3 months. (See Limitations section for total number of injections that may be performed in one year.)
- Recurrent pain at the site of previously diagnosed facet pain (dual MBBs) may be treated without additional diagnostic blocks if $> 50\%$ pain relief from the previous blocks lasted at least 3 months.

Thermal Medial Branch Radiofrequency Neurotomy (includes RF and microwave technologies):

- Only when dual MBBs provide $\geq 80\%$ relief of the primary or index pain and duration of relief is consistent with the agent employed may facet joint denervation with RF medial branch neurotomy be considered.
- Repeat denervation procedures involving the same joint will only be considered medically necessary if the patient experienced $\geq 50\%$ improvement of pain and improvement in patient specific ADLs documented for at least 6 months.

Limitations of Coverage:

- A maximum of five (5) facet joint injection sessions inclusive of medial branch blocks, intraarticular injections, facet cyst rupture and RF ablations may be performed per year in the cervical/thoracic spine and five (5) in the lumbar spine.
- For each covered spinal region (cervical/thoracic or lumbar), no more than two (2) thermal RF sessions will be reimbursed in any calendar year, involving no more than four (4) joints per session, e.g., two (2) bilateral levels or four (4) unilateral levels.

- Neither conscious sedation nor Monitored Anesthesia Care (MAC) is routinely necessary for intraarticular facet joint injections or medial branch blocks and are not routinely reimbursable. Individual consideration may be given for payment in rare unique circumstances if the medical necessity of sedation is unequivocal and clearly documented.
- Non-thermal RF modalities for facet joint denervation including chemical, low grade thermal energy (<80 degrees Celsius), as well as pulsed RF are not covered.
- Intraarticular and/or extraarticular facet joint prolotherapy is not covered.

DRAFT

Percutaneous Interventions for Cervical Spine Pain

Question: How should the HTAS Coverage Guidance regarding percutaneous interventions for cervical spine pain be applied to the Prioritized List?

Question source: Health Technology Assessment Subcommittee

Issue: HTAS approved a new Coverage Guidance at their July, 2014 meeting, and it is pending final approval by HERC at their January, 2015 meeting. The summary of the coverage guidance is shown below:

HERC COVERAGE GUIDANCE

Therapeutic cervical spinal epidural injections are recommended for coverage for cervical spine pain with radiculopathy of six weeks duration (*weak recommendation*) only when all of the following criteria are met:

- documented neuroforaminal stenosis (without infection or neoplasia)
- radicular pain in a corresponding dermatomal distribution,
- pain is intractable and conservative therapy has failed,
- fluoroscopic guidance or CT guidance is utilized,
- interlaminar approach is utilized,
- no more than two injections without clinically meaningful improvement in pain and function, and
- maximum of three injections in six months.

Epidural steroid injections of the cervical spine are not recommended for coverage (*strong recommendation*) for other types of neck pain or for headache.

Therapeutic cervical intraarticular facet joint injections and therapeutic cervical medial branch blocks are not recommended for coverage for facet joint pain (*strong recommendation*).

Facet joint radiofrequency neurotomy is recommended for coverage (*weak recommendation*) only when all the following criteria are met:

- at least 3 months of moderate to severe pain with functional impairment,
- pain is predominantly axial and not associated with radiculopathy,
- conservative therapy has failed, and
- complete or nearly complete pain relief (80% or greater) following fluoroscopically guided, low-volume local anesthetic blocks of the medial branch nerves, performed on two separate occasions using two commonly-used agents with different anticipated durations of action.

Percutaneous Interventions for Cervical Spine Pain

This coverage guidance was discussed at the August VBBS meeting, and clarification was requested of the level of evidence required to take a service off of the Ancillary List. The HERC responded to the VBBS that procedures on the Ancillary or other DMAP lists were not subject to the same higher level of evidence required for removal from the Prioritized List.

This coverage guidance was brought back to the November, 2014 VBBS meeting. At that time, the VBBS indicated a desire to exclude all of the services in the coverage guidance. However, the VBBS requested clarification from the HERC about whether the VBBS could reject another subcommittee's recommendations. VBBS felt that due to the conflict between the VBBS and HTAS, that the full HERC should make the determination of placement of the codes in this coverage guidance. The HERC felt strongly that VBBS has full purview over the Prioritized List, and if the VBBS feels that other subcommittee's decisions should not be adopted for the List, then the VBBS should feel comfortable in making this decision. The HERC will then review for final approval. HTAS and EGBS, when writing coverage guidances, have a larger audience than the Prioritized List, including private payers and others in the state.

HERC staff recommendations:

- 1) Add 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) to the Non-Covered List
 - a. Advise DMAP to remove 63210 from the Ancillary List
- 2) 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 List
- 3) Add an entry to the new "Non-Covered List" table for CPT 63210, 64633-64634, 64479-64480, 64490-64495

Percutaneous Interventions for Cervical Spine Pain

Appendix—materials previously provided to the VBBS

Current Prioritized List status (note: line numbers refer to January 1, 2015 Prioritized List)

CODES	DESCRIPTION	LOCATION	STAFF RECOMMENDATION
ICD-9 Diagnosis Codes			
720.9	Unspecified inflammatory spondylopathy	50 RHEUMATOID ARTHRITIS AND OTHER INFLAMMATORY POLYARTHROPATHIES	No change
721	Spondylosis , various	412 SPINAL DEFORMITY, CLINICALLY SIGNIFICANT <i>OR</i> 545 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT	No change
722	Degeneration/displacement intervertebral disc, various	374 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT 545	No change
723	Spinal stenosis, brachial neuritis or radiculitis, various	412 515 PERIPHERAL NERVE DISORDERS Therapy: MEDICAL THERAPY 541 PERIPHERAL NERVE DISORDERS Therapy: SURGICAL TREATMENT 545 588 SPINAL DEFORMITY, NOT CLINICALLY SIGNIFICANT	No change
724	Spinal stenosis, various	374,412,545,588	No change
738.4	Acquired spondylolisthesis	588	No change
ICD-10 Diagnosis Codes			
M43.00-3	Spondylolysis	588	No change
M43.10-3	Spondylolisthesis	588	No change
M47.10-3	Other spondylosis with myelopathy	412	No change
M47.20-3	Other spondylosis with radiculopathy	374	No change
M47.811-3, M47.819	Spondylosis without myelopathy or radiculopathy	545	No change
M47.891-3	Other spondylosis	545	No change
M48.00-3	Spinal stenosis	412,588	No change
M50	Cervical disc disorders	374	No change

Percutaneous Interventions for Cervical Spine Pain

M54.10-3	Radiculopathy	374	No change
M54.2	Cervicalgia	374,545	No change
CPT Codes			
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	Ancillary	Add to lines 374,412, 545,588 with a new guideline note Advise DMAP to remove from the Ancillary List
64479-80	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance; cervical or thoracic, single level and each additional	Excluded	Keep Excluded Add entry to new excluded list
64490-64492	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (flouro or CT), cervical, thoracic, lumbar or sacral; single, second or third level	Excluded	Add 64490-64492 to lines 412,545,588 with a new guideline note Advise DMAP to remove 64490-64492 from the Excluded List
64633-64634	Destruction by neurolytic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (flouro or CT), cervical, thoracic, lumbar or sacral; single, second or third level	Excluded	Add 64633 and 64634 to lines 412, 545,588 with a new guideline note Advise DMAP to remove 64633 and 64634 from the Excluded List
0213T–0215T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical, thoracic, lumbar or sacral; single, second or third level	Excluded	No change
77003	Fluoroguide for spine injection	Ancillary	No change

Percutaneous Interventions for Cervical Spine Pain

Relevant Guidelines

GUIDELINE NOTE 37, DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT

Lines 374,545

Diagnoses are included on Line 374 when 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.

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

Percutaneous Interventions for Cervical Spine Pain

Possible cause	Key features on history or physical examination	Imaging*	Additional studies*
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
	<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 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.

Utilization data:

Based on claims data analysis for the past 6 months, 63210 paired with diagnoses from the following lines (January 1, 2015 PL):

154 CERVICAL VERTEBRAL DISLOCATIONS/FRACTURES, OPEN OR CLOSED; OTHER VERTEBRAL DISLOCATIONS/FRACTURES, OPEN OR UNSTABLE; SPINAL CORD INJURIES WITH OR WITHOUT EVIDENCE OF VERTEBRAL INJURY

374 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT

412 SPINAL DEFORMITY, CLINICALLY SIGNIFICANT

484 CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT NEUROLOGIC INJURY OR STRUCTURAL INSTABILITY

515 PERIPHERAL NERVE DISORDERS

545 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT

588 SPINAL DEFORMITY, NOT CLINICALLY SIGNIFICANT

612 DISORDERS OF SOFT TISSUE

Percutaneous Interventions for Cervical Spine Pain

HERC staff recommended guidelines presented at the August VBBS meeting with meeting edits

GUIDELINE NOTE XXX CERVICAL SPINAL EPIDURAL INJECTIONS

Lines 374,412,545,588

Cervical spinal epidural injections (CPT 62310) are **not** included on these lines for use in diagnostic testing.

Cervical spinal epidural injections (CPT 62310) for therapeutic purposes are included on these [lines](#) for cervical spine pain with radiculopathy of 6 weeks duration when all of the following criteria are met:

- 1) documented neuroforaminal stenosis (without infection or neoplasia)
- 2) radicular pain in a corresponding dermatomal distribution,
- 3) pain is intractable and conservative therapy has failed,
- 4) fluoroscopic guidance or CT guidance is utilized,
- 5) interlaminar approach is utilized,
- 6) no more than two injections without clinically meaningful improvement in pain and function, AND
- 7) maximum of three injections in six months.

Epidural steroid injections of the cervical spine are not included on these lines for treatment of other types of neck pain or for headache.

GUIDELINE NOTE XXX [Cervical](#) FACET JOINT RADIOFREQUENCY NEUROTOMY AND DIAGNOSTIC INJECTIONS

Lines 412,545,588

[Cervical medial branch block](#) [Paravertebral facet joint diagnostic](#) injections (CPT 64490-64492) are included on these lines only when done as a diagnostic precursor to facet joint radiofrequency neurotomy as specified in #4 below.

[Cervical](#) Facet joint radiofrequency neurotomy (CPT 64633, 64634) is included on these lines only when all the following criteria are met:

- 1) at least 3 months of moderate to severe pain with functional impairment,
- 2) pain is predominantly axial and not associated with radiculopathy,
- 3) conservative therapy has failed, and
- 4) complete or nearly complete pain relief (80% or greater) following fluoroscopically guided, low-volume local anesthetic blocks of the medial branch nerves, performed on two separate occasions using two commonly-used agents with different anticipated durations of action.

[Thoracic, lumbar and sacral paravertebral facet joint diagnostic injections and radiofrequency neurotomy are not included on these lines.](#)

HERC Coverage Guidance – Percutaneous Interventions for Cervical Spine Pain Disposition of Public Comments

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Commenters

Identification	Stakeholder
A	North American Spine Society (NASS), Burr Ridge, IL <i>[Submitted June 6, 2014]</i>

HERC Coverage Guidance – Percutaneous Interventions for Cervical Spine Pain Disposition of Public Comments

Public Comments

Ident.	#	Comment	Disposition
A	1	<p>NASS agrees with a majority of the HERC guidance regarding coverage for therapeutic cervical spinal epidural injections for chronic cervical pain with radiculopathy. Regarding indications, in addition to the documentation of herniated intervertebral disc, other anatomic causes of radiculopathy should also be included such as:</p> <ul style="list-style-type: none"> • Neuroforaminal stenosis; • Central stenosis, disc protrusions; and/or • Segmental spondylosis with radicular pain. <p>NASS strongly agrees that all cervical epidural injections or selective nerve root blocks should be performed with fluoroscopic or CT-guidance.</p>	<p>Thank you for taking the time to comment.</p> <p>HTAS acknowledges that there are other anatomic causes of radiculopathy and has changed the criteria in the coverage recommendation to the following: “documented neuroforaminal stenosis (without infection or neoplasia)”</p>
	2	<p>NASS would like to clarify also that an epidural injection can be appropriately performed by either an interlaminar approach or a transforaminal approach. The HERC reference to a translaminar approach is incorrect as there is no translaminar approach with these injections and the terminology to reference either an interlaminar or a transforaminal approach should be corrected in your policy guidance.</p> <p>NASS also wishes to clarify, as referenced in your policy, the utility of diagnostic spinal nerve (root) blocks in the treatment and/or diagnosis of cervical radicular pain. These blocks use a foraminal approach and share the same CPT codes (64479-64480) as the technically similar transforaminal epidural injection.</p>	<p>These terms translaminar and interlaminar are used interchangeably in the WA HTA report and in CMS coverage decisions. Terminology changed to reflect your suggestions in the body of the guidance; however, when this term is used in coverage policies, no change has been made.</p> <p>The diagnostic blocks referred to in the coverage guidance are medial branch blocks, and the CPT codes utilized (64490-2) are different than those referred to by the commenter. Diagnostic spinal nerve root blocks (64479-80) were not reviewed in this document. Text in the guidance document has been clarified and</p>

HERC Coverage Guidance – Percutaneous Interventions for Cervical Spine Pain Disposition of Public Comments

Ident.	#	Comment	Disposition
			CPT codes added.
	3	Although many patients may respond to conservative treatment (rest, NSAIDs, PT), in patients with moderate to severe radicular pain with resulting functional limitations (i.e., inability to work, etc.) and appropriate correlated imaging findings, cervical epidural injections are indicated in the acute and sub-acute phases of treatment and is an appropriate conservative treatment option in this patient population.	All studies in the evidence review included only patients with chronic neck pain. When this was defined, it was pain of > 6 months duration or more. The background section of this document reports the definition of chronic to be greater than 3 months. HTAS has revised the box language to specify that coverage is recommended for pain of at least 6 weeks duration.
	4	NASS would like to recommend the Health Evidence Review Commission to include a transparent evidentiary table that will allow users to access and review available supporting literature as well as provide a definition of chronic for further clarification.	Links to the supporting literature, when publically available, are provided on page 2 of the guidance document. See comment 3 regarding definition of chronic.
	5	Please click on the link below for the NASS coverage recommendations on cervical epidural injections and diagnostic spinal nerve blocks for your reference: https://www.spine.org/Pages/PolicyPractice/Coverage/CoverageRecommendations.aspx	Thank you for providing this information.

HERC Coverage Guidance – Percutaneous Interventions for Cervical Spine Pain Disposition of Public Comments

References Provided by Commenters

Commenter	References
A	NASS. (2014). Cervical Epidural Injections And Diagnostic Spinal Nerve Block. https://www.spine.org/Documents/PolicyPractice/CoverageRecommendations/CervicalEpiduralInjections.pdf

DRAFT



Advanced Imaging for Staging of Prostate Cancer

Advanced Imaging for Staging of Prostate Cancer

Primary evidence source:

National Institute for Health and Clinical Excellence. (2014). *Prostate Cancer: diagnosis and treatment*. London: National Institute for Health and Clinical Excellence. Retrieved from <http://guidance.nice.org.uk/CG175/Guidance>

Two additional sources:

- 1 Medicare NCD Manual,
- 1 Guideline – NCCN Clinical Practice Guideline in Oncology (Prostate Cancer)

Advanced Imaging for Staging of Prostate Cancer Evidence Summary

- When determining when and how to image an individual, men with localized prostate cancer should be stratified into risk groups based on:
 - PSA level
 - Gleason score
 - Clinical stage

Advanced Imaging for Staging of Prostate Cancer Evidence Summary

- There is insufficient evidence to support the routine use of CT of the pelvis in men with low- or intermediate-risk localized prostate cancer
 - CT is considered inferior to MRI in this clinical situation

Advanced Imaging for Staging of Prostate Cancer Evidence Summary

- The evidence is insufficient to determine whether staging with MRI improve outcomes in men with prostate cancer
- There is low SOE that staging with MRI can result in change in management, and a very low SOE that MRI results in up-staging or down-staging a highly variable proportion of patients
- Most studies found staging with MRI more sensitive than staging with DRE or TRUS, but not consistently more specific or accurate

Advanced Imaging for Staging of Prostate Cancer Evidence Summary

- Two systematic reviews on role of radioisotope bone scans in staging of newly diagnosed prostate cancer.
 - One review found that serum PSA level and risk of a positive bone scan were strongly correlated.
 - The other review concluded that PSA level was the best means of identifying those at risk of a positive bone scan and that men with PSA < 10 ng/ml were unlikely to have a positive bone scan.

Advanced Imaging for Staging of Prostate Cancer Evidence Summary

- No direct evidence about influence of radioisotope bone scans on timing of systemic treatment or frequency of clinical follow-up in men for whom radical treatment is not intended.
 - Two small case series found extensive disease on bone scan was an adverse prognostic factor for survival.
 - There is observational evidence that extensive disease on bone scan is an independent risk factor for spinal cord compression in men without functional neurological impairment.

Advanced Imaging for Staging of Prostate Cancer Evidence Summary

- There is insufficient evidence to support the use of PET for any stage of prostate cancer

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: ADVANCED IMAGING FOR STAGING OF PROSTATE CANCER

DRAFT for 1/8/2015 VbBS and HERC meeting materials

HERC Coverage Guidance

To determine risk status and treatment options, prostate cancer clinical staging that includes PSA level and prostate biopsy with Gleason score is recommended for coverage. MRI is recommended for coverage for men with histologically proven prostate cancer if knowledge of the T or N stage could affect management. *(strong recommendation)*

CT of the pelvis is not recommended for coverage in men with low- to intermediate-risk localized prostate cancer, unless MRI is contraindicated. *(strong recommendation)*

Radionuclide bone scanning is not recommended for routine coverage in men with localized prostate cancer. *(weak recommendation)*

Radionuclide bone scanning is recommended for coverage when hormone therapy is being deferred (through watchful waiting) in asymptomatic men who are at high risk of developing bone complications. *(strong recommendation)*

PET imaging is not recommended for coverage in prostate cancer. *(strong recommendation)*

Note: Definitions for strength of recommendation are provided in Appendix B 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

National Institute for Health and Clinical Excellence. (2014). *Prostate Cancer: diagnosis and treatment*. London: National Institute for Health and Clinical Excellence. Retrieved from <http://guidance.nice.org.uk/CG175/Guidance>

Additional sources

Medicare National Coverage Determinations Manual: Chapter 1, Part 4 (Sections 200-310.1).
Retrieved from http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf on 11/11/14.

NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 1.2015. Retrieved from http://www.nccn.org/professionals/physician_gls/PDF/prostate.pdf on 11/11/14.

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

EVIDENCE OVERVIEW

Clinical background

Prostate cancer is the most common cancer in men and makes up 26% of all male cancer diagnoses in the United Kingdom. It is predominantly a disease of older men (aged 65–79 years) but around 25% of cases occur in men younger than 65. There is also higher incidence of and mortality from prostate cancer in men of black African-Caribbean family origin compared with white Caucasian men.

Prostate cancer is usually diagnosed after a blood test in primary care has shown elevated prostate-specific antigen (PSA) levels. The introduction of PSA testing has significantly reduced the number of men presenting with metastatic cancer since the 1980s. Most prostate cancers are now either localized or locally advanced at diagnosis, with no evidence of spread beyond the pelvis.

A number of treatments are available for localized disease, including: active surveillance, radical prostatectomy, external beam radiotherapy and brachytherapy. Hormone therapy (androgen deprivation or anti-androgens) is the usual primary treatment for metastatic prostate cancer, but is also increasingly being used for men with locally advanced, non-metastatic disease.

The TNM classification is used to stage prostate cancer (see Appendix A). It describes the extent of the primary tumor (T stage), the absence or presence of spread to nearby lymph nodes (N stage) and the absence or presence of distant spread, or metastasis (M stage). The clinical stage is determined from information that is available without surgery. The pathologic stage is based on the surgical removal and histological examination of the entire prostate gland, the seminal vesicles and surrounding structures and, if relevant, pelvic lymph nodes. The management of prostate cancer will depend on the TNM stage of the disease as well as both

biochemical information (e.g. PSA) and pathological information (e.g. Gleason score), which have prognostic value. The optimum treatment for a man with prostate cancer requires an assessment of the risk of metastatic spread as well as the risk of local recurrence. For this, the results of imaging can be assessed in the light of information from clinical nomograms.

EVIDENCE REVIEW

Men newly diagnosed with prostate cancer can initially be stratified into those for whom radical treatment is a possibility and those for whom it is not appropriate. The decision about treatment intent will be based on the man's life expectancy, his values, and the anticipated clinical course of the prostate cancer.

Recommendations:

- Determine the provisional treatment intent (radical or non-radical) before decisions on imaging are made.
- Do not routinely offer imaging to men who are not candidates for radical treatment.

Qualifying statement: There was guideline development group (GDG) consensus, in the absence of any research evidence, that this will reduce the amount of inappropriate investigation. The cost effectiveness of routine magnetic resonance imaging MRI could not be concluded.

Both the clinical presentation and the treatment intent influence the decision about when and how to image the individual. The risk of recurrence of prostate cancer after definitive local treatment is the basis for the stratification of men with localized prostate cancer into risk groups: low, intermediate and high (see Table 1). The recommendations for imaging of localized disease are similarly based on these prognostic groups.

Table 1

Level of risk	PSA		Gleason Score		Clinical stage
Low	< 10 ng/ml	And	≤ 6	And	T1-T2a
Intermediate	10-20 ng/ml	Or	7	Or	T2b
High	>20 ng/ml	Or	8-10	Or	≥ T2c

Imaging may inform the choice between different radical treatments (for example by determining whether the cancer has extended beyond the prostatic capsule). It also assists in the identification of metastatic disease thereby leading to more appropriate treatment options.

Imaging for T-staging and N-staging

The T-stage involves the assessment of the local extent of the primary tumor in the prostate and its relationship to surrounding structures. Using imaging to distinguish between T1 and T2 cancers does not usually affect treatment. But if radical treatment is being considered, it is important to decide whether a tumor is T2 (confined within the prostate) or T3/T4 (spread

outside the prostate). MRI is now the commonly used imaging technique for T-staging men with prostate cancer. Many of the original publications used now-outdated MRI technology, and the accuracy reported for MRI is improving. After transrectal prostate biopsy, intra-prostatic hematoma can affect image interpretation for at least four weeks. It is important to know the nodal status of men with localized disease, as the spread of cancer to the pelvic lymph nodes will affect the choice of treatment. Partin's Tables (Partin et al. 2001) are the most commonly used clinical nomograms for determining the risk of nodal spread. Currently, imaging is of some value for N-staging because computed tomography (CT) and conventional MRI rely on size criteria to assess the likelihood of metastatic spread to the lymph nodes. CT cannot characterize the internal architecture of an enlarged node and MRI is only able to provide partial information. Newer MRI contrast agents such as superparamagnetic iron oxide (SPIO) may improve the overall specificity of MRI for evaluating lymph nodes but are not yet routinely available.

Recommendation:

- Do not offer CT of the pelvis to men with low- or intermediate-risk localized prostate cancer (see Table 1).

Qualifying statement: There is not enough evidence to support the routine use of CT in men with intermediate-risk disease and it is considered inferior to MRI in this clinical situation.

No studies measuring the impact of diagnostic imaging on patient outcomes were found; instead most studies were of diagnostic test accuracy.

Two studies showed better staging accuracy with MRI than with CT. Other systematic reviews have considered the staging accuracy of MRI and CT separately. There was contradictory evidence, from small observational studies, about the benefit of adding of magnetic resonance spectroscopy (MRS) to MRI. There was consistent evidence, from observational studies, that MRI tumor stage was a prognostic factor for PSA relapse. One of the studies, however, concluded that MRI tumor staging only added clinically meaningful information for men at intermediate pre-treatment risk of PSA relapse. MRI tumor stage did not stratify PSA failure risk well enough to guide clinical decision making for other patients.

Clinical question: Does staging with MRI improve outcomes in men with prostate cancer?

Biochemical recurrence-free survival

One study provided very low quality evidence of no significant difference in the proportion of patients experiencing biochemical recurrence between those which had undergone imaging and those which had not ($p=0.50$). However, the study was not limited only to those patients who underwent MRI (18%) and included patients who had received computerized tomography (81%) and bone scans (73%), with many patients receiving more than one type of imaging. [Very low strength of evidence (SOE).]

Overall survival, treatment-related morbidity, and health-related quality of life

No studies reported overall survival, treatment-related morbidity, or health-related quality of life.

Clinical question: In which patients with prostate cancer will MRI staging alter treatment?

Four studies reported change in management following MRI, 23 reported change in staging following MRI, and eight reported the diagnostic accuracy of both clinical and MRI staging, using radical prostatectomy as reference standard. All studies were of low to very low quality evidence, with most (96%) considered unrepresentative of the patients who would receive MRI in practice. Many (68%) of the studies also used MRI as the reference standard which may not have classified the target condition correctly. A number of pre-specified sub-groups were available for analyses.

Change in management

Two studies found a change in the management of radiotherapy strategy following MRI in 31% and 9% of patients. Two further studies found a change in surgical procedure in 44% and 30% of patients following MRI respectively. (Low SOE.)

Change in stage

All studies found reported MRI to result in up-staging of a proportion of their patients, ranging from at least 5% to 100% of all patients. Where reported, MRI also resulted in down-staging of between 5% and 19% of patients. This was found for low, intermediate and high risk patients. (Very low SOE.)

Diagnostic accuracy

Four studies found that MRI was not consistently more sensitive, specific or accurate than staging by DRE or TRUS. Six studies found MRI to be more sensitive than clinical staging in identifying patients with extracapsular extension (stage T3a), but not consistently more specific or accurate. MRI was not consistently more sensitive, specific or accurate than clinical staging in identifying patients with seminal vesicle invasion (stage T3b). Three studies of patients with clinically localized disease found MRI to be more sensitive than clinical staging when identifying extracapsular extension or seminal vesicle invasion, but not consistently more specific or accurate. One study found MRI to have higher sensitivity but lower specificity than DRE or TRUS for overall staging of prostate cancer, while another found MRI to have higher accuracy.

Two studies only included patients with PSA < 10 ng/ml; one found the overall accuracy of staging to be the same between MRI and TRUS, while both found MRI to be more sensitive but less specific than TRUS when identifying extracapsular extension and less sensitive when identifying seminal vesicle invasion but not consistently more specific. Another study conducted a subgroup analysis by PSA level and found MRI to be more sensitive than TRUS in identifying both extracapsular extension and seminal vesicle invasion in patients with either PSA > 17 ng/ml or PSA < 10 ng/ml.

Two studies only included patients with Gleason ≤ 6 ; one found MRI to be more sensitive but less specific than TRUS when identifying extracapsular extension and less sensitive when identifying seminal vesicle invasion but of similar specificity. The other found MRI to have the same rate of false positives as clinical staging when identifying stage T3-T4 disease. Another study only included intermediate- and high-risk patients and found MRI to be more sensitive but less specific than clinical staging when identifying extracapsular extension, and to be more sensitive but have the same specificity when identifying seminal vesicle invasion.

Recommendations:

Consider multiparametric MRI, or CT if MRI is contraindicated, for men with histologically proven prostate cancer if knowledge of the T or N stage could affect management.

Imaging for M-staging

Isotope bone scans can be used to look for bone metastases at the time of presentation. The positivity rate for bone scans increases with PSA or Gleason score.

Recommendation:

Do not routinely offer isotope bone scans to men with low-risk localized prostate cancer.

Qualifying statement: This recommendation is supported by case series evidence and will reduce unnecessary investigation.

Two systematic reviews looked at the role of radioisotope bone scans in the staging of men with newly diagnosed prostate cancer. One summarized bone scan results by serum PSA level in men with newly diagnosed prostate cancer. Serum PSA level and risk of a positive bone scan were strongly correlated. The other review concluded that PSA level was the best means of identifying those at risk of a positive bone scan and that men with PSA less than 10 ng/ml were unlikely to have a positive bone scan.

Recommendation:

Offer isotope bone scans when hormonal therapy is being deferred through watchful waiting to asymptomatic men who are at high risk of developing bone complications.

Qualifying statement: In the absence of any evidence there was GDG consensus that making this recommendation would reduce the risk of patients developing spinal cord compression.

Searches found no direct evidence about the influence of imaging on the timing of systemic treatment or frequency of clinical follow-up in men for whom radical treatment is not intended. Small case series reported outcomes in men with positive bone scans at presentation. Two of these series found extensive disease on bone scan was an adverse prognostic factor for survival. There is observational evidence that extensive disease on bone scan is an independent risk factor for spinal cord compression in men without functional neurological impairment.

Role of Positron-emission tomography (PET) in staging prostate cancer

Positron-emission tomography imaging using the radiopharmaceutical agent 18-FDG does not reliably show primary prostate cancer. This is because of the relatively low metabolic activity in tumors which are slow-growing and because the radiopharmaceutical agent accumulates in the bladder, obscuring the prostate. Newer positron-emitting tracers are under evaluation.

Recommendation:

Do not offer PET imaging for prostate cancer in routine clinical practice.

Qualifying statement: There was a lack of evidence to support the use of PET imaging.

Managing relapse after radical treatment

Magnetic resonance imaging (MRI) scanning may have some value in those with biochemical relapse being considered for further local therapy. It may detect significant extracapsular disease, seminal vesicle involvement or lymphadenopathy which might preclude radical salvage therapy. The chance of finding skeletal metastases in men with biochemical relapse is best predicted by the absolute PSA level and the rate of rise.

For men with evidence of biochemical relapse following radical treatment and who are considering radical salvage therapy:

- do not offer routine MRI scanning prior to salvage radiotherapy in men with prostate cancer
- offer an isotope bone scan if symptoms or PSA trends are suggestive of metastases.

Qualifying statement: These recommendations are based on case series evidence and GDG consensus.

The literature search found no studies reporting the impact of staging after biochemical recurrence on patient outcomes. Small case series report good sensitivity and specificity of MRI for the detection of local recurrence after radical prostatectomy. The rate of bone scans positive for malignancy in men with biochemical recurrence after radical prostatectomy was 4 to 14% in four case series. The rate of suspicious or indeterminate (but ultimately non-malignant) scans was almost as high at between 3 and 8%, raising questions about the specificity of the bone scan. Trigger PSA, PSA slope, and PSA velocity were all significant predictors of bone scan result. The risk of a positive bone scan for men with PSA less than 10ng/ml was between 1 and 3% in two series, compared with 75% for PSA greater than 10 ng/ml.

PET scanning was not discussed in the NICE guideline as an option for managing relapse after radical treatment, or in any other section other than diagnosis and staging (presented above).

Evidence Summary

When determining when and how to image an individual, men with localized prostate cancer should be stratified into risk groups based on PSA level, Gleason score and clinical stage. There is insufficient evidence to support the routine use of CT of the pelvis in men with low- or

intermediate-risk localized prostate cancer, and it is considered inferior to MRI in this clinical situation. The evidence is insufficient to determine whether staging with MRI improve outcomes in men with prostate cancer. There is low SOE that staging with MRI can result in change in management, and a very low SOE that MRI results in up-staging or down-staging a highly variable proportion of patients. Most studies found staging with MRI more sensitive than staging with DRE or TRUS, but not consistently more specific or accurate. There is insufficient evidence to support the use of PET for any stage of prostate cancer.

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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
CT of pelvis	Inferior to MRI	Low	Low	Moderate variability (many would prefer to avoid radiation exposure)	Do not recommend (strong)	Insufficient/mixed evidence, similar or more risk than available alternatives.
MRI staging of prostate cancer	MRI may result in change in management, and possibly change in stage; may be more sensitive than DRE and/or TRUS	Low to Very Low	Low, if other diagnostic testing can be limited	Low variability	Recommend (strong)	Sufficient evidence shows more effective, less risk and similar or less cost than alternatives.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
Bone scan in evaluation of newly diagnosed, low risk prostate cancer	Positive bone scan highly correlated with PSA level; those with PSA level < 10 unlikely to have positive bone scan.	Low	Low	Moderate variability (avoidance of multiple tests vs. perceived value from those tests)	Do not recommend (weak)	Sufficient evidence; similar risk and effectiveness to alternatives, but higher cost.
Bone scan in asymptomatic high-risk men	May result in earlier treatment of metastatic disease, resulting in prevention of spinal cord compression	Very Low	Low	Low variability (avoidance of spinal cord compression)	Recommend (strong)	Insufficient/mixed evidence, no alternatives available, similar or less risk than no treatment. Treatment is prevalent and research study is not reasonable.
PET for staging of prostate cancer	Unknown	Very Low	Moderate	Low variability	Do not recommend (strong)	Insufficient/mixed evidence; risk is similar or more than available alternative effective treatments

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

Note: GRADE framework elements are described in Appendix B

POLICY LANDSCAPE

Quality measures

One quality measure was identified when searching the National Quality Measures Clearinghouse that was pertinent to this coverage guidance. It was formulated by the American Urological Association, and is endorsed by the National Quality Forum. It states the following:

Prostate cancer: percentage of patients, regardless of age, with a diagnosis of prostate cancer, at low risk of recurrence, receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.

Choosing Wisely®

Choosing Wisely® is part of a multi-year effort of the ABIM Foundation to help physicians be better stewards of finite health care resources. Originally conceived and piloted by the National Physicians Alliance through a Putting the Charter into Practice grant, more than 50 medical specialty organizations, along with Consumer Reports, have identified a number of tests or procedures commonly used in their field, whose necessity should be questioned and discussed. Each participating organization was free to determine how to create its own list, provided that it used a clear methodology and adhered to the following set of shared guidelines:

- Each item should be within the specialty's purview and control.
- The tests and/or interventions should be used frequently and/or carry a significant cost.
- Each recommendation should be supported by generally accepted evidence.
- The selection process should be thoroughly documented and publicly available on request.

One of the organizations that chose to participate in the Choosing Wisely® campaign is the American Society of Clinical Oncology. The first list created by this organization states the following:

Don't perform PET, CT, and radionuclide bone scans in the staging of early prostate cancer at low risk for metastasis.

- Imaging with PET, CT, or radionuclide bone scans can be useful in the staging of specific cancer types. However, these tests are often used in the staging evaluation of low-risk cancers, despite a lack of evidence suggesting they improve detection of metastatic disease or survival.
- Evidence does not support the use of these scans for staging of newly diagnosed low grade carcinoma of the prostate (Stage T1c/T2a, prostate-specific antigen (PSA) <10 ng/ml, Gleason score less than or equal to 6) with low risk of distant metastasis.

Unnecessary imaging can lead to harm through unnecessary invasive procedures, over-treatment, unnecessary radiation exposure, and misdiagnosis.

Medicare National Coverage Determination

Effective September 4, 2014, Medicare makes the following coverage determination pertaining to PET scanning and prostate cancer:

Initial Anti-Tumor Treatment Strategy Nationally Non-Covered Indications

- CMS continues to nationally non-cover initial anti-tumor treatment strategy in Medicare beneficiaries who have adenocarcinoma of the prostate.

Subsequent Anti-Tumor Treatment Strategy Nationally Covered Indications (includes prostate cancer)

- Three FDG PET scans are nationally covered when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy. Coverage of more than three FDG PET scans to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-cancer therapy shall be determined by the local Medicare Administrative Contractors.

National Comprehensive Cancer Network Guideline

This guideline states the following with regard to PET or PET/CT:

PET/CT using choline tracers may identify sites of metastatic disease in men with biochemical recurrence after primary treatment failure.

- Other choline radiotracers are under evaluation.
- Further study is needed to determine the best use of choline PET/CT imaging in men with prostate cancer.

Oncologic PET/CT is performed typically using [FDG]

- In certain clinical settings, the use of FDG-PET/CT may provide useful information, but FDG-PET/CT should not be used routinely since data on the utility of FDG-PET/CT in patients with prostate cancer is limited.

C-11 choline PET/CT has been used to detect and differentiate prostate cancer from benign tissue. The sensitivity and specificity of the technique in restaging patients with biochemical failure are 85% and 88%, respectively. C-11 choline PET/CT may be useful to detect distant metastases in these patients.

Newer technology using 18F-NaF as the tracer for a PET scan can be used as a diagnostic staging study. This test appears to have greater sensitivity than 99-technetium bone scan. However, there is controversy about how the results of 18F-NaF PET bone scan would be acted upon since all phase 3 clinical trials to date have based

progression criteria on the 99-technetium bone scans. PET and hybrid imaging bone scans appear more sensitive than conventional 99-technetium bone scans.

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. TNM STAGING FOR PROSTATE CANCER

Stage	Sub-Stage	Definition
<u>Tumor (T)</u>		Primary Tumor
TX		Primary tumor cannot be assessed
T0		No evidence of primary tumor
T1		Clinically inapparent tumor, neither palpable nor visible by imaging
	T1a	Tumor incidental histological finding in 5% or less of tissue resected
	T1b	Tumor incidental histological finding in more than 5% of tissue resected
	T1c	Tumor identified by needle biopsy, e.g., because of elevated prostate-specific antigen (PSA)
T2		Tumor confined within prostate
	T2a	Tumor involves one-half of one lobe or less
	T2b	Tumor involves more than one-half of one lobe, but not both lobes
	T2c	Tumor involves both lobes
T3		Tumor extends through the prostatic capsule
	T3a	Extracapsular extension (unilateral or bilateral) including microscopic bladder neck involvement
	T3b	Tumor invades seminal vesicle(s)
T4		Tumor is fixed or invades adjacent structures other than seminal vesicles: external sphincter, rectum, levator muscles, and/or pelvic wall
<u>Node (N)</u>		Regional lymph nodes
	NX	Regional lymph nodes cannot be assessed
	N0	No regional lymph nodes metastasis
	N1	Regional lymph node metastasis
<u>Metastasis (M)</u>		Distant metastasis
	M0	No distant metastasis
	M1	Distant metastasis
	M1a	Non-regional lymph node(s)
	M1b	Bone (s)
	M1c	Metastasis at other site(s)

APPENDIX B. 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 C. APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
185	Malignant neoplasm of prostate
233.4	Carcinoma in situ of prostate
ICD-10 Diagnosis Codes	
C61	Malignant neoplasm of prostate
D07.5	Carcinoma in situ of prostate
ICD-9 Volume 3 (Procedure Codes)	
88.38	Other computerized axial tomography
88.95	Magnetic resonance imaging of pelvis, prostate, and bladder
92.14	Bone scan
92.19	Scan of other sites
CPT Codes	
72192	Computed tomographic, pelvis; without contrast material
72193	Computed tomographic, pelvis; with contrast material(s)
72194	Computed tomographic, pelvis; without contrast material, followed by contrast material(s) and further sections
72195	Magnetic resonance, pelvis; without contrast material
72196	Magnetic resonance, pelvis; with contrast material(s)
72197	Magnetic resonance, pelvis; without contrast material, followed by contrast material(s) and further sequences
78300	Bone and/or joint imaging; limited area
78305	Bone and/or joint imaging; multiple areas
78306	Bone and/or joint imaging; whole body
78315	Bone and/or joint imaging; 3 phase study
78320	Bone and/or joint imaging; tomographic (SPECT)
78811	Positron emission tomography (PET) imaging; limited area
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body
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.

CT of pelvis; PET for staging of prostate cancer

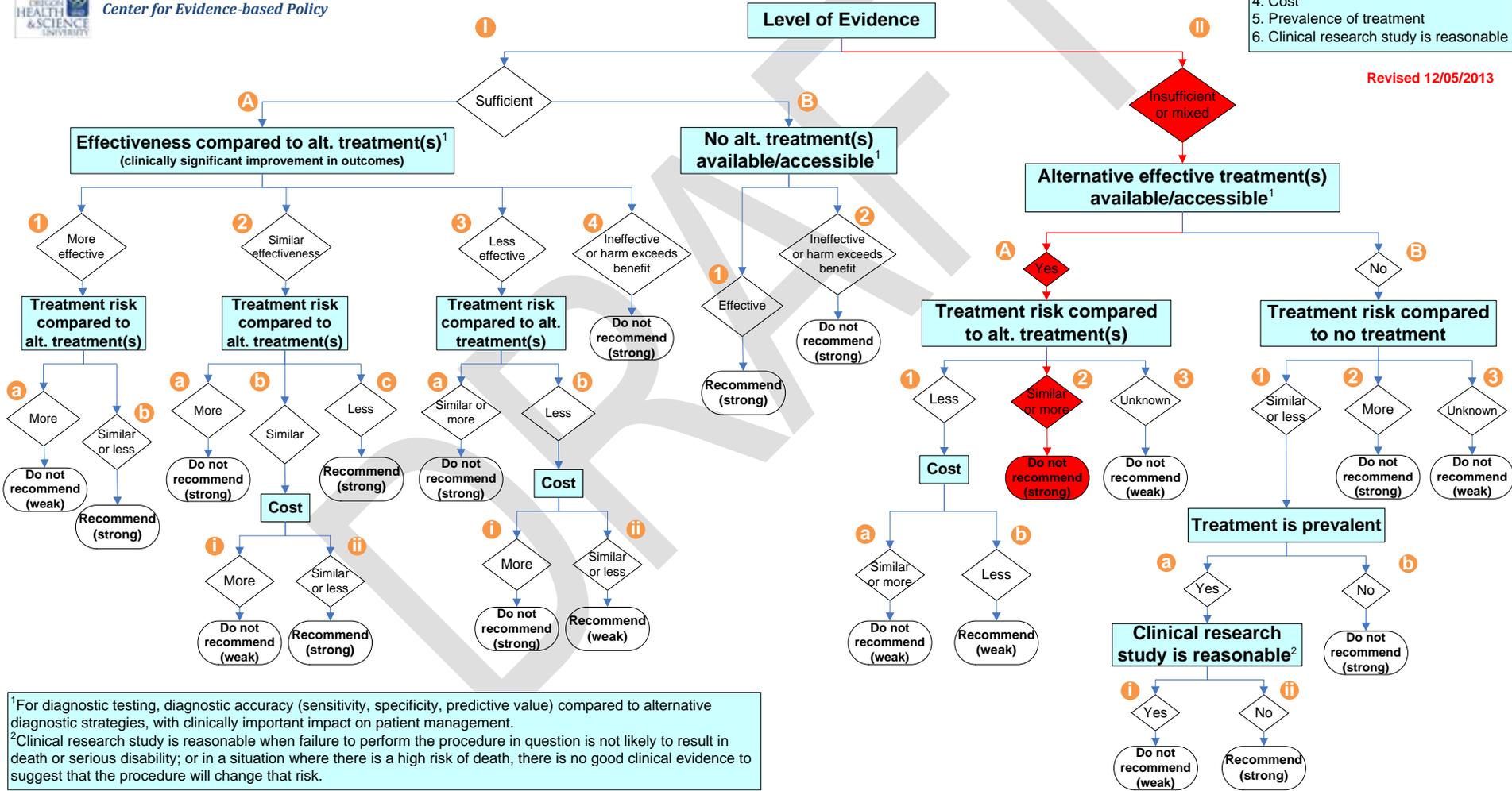


Center for Evidence-based Policy

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



1 For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
2 Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

MRI staging of prostate cancer

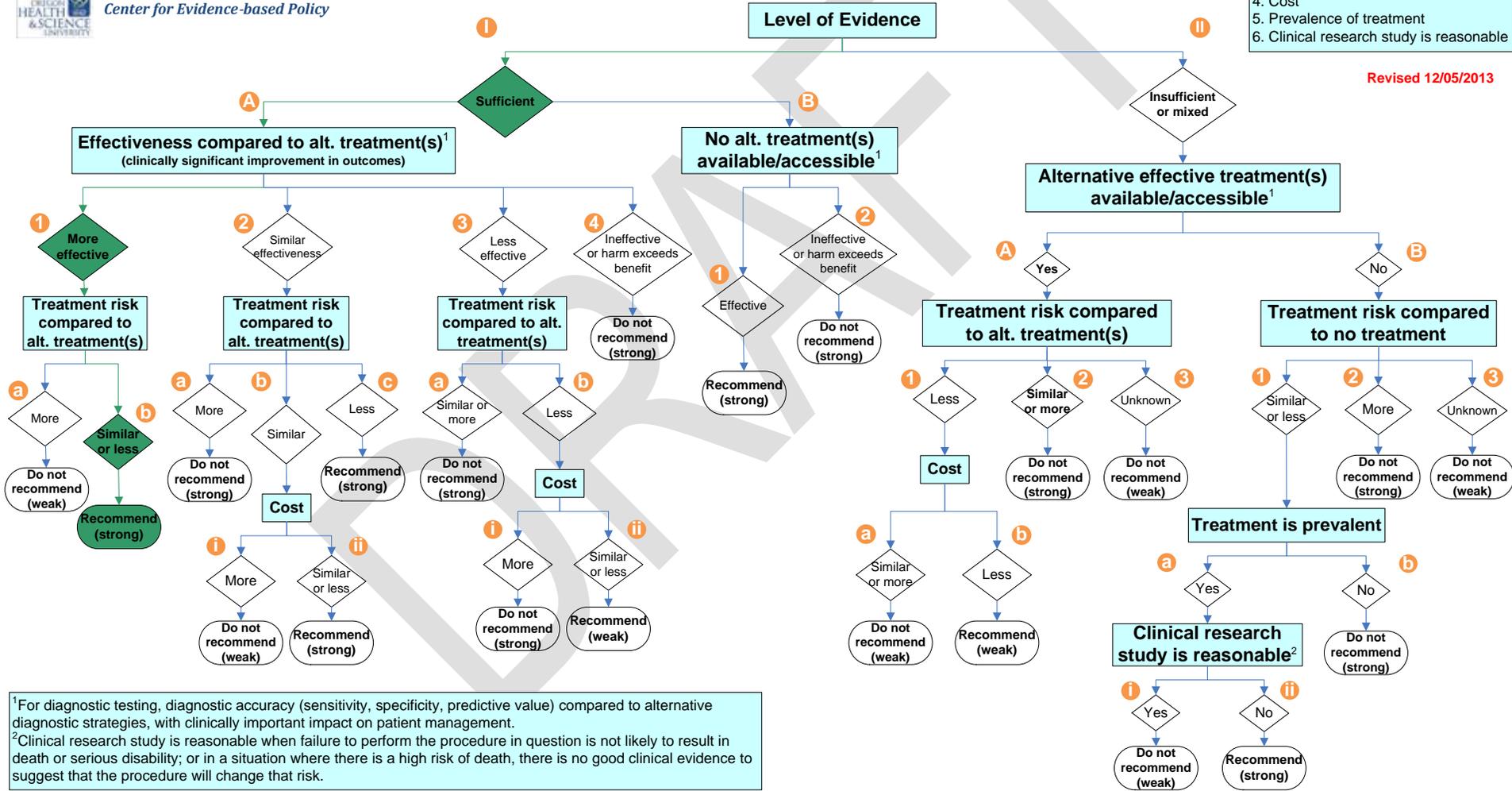


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Bone scan in evaluation of newly diagnosed, low-risk prostate cancer

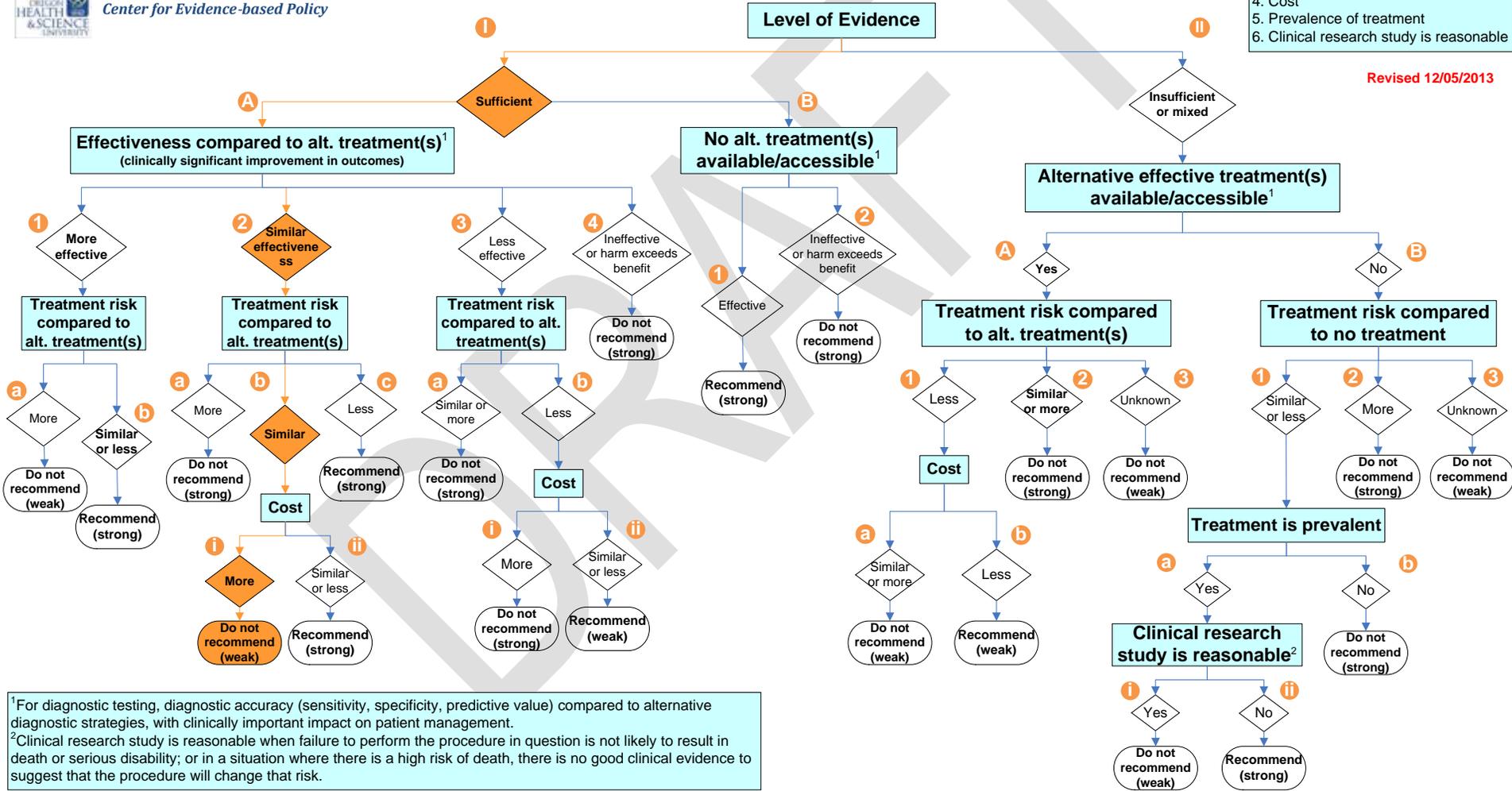


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Revised 12/05/2013



1 For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
2 Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

Bone scan in asymptomatic high-risk men

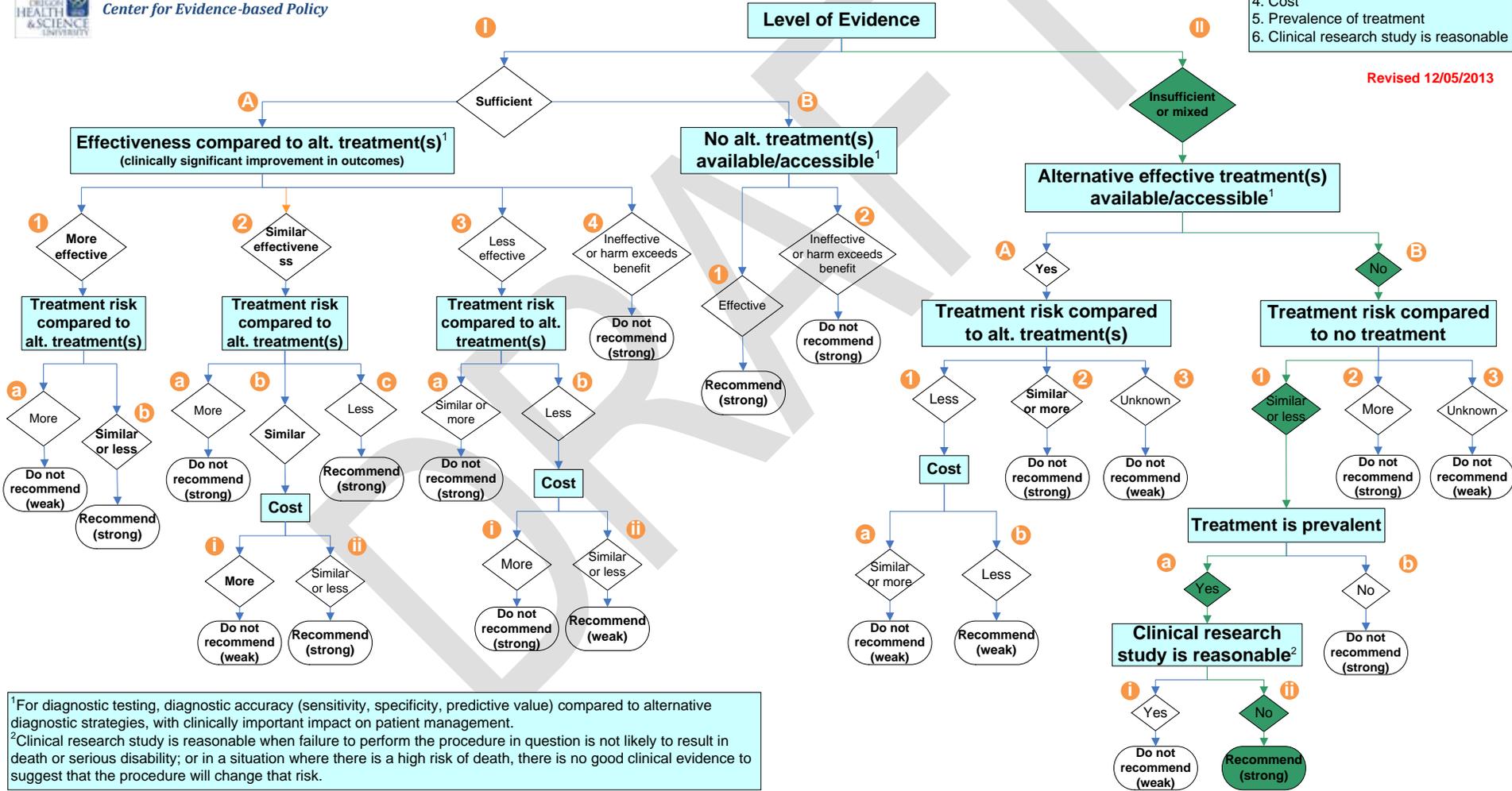


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Revised 12/05/2013



1 For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
2 Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

Advanced Imaging for Staging of Prostate Cancer

Question: How should the HTAS Coverage Guidance regarding advanced imaging for staging of prostate cancer be applied to the Prioritized List?

Question source: Health Technology Assessment Subcommittee

Issue: HTAS approved a new Coverage Guidance at their November, 2014 meeting. This CG needs final approval by HERC at the January, 2015 meeting. The summary of the coverage guidance is shown below:

HERC Coverage Guidance

To determine risk status and treatment options, prostate cancer clinical staging that includes PSA level and prostate biopsy with Gleason score is recommended for coverage. MRI is recommended for coverage for men with histologically proven prostate cancer if knowledge of the T or N stage could affect management. (*strong recommendation*)

CT of the pelvis is not recommended for coverage in men with low- to intermediate-risk localized prostate cancer, unless MRI is contraindicated. (*strong recommendation*)

Radionuclide bone scanning is not recommended for routine coverage in men with localized prostate cancer. (*weak recommendation*)

Radionuclide bone scanning is recommended for coverage when hormone therapy is being deferred (through watchful waiting) in asymptomatic men who are at high risk of developing bone complications. (*strong recommendation*)

PET imaging is not recommended for coverage in prostate cancer. (*strong recommendation*)

Evidence Summary

When determining when and how to image an individual, men with localized prostate cancer should be stratified into risk groups based on PSA level, Gleason score and clinical stage. There is insufficient evidence to support the routine use of CT of the pelvis in men with low- or intermediate-risk localized prostate cancer, and it is considered inferior to MRI in this clinical situation. The evidence is insufficient to determine whether staging with MRI improve outcomes in men with prostate cancer. There is low SOE that staging with MRI can result in change in management, and a very low SOE that MRI results in up-staging or down-staging a highly variable proportion of patients. Most studies found staging with MRI more sensitive than staging with DRE or TRUS, but not consistently more specific or accurate. There is insufficient evidence to support the use of PET for any stage of prostate cancer.

Advanced Imaging for Staging of Prostate Cancer

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
CT of pelvis	Inferior to MRI	Low	Low	Moderate variability (many would prefer to avoid radiation exposure)	Do not recommend (strong)	Insufficient/mixed evidence, similar or more risk than available alternatives.
MRI staging of prostate cancer	MRI may result in change in management, and possibly change in stage; may be more sensitive than DRE and/or TRUS	Low to Very Low	Low, if other diagnostic testing can be limited	Low variability	Recommend (strong)	Sufficient evidence shows more effective, less risk and similar or less cost than alternatives.
Bone scan in evaluation of newly diagnosed, low risk prostate cancer	Positive bone scan highly correlated with PSA level; those with PSA level < 10 unlikely to have positive bone scan.	Low	Low	Moderate variability (avoidance of multiple tests vs. perceived value from those tests)	Do not recommend (weak)	Sufficient evidence; similar risk and effectiveness to alternatives, but higher cost.
Bone scan in asymptomatic high-risk men	May result in earlier treatment of metastatic disease, resulting in prevention of spinal cord compression	Very Low	Low	Low variability (avoidance of spinal cord compression)	Recommend (strong)	Insufficient/mixed evidence, no alternatives available, similar or less risk than no treatment. Treatment is prevalent and

Advanced Imaging for Staging of Prostate Cancer

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
						research study is not reasonable.
PET for staging of prostate cancer	Unknown	Very Low	Moderate	Low variability	Do not recommend (strong)	Insufficient/mixed evidence; risk is similar or more than available alternative effective treatments

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

Advanced Imaging for Staging of Prostate Cancer

Current Prioritized List Status

Prostate cancer diagnoses (ICD-9 185 Malignant neoplasm of prostate and 233.4 Carcinoma in situ of prostate) are located on line 333 CANCER OF PROSTATE GLAND.

CPT code	Code description	Current Placement
55700-55706	Biopsy, prostate	Diagnostic Procedure File
72192-72194	Computed tomographic, pelvis	Diagnostic Procedure File
72195-72197	Magnetic resonance, pelvis	Diagnostic Procedure File
78300-78320	Bone and/or joint imaging, nuclear imaging	Diagnostic Procedure File
78811-78816	Positron emission tomography (PET) imaging	Lines 120, 137, 139, 161, 162, 167, 203, 204, 214, 233, 263, 266, 279, 292, 319
84152-84154	Prostate specific antigen (PSA)	Diagnostic Procedure File

HERC Staff Recommendations:

- 1) Do not add PET imaging to line 333 CANCER OF PROSTATE GLAND.
- 2) Select an option for management of MRI, CT and radionuclide bone scans:
 - a. Option 1: continue current coverage
 - i. Diagnostic, no guideline controls
 - b. Option 2: Adopt a new diagnostic guideline as shown below

DIAGNOSTIC GUIDELINE DX ADVANCED IMAGING FOR STAGING OF PROSTATE CANCER

MRI is covered for men with histologically proven prostate cancer if knowledge of the T or N stage could affect management. CT of the pelvis is covered only when MRI is contraindicated. Radionuclide bone scanning is not covered in men with low risk localized prostate cancer.

HERC Coverage Guidance – Advanced Imaging for Staging of Prostate Cancer Disposition of Public Comments

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Commenters

Identification	Stakeholder
A	Medical Imaging & Technology Alliance (MITA), Arlington, VA [Submitted October, 27, 2014]

DRAFT



HERC Coverage Guidance – Advanced Imaging for Staging of Prostate Cancer Disposition of Public Comments

Public Comments

Ident.	#	Comment	Disposition
A	1	The Medical Imaging & Technology Alliance (MITA) is pleased to submit comments on the Oregon Health Evidence Review Commission (HERC) Draft Guidance for advanced imaging in staging of prostate cancer. Specifically, MITA would like to address the draft guidance that PET imaging is not recommended for coverage in prostate cancer.	Thank you for taking the time to comment.
	2	As the leading trade association representing medical imaging, radiotherapy, and radiopharmaceutical manufacturers, MITA has in-depth knowledge of the significant benefits to the health of Americans that medical imaging and radiotherapy provide.	Thank you for letting us know who and what you represent.
	3	With regards to prostate cancer, PET is a powerful, noninvasive tool that can be useful in the restaging and treatment planning process for prostate cancer to help determine whether it has spread to the lymph nodes or other parts of the body. Other imaging technologies, such as magnetic resonance imaging (MRI) and computed tomography (CT), are often unable to detect prostate cancer cells that have spread to lymph nodes or soft tissue in other parts of the body.	No citations provided to support this assertion. Assuming the commenter is referring only to restaging, PET is not discussed in the NICE guidance. For initial staging, the NICE guidance notes that FDG-PET does not reliably show primary prostate cancer, because of the relatively low metabolic activity in tumors which are slow-growing and because the radiopharmaceutical agent accumulates in the bladder, obscuring the prostate.
	4	Both the Centers for Medicare and Medicaid Services (CMS) and the National Comprehensive Cancer Network (NCCN) recognize the value of the PET to assist in the restaging and monitoring of therapy in patients with prostate cancer. At the national level, CMS covers F-18 FDG-PET imaging for subsequent treatment strategy in prostate cancer patients as well as F-18 sodium fluoride for radionuclide bone scanning through the Coverage with Evidence Development (CED) process ¹ . In addition, where C-11 choline-PET imaging is available, it can be covered by local Medicare Administrative Contractors ¹ .	The reference provided does not include clinical rationale for the CMS decision to allow coverage of FDG-PET for restaging (subsequent treatment strategy), or use of F-18 sodium fluoride PET under the Coverage with Evidence Development program. It does not mention C-11 choline PET. The HTAS makes its decisions based on evidence of effectiveness and harms, not on

HERC Coverage Guidance – Advanced Imaging for Staging of Prostate Cancer Disposition of Public Comments

Ident.	#	Comment	Disposition
			the basis of other payers' coverage policies.
	5	The NCCN guidelines for prostate cancer suggest F-18 sodium fluoride-PET scanning to evaluate for bone metastases in patients at high risk of bone metastases at initial staging or when PSA is detectable or rising after prostatectomy. While additional data on the utility of F-18 FDG-PET and C-11 choline-PET is limited, the NCCN guidelines suggest that it can be useful for certain patients ² . As such, patients with prostate cancer should not be restricted from access to PET imaging where it may be clinically appropriate.	<p>NCCN guidelines make the following recommendations: “PET/CT using choline tracers may identify sites of metastatic disease in men with biochemical recurrence after primary treatment failure.</p> <ul style="list-style-type: none"> • Other choline radiotracers are under evaluation. • Further study is needed to determine the best use of choline PET/CT imaging in men with prostate cancer. <p>Oncologic PET/CT is performed typically using [FDG]</p> <ul style="list-style-type: none"> • In certain clinical settings, the use of FDG-PET/CT may provide useful information, but FDG-PET/CT should not be used routinely since data on the utility of FDG-PET/CT in patients with prostate cancer is limited.” <p>This is a category 2A recommendation: Based on lower level evidence, there is uniform NCCN consensus that</p>

HERC Coverage Guidance – Advanced Imaging for Staging of Prostate Cancer Disposition of Public Comments

Ident.	#	Comment	Disposition
			<p>the intervention is appropriate.</p> <p>References supporting the text statements are from 2006 and 2013. The 2006 reference was published before the date of the NICE guideline (last search date May 2013). The HTAS bases their guidance documents on reviews of the literature that utilize the highest standards of evidence based medicine. Studies are included or excluded based on transparent, reproducible criteria; therefore the HTAS does not investigate individual studies. The HTAS assumes that the conclusions reached by the authors of these reviews weigh all the available evidence in accordance with the principles of evidence based medicine, and does not attempt to re-review the entire body of evidence to reach its own conclusions.</p> <p>The 2013 reference is a SR of 11C-choline and 18 flourocholine PET. The authors conclude the following:“PET and PET/CT imaging with 11C-choline and 18F-fluorocholine in restaging of patients with biochemical failure after local</p>

DRAFT

HERC Coverage Guidance – Advanced Imaging for Staging of Prostate Cancer Disposition of Public Comments

Ident.	#	Comment	Disposition
			treatment for PCa might help guide further treatment decisions. In staging of patients with proven but untreated, high-risk PCa, there is limited but promising evidence warranting further studies. However, the current evidence shows crucial limitations in terms of its applicability in common clinical scenarios.”
	6	In consideration of the unique role that PET can play in the staging and treatment of a prostate cancer patient, we strongly recommend that you reconsider your draft guidance and instead recommend coverage for PET imaging in prostate cancer. MITA appreciates this opportunity to comment and would be pleased to answer any questions you have.	<i>For HTAS discussion</i>

HERC Coverage Guidance – Advanced Imaging for Staging of Prostate Cancer Disposition of Public Comments

References Provided by Commenters

Commenter	References
1	CMS National Coverage Determinations Manual http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_part4.pdf
2	National Comprehensive Cancer Network Guidelines http://www.nccn.org/professionals/physician_gls/f_guidelines.asp#site

DRAFT

Nuclear Cardiac Imaging

Nuclear Cardiac Imaging

Primary evidence source:

Washington State Health Care Authority Health Technology Assessment Program. (2013). *Cardiac Nuclear Imaging*. Olympia, WA: Health Technology Assessment Program. Retrieved December 2, 2013, from <http://www.hca.wa.gov/hta/Pages/nuclear.aspx>

Nuclear Cardiac Imaging Evidence Summary

- In **asymptomatic individuals** at high risk of CAD, there is no evidence of benefit for SPECT screening compared to no screening
- In **symptomatic patients at low to intermediate risk of CAD**, evidence is conflicting with regard to ability to predict mortality and cardiovascular events
 - one study finding no difference between ETT and SPECT
 - another finding that stress SPECT and stress ECHO were better predictors than ETT and rest ECHO

Nuclear Cardiac Imaging Evidence Summary

- In **symptomatic patients at high risk of CAD**, evidence is conflicting regarding rates of revascularization in those who undergo ETT compared to SPECT
- Prognostic value does not differ between stress ECHO and stress SPECT

Nuclear Cardiac Imaging Evidence Summary

- In **populations with mixed risk of CAD**, stress SPECT, stress ECHO, stress CMR and angiography do not differ in subsequent death or patient reported adverse cardiac events
- SPECT and ECHO have similar prognostic abilities, and those tests as well as cardiac MR result in similar proportions of referrals to angiography or change in medical management

Nuclear Cardiac Imaging Evidence Summary

- With regard to diagnostic accuracy, SPECT and ECHO have similar sensitivity (83% to 87%) and specificity (64% to 77%)
 - some analyses suggest that ECHO may be slightly more sensitive and SPECT may be slightly more specific
- Extracardiac findings (which may require additional evaluation) are identified rarely with SPECT, and significantly less frequently than CCTA

Nuclear Cardiac Imaging Evidence Summary

- Comparative evidence on the risks of various testing strategies is very limited, with the only apparent difference being that exercise stress has lower rates of adverse events than pharmacologic stress
- SPECT has the highest radiation exposure of any testing strategy at a range of 7 to 30 mSv

Nuclear Cardiac Imaging Evidence Summary

- SPECT appears to perform similarly in
 - men and women
 - Caucasians and African-Americans
 - normal weight and obese patients
 - patients with and without diabetes
 - patients with and without hypertension

Nuclear Cardiac Imaging Evidence Summary

- Evidence is conflicting regarding the economic value of ETT compared to SPECT
- In one RCT, direct referral to angiography was a lower-cost strategy than SPECT, ECHO, or cardiac MR
- The evidence pertaining to PET is insufficient to draw conclusions for any outcome.

HEALTH EVIDENCE REVIEW COMMISSION (HERC)
COVERAGE GUIDANCE: NUCLEAR CARDIAC IMAGING

DRAFT for HERC meeting materials 1/8/2015

HERC COVERAGE GUIDANCE

PET is not recommended for coverage for screening or diagnosis of coronary artery disease (CAD) (*strong recommendation*).

Single photon emission computed tomography (SPECT) is not recommended for coverage for screening for CAD in asymptomatic patients (*strong recommendation*).

SPECT is not recommended for coverage for diagnosis or risk stratification of CAD (*strong recommendation*)—except in patients for whom stress imaging is required and stress ECHO is contraindicated, is unavailable or would provide suboptimal imaging*)

**i.e. pre-existing cardiomyopathy, baseline regional wall motion abnormalities, left bundle branch block, paced rhythm, unsuitable acoustic windows due to body habitus, inability to utilize dobutamine in a setting where exercise is not possible or when the target workload is not achievable*

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 SOURCE

Washington State Health Care Authority Health Technology Assessment Program. (2013). *Cardiac Nuclear Imaging*. Olympia, WA: Health Technology Assessment Program. Retrieved December 2, 2013, from <http://www.hca.wa.gov/hta/Pages/nuclear.aspx>

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

SUMMARY OF EVIDENCE

Clinical Background

Coronary artery disease (CAD) is among the most common chronic conditions in the U.S., affecting over 16 million adults. Due to its prevalence, and because several options (e.g., surgery, medication) exist to reduce CAD-related morbidity and mortality, accurate diagnosis and/or risk stratification of CAD is critical. Currently the definitive standard for diagnosis is invasive coronary angiography. Because angiography primarily documents the anatomic presence of significant stenosis rather than identifying the “culprit” lesions likely to cause an adverse cardiovascular event, a growing number of non-invasive tests have been developed to identify CAD lesions significant enough to affect the flow of blood to the heart (i.e., myocardial perfusion). These functional tests are typically performed under exercise- or pharmacologically induced stress to determine whether blood flow deteriorates when the stressor is introduced.

The most common tests of cardiac function include the stress-electrocardiogram (ECG), or treadmill test (ETT), which measures cardiac activity via electrical signals, and the echocardiogram (ECHO), which uses ultrasound to measure abnormalities in heart wall motion using 2-dimensional imagery. ETT has fallen out of favor for use in patients at higher risk of CAD, however, as it has relatively low sensitivity in these patients, while stress-ECHO has been found to lack precision in detecting single-vessel versus multi-vessel disease and may produce suboptimal imagery in obese patients, those with chronic respiratory conditions, and patients with chest deformities or pre-existing myocardial damage.

To address some of these concerns, “nuclear imaging tests” have been developed to provide perfusion data in a broader spectrum of patients. The most longstanding of these is single photon emission computed tomography (SPECT), which uses a radioactive tracer and gamma camera to obtain 3-dimensional images of tracer uptake; areas of poor uptake are associated with abnormal levels of perfusion. Positron emission tomography (PET) scanners are also used with a radiotracer, and are felt by some to provide better image resolution in heavier patients and those with dense breast

tissue. So-called “hybrid” modalities have also been introduced to visualize both perfusion abnormalities and anatomic lesions using CT or MRI imagery in addition to nuclear testing.

There are trends in the use of cardiac nuclear imaging tests that are currently points of controversy, however. For one, the use of nuclear imaging for cardiovascular testing has grown substantially in recent years. In addition, questions have been raised about the appropriateness of nuclear imaging in certain populations. A substantial decrease in the prevalence of abnormal findings on such tests has been observed over time, due in part to greater recognition and treatment of cardiac risk factors but also to possible changes in referral patterns. This combination of substantial growth in utilization of cardiac nuclear imaging and declining rates of “positive” test results raises questions about the populations and indications for which such testing is appropriate.

Evidence Review

In the Washington HTA report, “symptomatic” means a patient with symptoms suggestive of myocardial ischemia (symptoms not specified). Risk categories of low, moderate and high were defined by the authors based on the Diamond-Forrester model of pretest probability, which incorporates age, gender and type of chest pain. These categories equate to probability ranges of <10%, 10-90% and >90% respectively. However, when other risk classification systems were used in the included studies, that information was utilized and reported by the authors.

Comparative Clinical Effectiveness

Asymptomatic Patients at High Risk of CAD

The one available study assessing the impact of cardiac nuclear imaging in asymptomatic, high-risk patients found no difference between SPECT screening and no screening in mortality or cardiovascular events, although many patients in both groups received subsequent stress testing for clinical reasons over approximately 5 years of follow-up. SPECT screening did increase the short-term rates of referral for angiography and revascularization vs. no screening.

Symptomatic Patients at Low-to-Intermediate Risk of CAD

Correlation of Imaging Study Findings with Mortality and Cardiovascular Events

Rates of mortality and major cardiac adverse events (MACE) did not generally differ between imaging modalities in available studies. Patients in the WOMEN study, an RCT of 772 women randomized to SPECT or ETT-based testing strategies were at very low CAD risk. The rates of all major adverse cardiovascular events at 2 years were 1.7% and 2.3% for ETT and rest/stress SPECT respectively, but this difference was not

significant (Hazard Ratio [HR]: 1.3; 95% CI: 0.5, 3.5; p=.59). The rate of revascularization also did not statistically differ between groups.

The long-term prognostic value of exercise SPECT, exercise ECHO, ETT, and clinical parameters was measured in a single cohort of 248 patients who were followed for a mean of 3.7 years. A total of 64 MACE occurred during follow-up. In multivariate analyses examining the incremental impact of (1) clinical + ETT data; (2) data in (1) + rest ECHO data; (3) data in (1) + exercise ECHO data; and (4) data in (1) + exercise SPECT data on predicting MACE events, the area under the curve¹ did not statistically differ between the SPECT and ECHO models (0.78 and 0.77 respectively), but was significantly (p<.05) higher than the base model (0.68) or the rest ECHO model (0.72).

One study evaluated the impact on all-cause mortality of normal findings on stress-only vs. stress/rest SPECT protocols in nearly 17,000 low-to-intermediate risk patients followed for a median of 4.5 years. Annualized unadjusted mortality rates were statistically-significantly greater in the stress/rest group (2.92% vs. 2.57% for stress-only, p=.02); however, this difference was no longer apparent after multivariate adjustment for differences in baseline characteristics. The authors conclude that a stress/rest protocol may be unnecessary in lower-risk individuals.

Downstream Testing and Clinical Decision-Making

The impact of testing on downstream resource utilization and clinical decisions was evaluated only in the WOMEN study. Over 2 years of follow-up, repeat testing with the same modality was more frequent in the SPECT group vs. ETT (9% vs. 3%), although this difference was not statistically tested. However, 18% of women randomized to ETT crossed over to SPECT during follow-up. The overall rate of referral to angiography was higher in the ETT group (9.0% vs. 5.5% for SPECT, p<.0001). Changes in the use of nitrates, beta-blockers, and antidepressant therapies during follow-up did not differ between the two arms in the study.

Health-related Quality of Life

The impact of testing on health-related quality of life (HrQOL) also was examined only in the WOMEN study. Similar proportions of women in each treatment group reported “excellent” or “very good” QoL as well as “best” or “average” life satisfaction, with no statistical differences between groups. There were also no statistically-significant differences between ETT and SPECT groups in relation to changes in any of the subscales.

¹ This measure refers to the receiver operating characteristic (ROC) curve, a figure depicting the power of a diagnostic test. It includes both test sensitivity and specificity. A ROC curve for a perfect test has an area under the ROC curve of 1.0, while a test that performs no better than chance has an area under the curve of 0.5.

Symptomatic Patients at High Risk of CAD

Correlation of Imaging Study Findings with Mortality and Cardiovascular Events

In high risk populations, some differences in event rates by modality were apparent. An RCT of ETT vs. SPECT in 457 intermediate-to-high risk patients focused primarily on the period between testing and diagnosis, but did report on the rate of revascularization, which occurred more frequently in the ETT group (18% vs. 11% for SPECT, not statistically tested). In the “SPARC” registry, a study comparing short-term outcomes of PET, SPECT and coronary CT angiography (CCTA), revascularization rates at 90 days did not materially differ between PET and SPECT, regardless of whether findings were mildly or moderately-severely abnormal. Neither of these studies evaluated longer term outcomes such as mortality or cardiovascular events.

Another study assessed the prognostic value of both dobutamine ECHO and dobutamine SPECT in 301 patients who were unable to exercise and were at intermediate-to-high risk of CAD; patients were followed for a mean of 7.3 years. Event-free survival was significantly better for patients with normal vs. abnormal findings on both tests, and did not differ statistically between tests. In multivariate models based on clinical data, stress testing, and imaging results, abnormal findings on either SPECT or ECHO were the strongest predictors of both cardiac death (HR [95% CI]: 4.4 [1.2, 21.0] and 3.4 [1.2, 12.0] for SPECT and ECHO respectively) and cardiac events (3.1 [1.1, 8.9] and 2.6 [1.1-6.2] respectively).

Downstream Testing and Clinical Decision-Making

Two studies reported on the effects of testing on downstream resource use and/or clinical decisions. Of the 207 patients randomized to ETT in one RCT, a total of 146 (71%) were referred for further testing (47% to angiography and 23% to stress ECHO). In contrast, further testing was requested in only 16% of patients randomized to SPECT, all of which were angiography procedures ($p < .0001$ for the comparison). ETT also appeared to generate more false-positives for significant CAD. Only 38% of ETT patients referred to angiography were revascularized, vs. 66% of SPECT patients so referred ($p < .05$).

In a registry study, referral for angiography occurred in a greater percentage of PET patients (11.1% vs. 4.3% for SPECT; $p < .001$). In multivariate analyses controlling for patient characteristics, comorbidities, and testing location, imaging modality was significantly and positively correlated with referral to angiography for PET (OR: 5.0; 95% CI: 1.0, 24.4) in comparison to SPECT. Neither PET nor SPECT were associated with significant medication changes.

Health-Related Quality of Life

There were no studies in symptomatic, high-risk individuals that reported on the impact of cardiac nuclear imaging tests on HrQoL.

Known CAD

Correlation of Imaging Study Results with Mortality and Cardiovascular Events

One comparative cohort study compared the rate of revascularization in 2,951 patients with known CAD and left ventricular dysfunction and (1) who had been tested with SPECT before referral for angiography; (2) were tested with SPECT only after a positive angiography; or (3) had no SPECT before or after angiography. The rate of revascularization differed significantly ($p=.001$) among groups, with the lowest rate of 35.8% seen in postangiography SPECT patients, 45.6% in patients who had SPECT pre-angiography, and 53.2% among patients undergoing angiography with SPECT neither before nor afterward.

Downstream Testing and Clinical Decision-Making

In one study, 100 consecutive patients, 79% of whom had known CAD, underwent rest-stress PET perfusion testing. Physicians were first queried on proposed patient management strategies without PET perfusion data; actual patient management was measured 4 weeks after PET. Proposed patient management was altered in 78% of patients. Most prominently, conservative medical management was initially proposed in 28% of patients; after PET testing, 76% were managed this way in actuality. In addition, use of angiography to guide treatment via PTCA was proposed in 6%, but was performed in 20% after PET testing.

Health-Related Quality of Life

There were no studies in patients with known CAD that reported on the impact of cardiac nuclear imaging tests on HrQoL.

No comparative studies evaluating the impact of serial nuclear imaging in asymptomatic patients with known CAD were identified.

Mixed Populations

The largest number of studies was available for populations that did not fit neatly into the categories described above. They represented a true “mix” of patients based on relatively uniform distributions by risk or pretest probability, presence or absence of symptoms, and/or inclusion of patients with known vs. suspected CAD. A total of 10 studies were identified.

Correlation of Imaging Study Results with Mortality and Cardiovascular Events

Data on mortality and cardiovascular events were available in 8 studies. The Cost-Effectiveness of Functional Cardiac Testing (CeCAT) Trial was an RCT comparing multiple diagnostic strategies—rest-adenosine stress SPECT, ECHO (dobutamine stress), adenosine stress cardiac magnetic resonance imaging (cardiac MR), and direct referral to angiography—among 898 primarily high-risk patients with known or suspected CAD and stable symptoms of ischemia who were referred to a tertiary center

in the UK for angiography and were followed for 18 months. In this study, the number of total, cardiac, and noncardiac deaths did not statistically differ by imaging modality. When compared with the referent angiography group, the number of nonfatal adverse cardiac events did not differ for SPECT or cardiac MR, but was statistically-significantly higher for ECHO (relative risk [RR]: 1.95; 95% CI: 1.23, 3.08; $p=.012$), primarily because of more admissions for chest pain. When the number of patients reporting adverse cardiac events was compared, however, no significant differences were observed (one patient in the ECHO group was responsible for seven hospital admissions).

Findings from a study comparing PET and SPECT were somewhat mixed. No differences in cardiovascular mortality or the rate of MI were observed between groups. However, the rates of CABG (3.4% vs. 7.8%, $p<.01$) and any revascularization (6.0% vs. 11.4%, $p<.01$) were statistically-significantly lower for PET vs. the internal (identified by report authors) SPECT control group. The rate of any revascularization was also significantly lower in comparison to the external (using results from another published trial) SPECT control group (6.0% vs. 13.0%, $p<.0001$).

Three cohort studies comparing the prognostic ability of SPECT and ECHO generally showed comparable results for both tests. No statistical differences between imaging modalities in event rates or event-free survival were observed in 2 studies. In the third, an evaluation of exercise stress ECHO vs. exercise stress SPECT in 206 symptomatic veterans who received both tests and were followed for up to 10 years, moderate-to-large ischemia on ECHO was the strongest independent predictor of overall mortality (RR: 6.2; $p<.0001$), cardiovascular death (RR: 17.6; $p=.01$), congestive heart failure (RR: 17.4; $p=.0005$), or sudden death (RR: 26.8; $p=.003$). The presence of moderate-to-large fixed defects on SPECT was the strongest independent predictor of nonfatal MI (RR: 8.1; $p=.0002$) and unstable angina (RR: 3.0; $p=.005$).

One study assessed the predictive capability of functional data from ETT, exercise stress SPECT, and the "Gensini score" from angiography evaluation in 732 patients who were followed for a mean of 3.5 years. Abnormal results on SPECT and the Gensini score were significantly ($p\leq.01$) associated with poorer event-free survival, while ETT data were not. Analyses of the receiver operator curve (ROC) for events indicated that SPECT was the strongest independent predictor of events (0.67 vs. 0.61 and 0.46 for Gensini score and ETT, $p<.05$).

Downstream Testing and Clinical Decision-Making

A total of three studies examined the impact of cardiac nuclear imaging on further testing and clinical decision-making. In the CeCAT trial, the proportions of patients in the SPECT, ECHO, and cardiac MR groups who were referred to angiography ranged between 75-80% and did not statistically differ between groups; in addition, decisions on

further invasive or medical management were also similar. The rate of referral to angiography in the study comparing PET and SPECT was statistically-significantly lower for PET (13%) in comparison to both the internal (identified by report authors) and external (using results from another published trial) SPECT groups (31% and 34% respectively, $p < .0001$). The rate of angiography negative results was also significantly lower for PET vs. internal SPECT controls (5.2% vs. 15.6%, $p < .0001$).

Finally, a hypothetical referral rate to angiography was assessed in 955 patients undergoing ETT and rest-exercise stress SPECT. Algorithms using ETT data alone, SPECT data alone, and a combination of the 2 tests were applied. An estimated 27% of patients would have been referred to angiography based on ETT results alone, vs. 13% for SPECT data alone and 12% using both ETT and SPECT data ($p < .01$ for both comparisons to ETT alone). Findings were similar when compared among patients without known CAD.

Health-Related Quality of Life

HrQoL was assessed in the CeCAT trial. While some statistically-significant differences were noted in certain subscales at particular time points, improvements in HrQoL were clinically comparable across testing groups for all measures.

Diagnostic Accuracy

A total of 8 studies were available that examined the accuracy of cardiac nuclear imaging tests in relation to a functional reference standard. This is currently believed to be a more accurate method to determine whether a defect noted on non-invasive imaging relates to CAD that is functionally-significant—that is, likely to be the cause of an adverse cardiovascular event if not treated. Recent research has raised questions about the use of anatomic data on angiography to confirm findings of functional tests such as ECHO, SPECT, and PET. There is nevertheless a large body of evidence evaluating the accuracy of noninvasive functional tests using visualization of coronary arteries as the reference standard.

One of the most widely-cited meta-analyses compared the diagnostic accuracy of exercise ECHO and exercise SPECT based on 44 studies. Pooled sensitivity of the 2 tests was similar (85% and 87% for ECHO and SPECT respectively), but pooled specificity was rated higher for ECHO (77% vs. 64% for SPECT, $p < .05$). However, substantial heterogeneity in study populations, imaging protocols, and SPECT radiotracers was noted for this sample; subsequent reanalysis with controls for heterogeneity found no statistical differences between the tests.

Methods to assess diagnostic accuracy have also evolved, and feature newer techniques designed to capture the natural correlation between sensitivity and specificity. A recent meta-analysis using newer bivariate methods found that ECHO was

slightly more sensitive than SPECT (87% vs. 83% respectively), while SPECT was somewhat more specific (77% vs. 72% for ECHO). An additional bivariate meta-analysis using a much larger set of 113 SPECT studies found greater sensitivity (88%) and similar specificity (76%), although other commentators have noted that the older SPECT studies included in this review were subject to “verification bias” (i.e., use of the reference standard only in test-positive or other selected individuals), which tends to inflate sensitivity and may also reduce specificity. This meta-analysis also included estimates of diagnostic accuracy from 9 PET studies (pooled estimates of 93% and 81% for sensitivity and specificity respectively).

Finally, a third recent meta-analysis estimated diagnostic performance from 114 SPECT and 15 PET studies. SPECT sensitivity was similar to that reported elsewhere (88%), but specificity was somewhat lower (61%). Sensitivity and specificity for PET was estimated to be 84% and 81% respectively.

Other Outcomes

Extracardiac Findings

With the enhanced imagery available for many noninvasive tests, incidental findings outside of the area of interest can be problematic given the additional resources required for investigation. The reported rate of incidental extracardiac findings is very low with nuclear imaging tests given the limited field of detection, however; most available studies are limited to case reports of mediastinal masses. One recent study compared the rate of such findings between CCTA and SPECT in 479 patients; extracardiac findings requiring further investigation were detected in 7% of CCTA patients but in no SPECT patients ($p=.0001$). Another analysis examined images of 2,155 patients undergoing SPECT studies, 6 (0.3%) of whom had extracardiac findings requiring follow-up. Four of the 6 patients had malignancies requiring further treatment. No PET studies reported on extracardiac findings.

While SPECT itself is associated with a low rate of extracardiac findings, the increasing use of CT for attenuation correction may result in increased detection of these findings. In a cohort study assessing prevalence of extracardiac findings from 582 SPECT/CT studies, a total of 400 (68.7%) included noncardiac findings, 196 (33.7%) of which were felt to be potentially relevant.

Equivocal/Indeterminate Results

While equivocal or indeterminate findings are possible with any diagnostic test, these results are rarely published. A recent systematic review of nearly 1,200 diagnostic accuracy studies found that 35% reported the presence of inconclusive results. Inconclusive results were reported in only one of the studies in this report. In the CeCAT

trial comparing SPECT with ECHO, cardiac MR, and angiography, rates of equivocal findings were 4.0%, 6.6%, 6.6% and 2.0% respectively.

Risks of Testing

Patients appear to be at minimal immediate risk from cardiac nuclear imaging tests in and of themselves, although harms data are reported in only a small number of comparative studies. The risks that are reported are related primarily to the stressor employed (i.e., exercise or pharmacologic stress).

Comparative Data on Testing Risks

Only 2 studies compared adverse effects of multiple testing modalities. In the WOMEN study that randomized patients to ETT or exercise SPECT, no statistically significant differences between groups were noted in rates of chest pain, dyspnea, or fatigue after testing. In the CeCAT trial comparing SPECT, ECHO, cardiac MR, and angiography, specific reasons for failed tests were recorded. Failure to complete the test due to adverse effects occurred in 4 ECHO patients (1.8%), due to vasovagal reactions, blood pressure changes and dyspnea; no patient failed to complete SPECT due to adverse effects.

Adverse Effects by Stressor

Information on adverse effects attributed to specific stressors was obtained from 15 studies. Regardless of the comparisons made, events were typically described as non-serious and resolved once the stressor infusion ended. Reported ranges of adverse effects were similar across pharmacologic agents. Limited data suggest lower rates of adverse effects for exercise vs. pharmacologic stress in the 2 studies making this comparison, although statistical comparisons were not available for all event types.

Radiation Exposure

Potential adverse health effects associated with radiation exposure are important factors to consider in the evaluation of cardiac nuclear imaging tests, particularly because patients may already be exposed to radiation at other points along the diagnostic pathway (e.g., CCTA, angiography), cumulative radiation dose may be substantial in patients receiving serial imaging studies, and imaging alternatives such as ECHO and cardiac MR exist that do not involve radiation. Radiation dose is a measure of ionizing energy absorbed per unit of mass, expressed as units of Gy (Gray) or mGy; it often is quoted as an equivalent “effective” dose to major organs in the scanned area, in units of Sv (Sievert) or mSv. For x-rays, the radiation type produced by CT scanners, 1 mSv = 1 mGy. Average total effective dosages for SPECT range from 7 to 30 mSv, while for PET and CCTA the range is 2 to 14 mSv, and for invasive coronary angiography the range for is 5 to 7. While exposure to ionizing radiation at these levels

is associated with potential increase in cancer risk, the latency period for the development of such cancers may range from 10 to 40 years for solid tumors depending on the age and sex of the patient being tested. The intended use of cardiac imaging tests then becomes a critical consideration.

Differential Effectiveness/Safety for Key Patient Subgroups

The *comparative* impact of cardiac nuclear imaging tests vs. alternative testing strategies in certain subgroups is presented below.

Patient Age, Sex, Race or Ethnicity, and Comorbidities

A single comparative cohort study was available that assessed all-cause mortality for stress only vs. stress-rest SPECT (n=16,854) in specific subgroups over a mean of 4.5 years of follow-up. On a univariate basis, stress-rest protocols were associated with a statistically-significantly higher mortality rate in older (age >65) individuals, men, patients with a BMI <30 kg/m², and patients with diabetes. However, after multivariate adjustment for baseline characteristics, no statistically-significant differences remained. Several large cohort studies and meta-analyses have assessed the performance of SPECT in certain patient subgroups. For example, several studies have found that SPECT's diagnostic and prognostic performance is similar for women and men. Comparable results have also been found in several large ECHO studies. A meta-analysis of risk-stratification studies in over 13,000 patients age >65 years found that both stress SPECT and stress ECHO accurately risk-stratified patients vs. ETT. A multicenter cohort study of approximately 1,100 patients found that SPECT results were predictive of cardiac events in both Caucasian and African-American patients.

Analyses comparing patients with and without diabetes suggest that, while diabetes is a predictor of mortality for any nuclear imaging result, SPECT testing provides incremental prognostic information in patients with and without diabetes alike. Multiple studies have found that SPECT is feasible and has comparable diagnostic and prognostic performance in normal-weight, overweight, and obese patients. Finally, a meta-analysis of SPECT and ECHO studies in hypertensive patients showed diagnostic accuracy similar to that observed in all patients with suspicion of CAD.

Clinical Setting

In a comparison of stress-only vs. stress-rest SPECT, mortality was initially statistically-significantly higher in stress-rest patients in an inpatient setting. After multivariate adjustment, however, no significant differences remained. Limited additional data are available explicitly comparing the performance of SPECT by setting. One study evaluating the potential benefit of an emergency department chest pain clinic estimated that unnecessary hospitalizations would be reduced in 30% of patients and inappropriate discharges avoided in 6% through the use of a selective SPECT protocol.

Selection of Test by Primary Care vs. Specialty Physician

No study assessed the impact of ordering specialty on patient outcomes, clinical decision-making, or costs. There are, however, several studies that have assessed the impact of specialty on whether ordered cardiac SPECT studies meet published appropriate use criteria (AUC). In a multicenter assessment of an online SPECT appropriateness classification system, one study found that the rate of inappropriate studies was statistically-significantly higher among non-cardiologists (19.5% vs. 13.2% for cardiologists, $p < .0001$). Similar findings have been observed in several single center studies. Of note, most inappropriate ordering of SPECT perfusion studies appears to have occurred in women, younger patients, and/or those without symptoms.

Scan Vendor, Type of Assessment, Type of Radioisotope, and Type of Stressor

No study assessed the impact of scan vendor or qualitative vs. quantitative assessment on patient outcomes, clinical decision-making, or costs. Most of the studies evaluating differences according to stressor type focused on rates of adverse effects of pharmacologic testing. The study that evaluated stress-only vs. stress-rest SPECT found no statistically-significant effects on mortality with subgroups defined by exercise vs. pharmacologic stress.

Two studies examined the impact of different SPECT radiotracers on outcomes. In one, a total of 1,818 patients underwent exercise or pharmacologic stress SPECT with Tc-99m sestamibi or Tc-99m tetrofosmin. Patients were followed for a mean of 1.5 years, during which no statistically-significant differences were observed between groups in the rates of overall mortality, cardiovascular mortality, or the composite endpoint of cardiovascular mortality or nonfatal MI.

The other study compared mortality outcomes among 2,147 patients with known CAD undergoing pharmacologic stress SPECT with either Tc-99m sestamibi or Tc-99m tetrofosmin who were followed for a median of 4 years. During follow-up, a total of 704 all-cause deaths (493 cardiovascular-related) were reported. There was no significant difference in either overall or cardiovascular mortality between radiotracer groups on both an unadjusted and multivariate-adjusted basis.

Analysis of Comparative Value

Limited evidence is available that directly measured and compared the economic impact of non-invasive testing strategies for CAD. Three RCTs compared costs of SPECT to other imaging. In the only economic study performed in the US, an RCT of ETT vs. SPECT in 772 women at low-to-intermediate risk of CAD in 43 cardiology practices across the U.S., total mean costs of testing over 2 years were higher in the SPECT arm (\$643 vs. \$338, $p < .001$), as the higher costs of initial SPECT testing outweighed the increased costs of downstream testing in the ETT arm. In another 2-year RCT

conducted in 457 primarily intermediate-risk patients in the UK, however, downstream testing costs were substantially higher in the ETT arm, leading to significantly higher total costs from randomization to diagnosis using National Health Service (NHS) estimates (\$1,244 v \$743 for SPECT, $p < .001$). The final UK RCT compared costs of initial and repeat testing, treatment, and adverse events over 18 months of follow-up for mixed-risk patients randomized to SPECT, ECHO, cardiac MR, or direct referral to angiography. Direct referral to angiography was the lowest-cost strategy. Incremental costs (relative to angiography) were similar for the SPECT and cardiac MR strategies (~\$650), but were twice as high for patients in the ECHO group (~\$1,250) due to a higher rate of hospital readmissions.

Economic evidence for PET was limited to 2 studies. In one, an evaluation of planned vs. actual management before and after PET perfusion testing in 100 patients with known CAD, savings from reduced need for angiography were greater than the incremental costs of PET testing and revascularization, leading to overall savings of \$240 per patient. In the other, a matched comparative cohort analysis of PET and SPECT, mean costs of all diagnostic testing were approximately \$2,500 in both groups, but greater requirements for revascularization at 1 year led to higher total costs in the SPECT group (\$5,937 vs. \$4,110 for PET).

Because evidence is limited comparing the short-term clinical consequences and costs for all relevant non-invasive strategies for CAD diagnosis, the authors of this report developed a decision-analytic model to provide additional information. The target population involved men and women with suspected or known CAD who had stable symptoms of myocardial ischemia (i.e., atypical or typical chest pain or other symptoms such as dyspnea). Model outcomes and costs were estimated over a 90-day period. The authors of the Washington HTA report developed 7 different strategies, alone and in combination, to capture a wide range of management approaches:

1. ECHO, followed by invasive coronary angiography if ECHO is positive or inconclusive
2. ETT, followed by angiography if ETT is positive or inconclusive
3. SPECT, followed by angiography if ETT is positive or inconclusive
4. PET, followed by angiography if ETT is positive or inconclusive
5. ETT, followed by ECHO if ETT is positive or inconclusive, followed by angiography if the ECHO is positive or inconclusive
6. ETT, followed by SPECT if ETT is positive or inconclusive, followed by angiography if the SPECT is positive or inconclusive
7. ETT, followed by PET if ETT is positive or inconclusive, followed by angiography if the PET is positive or inconclusive

Because the underlying CAD prevalence varies in different patient populations, the authors calculate results of the identical testing strategies for a population with 10%, 30%, 50% and 70% CAD prevalence. Comparing these results demonstrates the importance of the underlying prevalence on the relative balance of false negatives, false positives, rates of referral to angiography, and costs. For example, among a patient population with a CAD prevalence of 10%, the difference in false negatives between SPECT and ECHO almost vanishes (4 per 1,000). In contrast, the difference in false positives between SPECT and ECHO in a population with 50% CAD prevalence was 33 per 1,000 but is increased to 60 per 1,000 when the underlying prevalence of CAD is only 10%. The relative differences in angiography referral, patients exposed to radiation, and costs also shift.

The authors of this report have devised their own evidence rating system, and reach the following conclusions for specific populations:

- Asymptomatic, high-risk individuals
 - SPECT vs. no screening – high certainty of a comparable net health benefit, low value
 - SPECT vs. ETT or ECHO – insufficient evidence
 - PET vs. any alternative – insufficient evidence
- Symptomatic individuals at low-to-intermediate CAD risk
 - SPECT vs. ETT – moderate certainty of a comparable net health benefit, low value
 - SPECT vs. ECHO – high certainty of a comparable net health benefit, reasonable/comparable value
 - PET vs. any alternative – insufficient evidence
- Symptomatic individuals at high CAD risk
 - SPECT vs. ETT – moderate certainty of a small net health benefit, reasonable/comparable value
 - SPECT vs. ECHO – high certainty of a comparable net health benefit, comparable/reasonable value
 - PET vs. any alternative – insufficient evidence
- Known CAD
 - SPECT vs. ETT – insufficient evidence
 - SPECT vs. ECHO – high certainty of a comparable net health benefit, comparable/reasonable value

- PET vs. any alternative – insufficient evidence

[\[Evidence Source\]](#)

Evidence Summary

In **asymptomatic individuals** at high risk of CAD, there is no evidence of benefit for SPECT screening compared to no screening. In **symptomatic patients at low to intermediate risk of CAD**, evidence is conflicting with regard to ability to predict mortality and cardiovascular events, with one study finding no difference between ETT and SPECT, and another finding that stress SPECT and stress ECHO were better predictors than ETT and rest ECHO. In **symptomatic patients at high risk of CAD**, evidence is conflicting regarding rates of revascularization in those who undergo ETT compared to SPECT. Prognostic value does not differ between stress ECHO and stress SPECT. In **populations with mixed risk of CAD**, stress SPECT, stress ECHO, stress CMR and angiography do not differ in subsequent death or patient reported adverse cardiac events. SPECT and ECHO have similar prognostic abilities, and those tests as well as cardiac MR result in similar proportions of referrals to angiography or change in medical management.

With regard to diagnostic accuracy, SPECT and ECHO have similar sensitivity (83% to 87%) and specificity (64% to 77%), although some analyses suggest that ECHO may be slightly more sensitive and SPECT may be slightly more specific. Extracardiac findings (which may require additional evaluation) are identified rarely with SPECT, and significantly less frequently than CCTA.

Comparative evidence on the risks of various testing strategies is very limited, with the only apparent difference being that exercise stress has lower rates of adverse events than pharmacologic stress. SPECT has the highest radiation exposure of any testing strategy at a range of 7 to 30 mSv. SPECT appears to perform similarly in men and women, Caucasians and African-Americans, normal weight and obese patients, those with and without diabetes and those with and without hypertension.

Evidence is conflicting regarding the value of ETT compared to SPECT. One study suggests that direct referral to angiography is the most cost effective strategy, with SPECT and cardiac MR being of moderate cost, and ECHO being the most costly. Another analysis finds that SPECT has low value compared to no screening in an asymptomatic population and compared to ETT in a low-to-intermediate risk population, and has comparable value compared to ECHO in all other populations.

The evidence pertaining to PET is insufficient to draw conclusions for any outcome.

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	Variation in values and preferences	Coverage recommendation	Rationale
SPECT in asymptomatic at high risk of CAD	No net benefit, potential harm of radiation	High	Moderate	Low variability	Not recommended for coverage (strong recommendation)	Sufficient evidence of no net benefit, potential harms due to radiation, and higher cost.
SPECT in symptomatic with low/mod risk of CAD	Comparable to ETT and ECHO; potential harms from radiation	Moderate (ETT) High (ECHO)	Moderate	Moderate variability	Not recommended for coverage (strong recommendation)	Sufficient evidence of no net benefit, potential harms due to radiation. **
SPECT in symptomatic with high risk of CAD	Small health benefit compared to ETT, comparable to ECHO but potential harms from radiation	Moderate (ETT) High (ECHO)	Moderate	Moderate variability	<i>SPECT vs. ETT</i> Not recommended for coverage (weak recommendation) <i>SPECT vs. ECHO</i> Not recommended for coverage (strong recommendation)	<i>SPECT vs. ETT</i> Sufficient evidence of small net benefit over ETT, may outweigh potential harms due to radiation, upgrading algorithmic derived recommendation against from “strong” to “weak”. <i>SPECT vs. ECHO**</i> Sufficient evidence of no net benefit, potential harms due to radiation.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variation in values and preferences	Coverage recommendation	Rationale
SPECT in known CAD	Unknown compared to ETT Comparable to ECHO but potential harms from radiation	Insufficient (ETT) High (ECHO)	Moderate	Moderate variability	Not recommended for coverage (strong recommendation)	<i>SPECT vs. ETT</i> Insufficient evidence, but has potential risks of radiation exposure, unlike alternatives, and is higher cost. <i>SPECT vs. ECHO**</i> Sufficient evidence of no net benefit, potential harms due to radiation.
PET in all populations	Unknown compared to all interventions	Insufficient	High	Low variability	Not recommended for coverage (strong recommendation)	Insufficient evidence; also has potential risks of radiation exposure, unlike alternatives and is higher cost.

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

**Expert input let to the decision to recommend coverage for SPECT when stress echo may be contraindicated or provide suboptimal imaging, in the following circumstances: pre-existing cardiomyopathy, baseline regional wall motion abnormalities, left bundle branch block, paced rhythm, unsuitable acoustic windows due to body habitus, inability to utilize dobutamine in a setting where exercise is not possible or when the target workload is not achievable

Note: GRADE framework elements are described in Appendix A

POLICY LANDSCAPE

There were no quality measures that pertained to this topic identified when searching the [National Quality Measures Clearinghouse](#).

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/outcome²

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.

² Includes risk of bias, precision, directness, consistency and publication bias

Appendix B. Applicable Codes

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
402.0-402.9	Hypertensive heart disease
411.0	Postmyocardial infarction syndrome
411.1	Intermediate coronary syndrome (impending infarction, preinfarction angina, preinfarction syndrome, unstable angina)
411.8	Other acute and subacute forms of ischemic heart disease
411.81	Acute coronary occlusion without myocardial infarction
411.89	Other acute and subacute forms of ischemic heart disease, other
413.0	Angina decubitus (nocturnal angina)
413.1	Prinzmetal angina (variant angina pectoris)
413.9	Other and unspecified angina pectoris (NOS, cardiac, equivalent, of effort, angina syndrome, status anginosus, stenocardia, syncope anginosa)
428.0	Congestive heart failure, unspecified
428.1	Left heart failure
428.20	Systolic heart failure, unspecified
428.21	Acute systolic heart failure
428.22	Chronic systolic heart failure
428.23	Acute on chronic systolic heart failure
428.30	Diastolic heart failure, unspecified
428.31	Acute diastolic heart failure
428.32	Chronic diastolic heart failure
428.33	Acute on chronic diastolic heart failure
428.40	Combined systolic and diastolic heart failure, unspecified
428.41	Acute combined systolic and diastolic heart failure
428.42	Chronic combined systolic and diastolic heart failure
428.43	Acute on chronic combined systolic and diastolic heart failure
428.9	Heart failure, unspecified (cardiac failure, NOS, heart failure NOS, myocardial failure NOS, weak heart)
429.2	Cardiovascular disease, unspecified
429.3	Cardiomegaly
429.4	Functional disturbances following cardiac surgery
429.7	Certain sequelae of myocardial infarction not elsewhere classified
429.79	Certain sequelae of myocardial infarction not elsewhere classified, other
429.83	Takotsubo syndrome
429.9	Heart disease, unspecified
786.50	Chest pain, unspecified
ICD-9 Volume 3 (Procedure Codes)	
92.05	Cardiovascular scan and radioisotope function study
CPT Codes	
75557	Cardiac magnetic resonance imaging for morphology and function without

CODES	DESCRIPTION
	contrast material
75559	with stress imaging
75561	Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences
75563	with stress imaging
75565	Cardiac magnetic resonance imaging for velocity flow mapping (List separately in addition to code for primary procedure)
75571	Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium
75572	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)
75573	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation of venous structures, if performed)
78451	Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)
78452	multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection
78453	Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)
78454	multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection
78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation
78472	Cardiac blood pool imaging, gated equilibrium; planar, single study at rest or stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without additional quantitative processing
78473	multiple studies, wall motion study plus ejection fraction, at rest and stress (exercise and/or pharmacologic), with or without additional quantification
78481/3	Cardiac blood pool imaging (planar), first pass technique; single study, at rest or with stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without quantification (single/multiple)
78491	Myocardial imaging, positron emission tomography (PET), perfusion; single study at rest or stress
78492	multiple studies at rest and/or stress
78499	Unlisted cardiovascular procedure, diagnostic nuclear medicine

CODES	DESCRIPTION
93000	Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report
93005	tracing only, without interpretation and report
93010	interpretation and report only
93015	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; with supervision, interpretation and report
93016	supervision only, without interpretation and report
93017	tracing only, without interpretation and report
93018	interpretation and report only
93350	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report
93351	including performance of continuous electrocardiographic monitoring, with supervision by a physician or other qualified health care professional
93454	Catheter placement in coronary arter(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation
93455	with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography
93456	with right heart catheterization
HCPCS Level II Codes	
A9500	Technetium tc-99m sestamibi, diagnostic, per study dose
A9502	Technetium tc-99m tetrofosmin, diagnostic, per study dose
A9505	Thallium tl-201 thallos chloride, diagnostic, per millicurie
A9526	Nitrogen n-13 ammonia, diagnostic, per study dose, up to 40 millicuries
A9555	Rubidium rb-82, diagnostic, per study dose, up to 60 millicuries
A9560	Technetium tc-99m labeled red blood cells, diagnostic, per study dose, up to 30 millicuries
J0280	Injection, aminophyllin, up to 250 mg
J0461	Injection, atropine sulfate, 0.01 mg
J0151	Injection, adenosine for diagnostic use, 1 mg
J1245	Injection, dipyridamole, per 10 mg
J1250	Injection, dobutamine hydrochloride, per 250 mg
J2785	Injection, regadenoson, 0.1 mg

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.

SPECT in: Asymptomatic at high risk of CAD; Symptomatic with low/mod risk of CAD (compared to ETT and ECHO); Symptomatic with high risk of CAD (compared to ECHO); Known CAD (compared to ECHO)



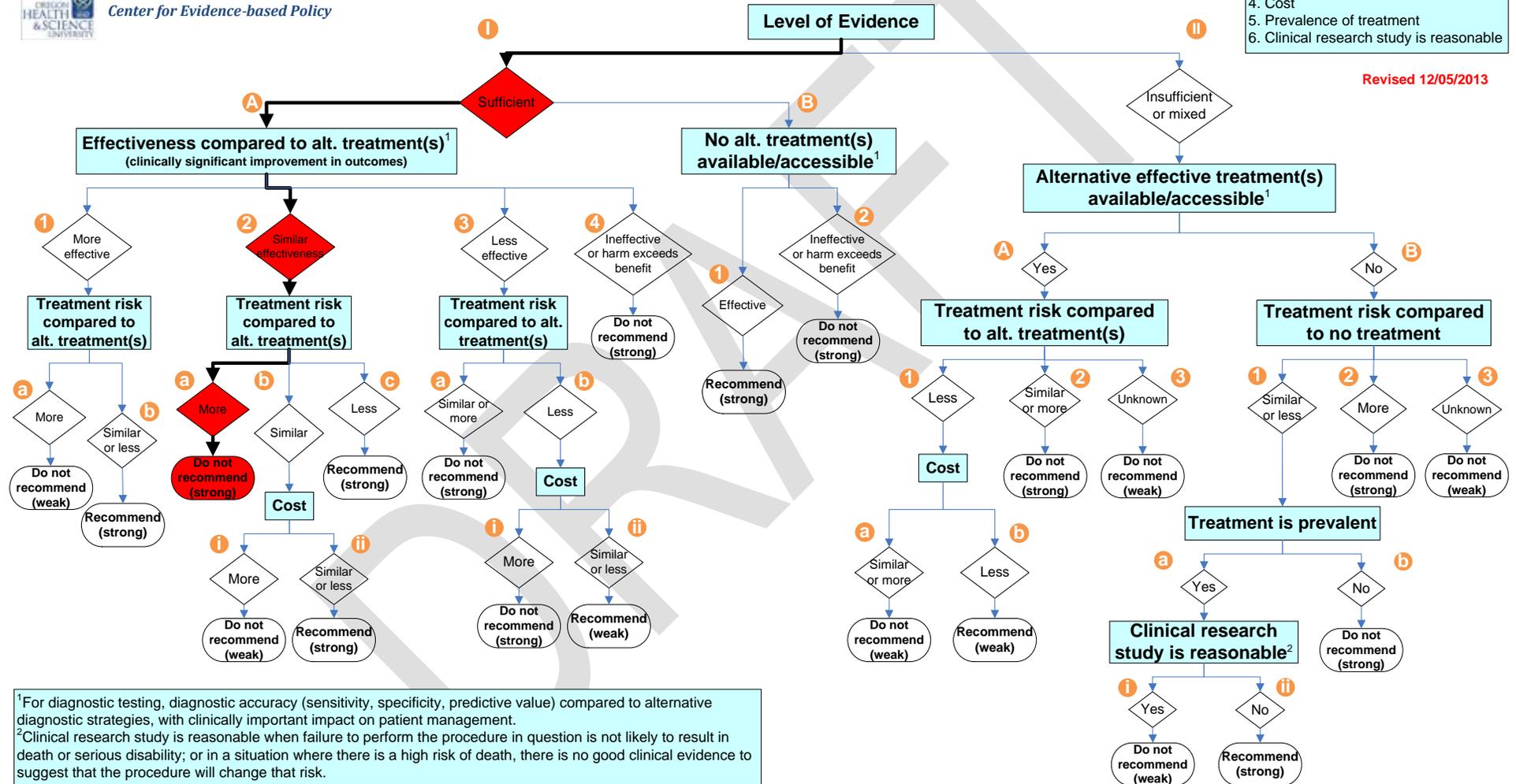
Center for Evidence-based Policy

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.

SPECT in known CAD (compared to ETT); PET in all populations

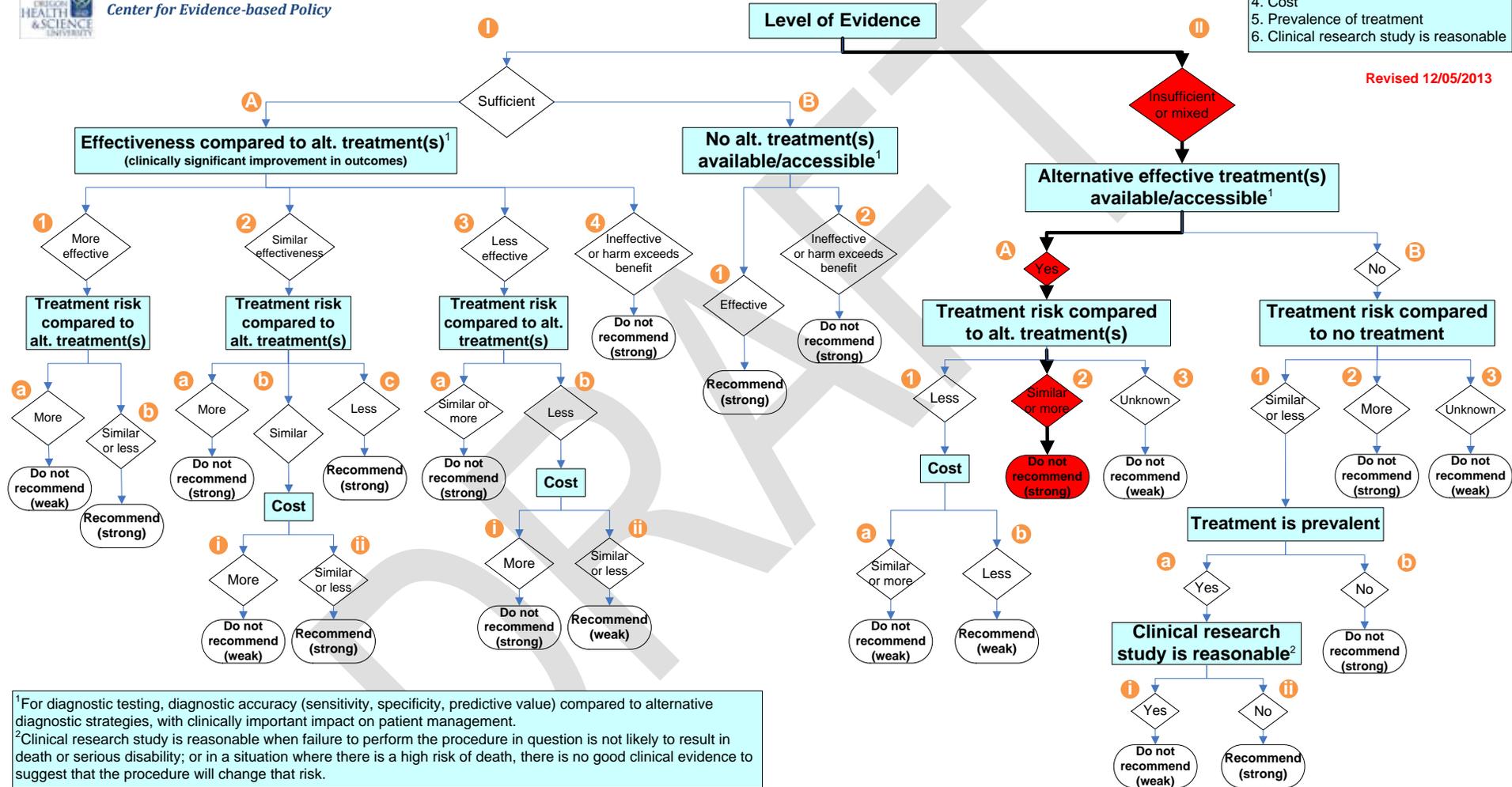


Center for Evidence-based Policy

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



COVERAGE GUIDANCE: NUCLEAR CARDIAC IMAGING

This issue summary was reviewed by VbBS 11/13/2014. The VbBS affirmed the staff recommendations for consideration by HERC.

Question: How should the EBGs Coverage Guidance regarding nuclear cardiac imaging be applied to the Prioritized List?

Question source: Evidence Based Guideline Subcommittee

Issue: EBGs approved a new Coverage Guidance at their September, 2014 meeting. This CG needs final approval by HERC at the November, 2014 meeting. The summary of the coverage guidance is shown below.

HERC COVERAGE GUIDANCE

PET is not recommended for coverage for screening or diagnosis of coronary artery disease (CAD) (*strong recommendation*).

Single photon emission computed tomography (SPECT) is not recommended for coverage for screening for CAD in asymptomatic patients (*strong recommendation*).

SPECT is not recommended for coverage for diagnosis or risk stratification of CAD (*strong recommendation*)—except in patients for whom stress imaging is required and stress ECHO is contraindicated, is unavailable or would provide suboptimal imaging*)

**i.e. pre-existing cardiomyopathy, baseline regional wall motion abnormalities, left bundle branch block, paced rhythm, unsuitable acoustic windows due to body habitus, inability to utilize dobutamine in a setting where exercise is not possible or when the target workload is not achievable*

Evidence Summary

In **asymptomatic individuals** at high risk of CAD, there is no evidence of benefit for SPECT screening compared to no screening. In **symptomatic patients at low to intermediate risk of CAD**, evidence is conflicting with regard to ability to predict mortality and cardiovascular events, with one study finding no difference between ETT and SPECT, and another finding that stress SPECT and stress ECHO were better predictors than ETT and rest ECHO. In **symptomatic patients at high risk of CAD**, evidence is conflicting regarding rates of revascularization in those who undergo ETT compared to SPECT. Prognostic value does not differ between stress ECHO and stress SPECT. In **populations with mixed risk of CAD**, stress SPECT, stress ECHO, stress CMR and angiography do not differ in subsequent death or patient reported adverse cardiac events. SPECT and ECHO have similar prognostic abilities, and those tests as well as cardiac MR result in similar proportions of referrals to angiography or change in medical management.

With regard to diagnostic accuracy, SPECT and ECHO have similar sensitivity (83% to 87%) and specificity (64% to 77%), although some analyses suggest that ECHO may be slightly more sensitive and SPECT may be slightly more specific. Extracardiac findings (which may require additional evaluation) are identified rarely with SPECT, and significantly less frequently than CCTA.

Comparative evidence on the risks of various testing strategies is very limited, with the only apparent difference being that exercise stress has lower rates of adverse events than pharmacologic stress. SPECT has the highest radiation exposure of any testing strategy at a range of 7 to 30 mSv. SPECT appears to perform similarly in men and women, Caucasians and African-Americans, normal weight and obese patients, those with and without diabetes and those with and without hypertension.

Evidence is conflicting regarding the value of ETT compared to SPECT. One study suggests that direct referral to angiography is the most cost effective strategy, with SPECT and cardiac MR being of moderate cost, and ECHO being the most costly. Another analysis finds that SPECT has low value compared to no screening in an asymptomatic population and compared to ETT in a low-to-intermediate risk population, and has comparable value compared to ECHO in all other populations.

The evidence pertaining to PET is insufficient to draw conclusions for any outcome.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variation in values and preferences	Coverage recommendation	Rationale
SPECT in asymptomatic at high risk of CAD	No net benefit, potential harm of radiation	High	Moderate	Low variability	Not recommended for coverage (strong recommendation)	Sufficient evidence of no net benefit, potential harms due to radiation, and higher cost.
SPECT in symptomatic with low/mod risk of CAD	Comparable to ETT and ECHO; potential harms from radiation	Moderate (ETT) High (ECHO)	Moderate	Moderate variability	Not recommended for coverage (strong recommendation)	Sufficient evidence of no net benefit, potential harms due to radiation. **
SPECT in symptomatic with high risk of CAD	Small health benefit compared to ETT, comparable to ECHO but potential harms from radiation	Moderate (ETT) High (ECHO)	Moderate	Moderate variability	<i>SPECT vs. ETT</i> Not recommended for coverage (weak recommendation) <i>SPECT vs. ECHO</i> Not recommended for coverage (strong recommendation)	<i>SPECT vs. ETT</i> Sufficient evidence of small net benefit over ETT, may outweigh potential harms due to radiation, upgrading algorithmic derived recommendation against from “strong” to “weak”. <i>SPECT vs. ECHO**</i> Sufficient evidence of no net benefit, potential harms due to radiation.
SPECT in known CAD	Unknown compared to ETT Comparable to ECHO but potential harms from radiation	Insufficient (ETT) High (ECHO)	Moderate	Moderate variability	Not recommended for coverage (strong recommendation)	<i>SPECT vs. ETT</i> Insufficient evidence, but has potential risks of radiation exposure, unlike alternatives, and is higher cost.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variation in values and preferences	Coverage recommendation	Rationale
						<i>SPECT vs. ECHO</i> ** Sufficient evidence of no net benefit, potential harms due to radiation.
PET in all populations	Unknown compared to all interventions	Insufficient	High	Low variability	Not recommended for coverage (strong recommendation)	Insufficient evidence; also has potential risks of radiation exposure, unlike alternatives and is higher cost.

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

**Expert input led to the decision to recommend coverage for SPECT when stress echo may be contraindicated or provide suboptimal imaging, in the following circumstances: pre-existing cardiomyopathy, baseline regional wall motion abnormalities, left bundle branch block, paced rhythm, unsuitable acoustic windows due to body habitus, inability to utilize dobutamine in a setting where exercise is not possible or when the target workload is not achievable

Current Prioritized List status

CODES	DESCRIPTION	Current Lines
402.0-402.9	Hypertensive heart disease	80 HYPERTENSION AND HYPERTENSIVE DISEASE
411.0	Postmyocardial infarction syndrome	73 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION
411.1	Intermediate coronary syndrome (impending infarction, preinfarction angina, preinfarction syndrome, unstable angina)	73
411.8	Other acute and subacute forms of ischemic heart disease	73
411.81	Acute coronary occlusion without myocardial infarction	73
411.89	Other acute and subacute forms of ischemic heart disease, other	73
413.0	Angina decubitus (nocturnal angina)	193 CHRONIC ISCHEMIC HEART DISEASE
413.1	Prinzmetal angina (variant angina pectoris)	193
413.9	Other and unspecified angina pectoris (NOS, cardiac, equivalent, of effort, angina syndrome, status anginosus, stenocardia, syncope anginosa)	193
428.0	Congestive heart failure, unspecified	102 HEART FAILURE 267 CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL HEART DISEASE Treatment: CARDIAC TRANSPLANT
428.1	Left heart failure	102,267
428.20	Systolic heart failure, unspecified	102,267 286 LIFE-THREATENING CARDIAC ARRHYTHMIAS
428.21	Acute systolic heart failure	102,267,286
428.22	Chronic systolic heart failure	102,267,286
428.23	Acute on chronic systolic heart failure	102,267,286
428.30	Diastolic heart failure, unspecified	102,267,286
428.31	Acute diastolic heart failure	102,267,286
428.32	Chronic diastolic heart failure	102,267,286
428.33	Acute on chronic diastolic heart failure	102,267,286

CODES	DESCRIPTION	Current Lines
428.40	Combined systolic and diastolic heart failure, unspecified	102,267,286
428.41	Acute combined systolic and diastolic heart failure	102,267,286
428.42	Chronic combined systolic and diastolic heart failure	102,267,286
428.43	Acute on chronic combined systolic and diastolic heart failure	102,267,286
428.9	Heart failure, unspecified (cardiac failure, NOS, heart failure NOS, myocardial failure NOS, weak heart	102,267,286
429.2	Cardiovascular disease, unspecified	73,193
429.3	Cardiomegaly	662 CARDIOVASCULAR CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
429.4	Functional disturbances following cardiac surgery	286, 350 CARDIAC ARRHYTHMIAS
429.7	Certain sequelae of myocardial infarction not elsewhere classified	193
429.79	Certain sequelae of myocardial infarction not elsewhere classified, other	193
429.83	Takotsubo syndrome	102
429.9	Heart disease, unspecified	662
786.50	Chest pain, unspecified	Diagnostic Workup File
CPT Codes		
75557	Cardiac magnetic resonance imaging for morphology and function without contrast material	Congenital heart disease lines (48, 71,74,89,90,93,94,109, 110, 115, 132,134,142,180,192,236) 190 RHEUMATIC MULTIPLE VALVULAR DISEASE 227 DISEASES AND DISORDERS OF AORTIC VALVE 261 DISEASES OF MITRAL, TRICUSPID, AND PULMONARY VALVES 267 CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL HEART DISEASE 662

CODES	DESCRIPTION	Current Lines
75559	with stress imaging	See 75557 above (but not 662)
75561	Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences	See 75557 above
75563	with stress imaging	See 75557 above (but not 48)
75565	Cardiac magnetic resonance imaging for velocity flow mapping (List separately in addition to code for primary procedure)	See 75557 above
75571	Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium	Excluded
75572	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)	Excluded
75573	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation of venous structures, if performed)	See 75557 above (but not 48)
78451	Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)	Diagnostic Procedure File
78452	multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection	Diagnostic Procedure File
78453	Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)	Diagnostic Procedure File
78454	multiple studies, at rest and/or stress (exercise or pharmacologic) and/or	Diagnostic Procedure File

CODES	DESCRIPTION	Current Lines
	redistribution and/or rest reinjection	
78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation	Excluded
78472	Cardiac blood pool imaging, gated equilibrium; planar, single study at rest or stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without additional quantitative processing	Diagnostic Procedure File
78473	multiple studies, wall motion study plus ejection fraction, at rest and stress (exercise and/or pharmacologic), with or without additional quantification	Diagnostic Procedure File
78481/3	Cardiac blood pool imaging (planar), first pass technique; single study, at rest or with stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without quantification (single/multiple)	Diagnostic Procedure File
78491	Myocardial imaging, positron emission tomography (PET), perfusion; single study at rest or stress	Excluded
78492	multiple studies at rest and/or stress	Excluded
78499	Unlisted cardiovascular procedure, diagnostic nuclear medicine	Diagnostic Procedure File

HERC staff recommendations:

- 1) Make no change in current non-coverage of cardiac PET scan
 - a. CPT 78459, 78491, and 78492 are Excluded
 - b. Will add entries to the non-covered table for these CPT codes
- 2) Keep SPECT on the Diagnostic List; adopt the new diagnostic guideline below for SPECT imaging

DIAGNOSTIC GUIDELINE DXX, SPECT

SPECT (CPT 78451, 78452) is not covered for screening for coronary artery disease in asymptomatic patients.

SPECT is only covered for diagnosis or risk stratification of coronary artery disease in patients for whom stress imaging is required and stress ECHO is contraindicated, is unavailable or would provide suboptimal imaging (i.e. pre-existing cardiomyopathy, baseline regional wall motion abnormalities, left bundle branch block, paced rhythm, unsuitable acoustic windows due to body habitus, inability to utilize dobutamine in a setting where exercise is not possible or when the target workload is not achievable).

HERC Coverage Guidance – Nuclear Cardiac Imaging Disposition of Public Comments

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Commenters

Identification	Stakeholder
A	Medical Imaging and Technology Alliance, Arlington, VA [<i>Submitted July 23, 2014</i>]
B	Oregon Chapter of the American College of Cardiology, the American College of Cardiology, the American Society of Nuclear Cardiology, the Society of Nuclear Medicine and Molecular Imaging, and the Society of Cardiovascular Computed Tomography [<i>Submitted July 24, 2014</i>]

HERC Coverage Guidance – Nuclear Cardiac Imaging Disposition of Public Comments

Public Comments

Ident.	#	Comment	Disposition
A	1	The Medical Imaging and Technology Alliance (MITA) is pleased to submit comments on the Oregon Health Evidence Review Commission (HERC) draft guidance for Nuclear Cardiac Imaging posted on June 25, 2014. As the leading trade association representing medical imaging, radiotherapy, and radiopharmaceutical manufacturers, MITA has in-depth knowledge of the significant benefits to the health of Americans that medical imaging and radiotherapy provide.	Thank you for taking the time to comment and providing this background.
A	2	Myocardial perfusion imaging is an important and established technology which has provided great benefit to patients suffering from coronary artery disease (CAD) for decades. By using a radiopharmaceutical to pinpoint perfusion defects, cardiologists/doctors are able to identify areas of blockages in the coronary arteries and to determine severity of disease.	EbGS is aware of the value of myocardial perfusion imaging (MPI).
A	3	Because the value of myocardial perfusion imaging is widely acknowledged, we are concerned that the limitations introduced by the draft guidance would negatively affect access to this timely and important modality for your beneficiaries. Instead, we urge you to adopt the established Appropriate Use Criteria (AUC) for Cardiac Radionuclide Imaging (attachment 1). This document represents years of extensive and careful consideration of numerous studies representing thousands of patients and the cumulative experience of experts in cardiology. To wit, the AUC Task Force comprises expertise from the American Society of Nuclear Cardiology, the American College of Cardiology, the American College of Radiology, the American Heart Association, the American Society of Echocardiography, the Society of Cardiovascular Computed Tomography, the Society for Cardiovascular Magnetic Resonance, the Society of Nuclear Medicine and has been endorsed by the American College of Emergency Physicians.	<p>Methodology of appropriate use criteria is a combination of literature review and expert opinion. Neither aspect meets HERC standards as an appropriate data source to override ‘trusted source’ systematic reviews such as those provided by AHRQ or WA HTA. Panel members were “asked to refer to the relevant guidelines for a summary of the relevant literature”. Relationships to industry were reported (and extensive) but not managed in any stated way. Indications for MPI are rated by panel members as “appropriate”, “uncertain”, or “inappropriate”. A total of eight clinical scenarios were rated. The following received “appropriate” scores:</p> <ul style="list-style-type: none"> • <u>Detection of CAD</u>: symptomatic; evaluation of ischemic equivalent (nonacute) if ECG uninterpretable or unable to exercise, or intermediate or high probability of CAD; • <u>Detection of CAD</u>: symptomatic; acute chest pain (5 different scenarios for possible ACS); • <u>Detection of CAD/risk assessment</u>: without ischemic equivalent; asymptomatic if high risk OR new onset heart failure with LV systolic

HERC Coverage Guidance – Nuclear Cardiac Imaging Disposition of Public Comments

Ident.	#	Comment	Disposition
			<p>dysfunction OR ventricular tachycardia OR syncope OR elevated troponin;</p> <ul style="list-style-type: none"> • Risk assessment with prior test results and/or known chronic stable angina; prior non-invasive evaluation inconclusive OR new/worsening symptoms OR angiography with coronary stenosis of uncertain significance OR asymptomatic with coronary calcium score 100 to 400 and high risk, or >400 OR duke treadmill score intermediate or high risk; • <u>Risk assessment</u>: Preoperative evaluation for vascular surgery; • <u>Risk assessment</u>: within 3 months of an ACS; • <u>Risk assessment</u>: postrevascularization; • Assessment of viability/ischemia in ischemic cardiomyopathy; and • Evaluation of ventricular function. <p>The following comment is made pertaining to other imaging modalities: “technical panel members were asked to rate indications for cardiac RNI in a manner independent and irrespective of the prior published ACCF ratings for SPECT MPI (1) as well as the prior ACCF ratings for similar diagnostic stress imaging modalities, such as stress echocardiography (2), cardiac computed tomography, or cardiac magnetic resonance (3). Given the iterative nature of the process, readers are counseled not to compare too closely individual appropriate use ratings among modalities rated at different times over the past 2 years.”</p>
A	4	Finally, each patient is unique and, by following the AUC instead of more rigid criteria, decision-making would rightly take place between the physician and the patient to determine the best path for the individual patient’s care, which may or may not include nuclear cardiac imaging at a particular decision point.	EbGS is aware of the uniqueness of patients, but that does not obviate the need for development of coverage policy.

HERC Coverage Guidance – Nuclear Cardiac Imaging Disposition of Public Comments

Ident.	#	Comment	Disposition
A	5	In consideration of the established Appropriate Use Criteria for nuclear cardiac imaging, we strongly recommend that you reconsider your draft guidance and instead follow the AUC as developed by medical professional societies.	The AUC criteria do not compare MPI to other cardiac imaging technologies. The evidence reviewed in the guidance document that compares stress ECHO and MPI indicates equivalence of the two procedures in most circumstances, and stress ECHO is less costly and is associated with less harm.
B	1	The Oregon Chapter of the American College of Cardiology, the American College of Cardiology, the American Society of Nuclear Cardiology, the Society of Nuclear Medicine and Molecular Imaging and the Society of Cardiovascular Computed Tomography appreciate the opportunity to provide comments on the Health Evidence Review Commission’s (HERC) Coverage Guidance on Nuclear Cardiac Imaging (NCI).	Thank you for taking the time to comment.
B	2	We strongly disagree with the HERC’s draft coverage recommendations for NCI as well its attempting to define a selection algorithm between two appropriate and indicated tests. We do not feel that the algorithm will improve upon the judgment of the ordering physician, lower costs or improve outcomes.	The algorithm (Guidance Development Framework) is a tool to assist the HERC with development of coverage recommendations. It does not apply to individual patients or specific clinical situations.
B	3	We strongly urge the HERC to adopt the recommendations finalized last year by the Washington State Health Care Authority Health Technology Assessment Program on this matter.	<p>The WA HTA decision is as follows: Cardiac Nuclear Imaging is a covered benefit with conditions including:</p> <ul style="list-style-type: none"> - SPECT - Covered for patients with symptoms of myocardial ischemia (symptomatic) who are: <ul style="list-style-type: none"> • At high risk of coronary artery disease (CAD), or • At low to intermediate risk of CAD, and <ul style="list-style-type: none"> ○ Have abnormal/indeterminate exercise treadmill test (ETT), or ○ Unable to perform ETT, or ○ ECG abnormality that prevents accurate interpretation of ETT - For patients with known CAD, monitoring: <ul style="list-style-type: none"> • Changes in symptoms - PET - Covered under the same conditions as SPECT when: <ul style="list-style-type: none"> • SPECT is not technically feasible; or

HERC Coverage Guidance – Nuclear Cardiac Imaging Disposition of Public Comments

Ident.	#	Comment	Disposition
			<ul style="list-style-type: none"> SPECT is inconclusive <p>Non-Covered Indicators</p> <p>- Cardiac Nuclear Imaging is not a covered benefit for:</p> <ul style="list-style-type: none"> Asymptomatic patients* Patients with known CAD and no changes in symptoms <p>*Does not apply to pre-operative evaluation of patients undergoing high-risk non-cardiac surgery or patients who have undergone cardiac transplant.</p>
B	4	<p>First, we would like to highlight the paper, Appropriate Use Criteria for Cardiac Radionuclide Imaging, published in JACC Vol. 53, No 23, 2009 (June 9, 2009, pages 2201-29), a copy of which is enclosed. The paper covers SPECT myocardial perfusion imaging (MPI) and cardiac PET, and reviews appropriate use of imaging, defined by specific clinical indication (Tables 1-8, Pages 2207-2210). The appropriate use criteria (AUC) describe a rigorous process of literature review and decision making, are endorsed by eight different specialty societies, and have become widely accepted by the medical community and third-party payers. This paper should answer the majority of the commission’s concerns and questions about imaging selection for patients. Of note, the terms Appropriate, Uncertain, and Inappropriate have been replaced in new guidelines with the terms Appropriate Care, May be Appropriate Care, and Rarely Appropriate Care (Hendel 2013).</p>	See comment #A3 and #A5
B	5	<p><u>Sensitivity and Specificity</u></p> <ul style="list-style-type: none"> There are a large number of papers which look at MPI accuracy, and the “gold standard” for comparison is most commonly invasive coronary angiography. Generally, the sensitivity and specificity of MPI is in the range of 80-90%. Predictive value, of course, is based upon the pretest prevalence of the disease in the population studied. Though comparative “head to head” studies against stress echo are few, most indicate a superior sensitivity and specificity for MPI, although not all comparisons reach statistical significance. Since sensitivity and specificity of both echo and MPI technologies are quite good, relative differences (favoring MPI) tend to be modest. Subsets where MPI compares particularly favorably to stress echo include patients with single vessel coronary disease, patients who are obese, patients who are unable to exercise or achieve target heart rate, patients with pacemakers or implantable defibrillators or left bundle branch block, patients with prior myocardial infarction or other known coronary or other heart disease, patients with resting ECG abnormalities, and patients with otherwise poor echo image quality. Many patients in 	<p>EbGS agrees that sensitivity and specificity of both ECHO and MPI technologies are good, and that relative differences are modest. However, ECHO is not associated with harms of radiation and is substantially less expensive.</p> <p>EbGS agrees that there are certain subpopulations in which MPI compares favorably to ECHO, and these are accounted for in the coverage guidance recommendation:</p> <p>“patients for whom stress imaging is required and stress ECHO is contraindicated or would provide suboptimal imaging*</p> <p>*i.e. pre-existing cardiomyopathy or regional wall motion</p>

HERC Coverage Guidance – Nuclear Cardiac Imaging Disposition of Public Comments

Ident.	#	Comment	Disposition
		these subsets cannot be identified prospectively.	abnormalities, left bundle branch block, paced rhythm, unsuitable acoustic windows due to body habitus, inability to utilize dobutamine in a setting where exercise is not possible or when the target workload is not achievable.”
B	6	<ul style="list-style-type: none"> • Head-to-head comparisons of MPI versus stress echo in the literature tend to include only patients who have a clinical indication to undergo invasive coronary angiography. In these studies, invasive angiography determines which of the noninvasive tests is “correct”. This approach has several limitations. <ul style="list-style-type: none"> ○ First, patients already selected for invasive angiography on clinical grounds have a much higher likelihood of obstructive coronary disease than those undergoing testing in an office setting. Patients with a negative study most often are reassured in practice, and are then seldom referred for angiography. A better outcome measure for patients with a negative test might be “percent event free survival at 3 years,” though this is an exceedingly difficult assessment to make in patients who will not be having regular cardiac follow up. 	<p>EbGS agrees that a better outcome measure is event-free survival. Indeed, one study included in the WA HTA review compared the ability of SPECT and stress ECHO to predict major adverse coronary events (MACE) after 3.7 years, and found no significant difference between the two when evaluating the area under the ROC curve.</p> <p>Another study assessed the prognostic value of stress ECHO and SPECT in patients who were followed for 7.3 years and found no statistical differences between the tests.</p> <p>Three additional cohort studies also did not find significant differences in the prognostic ability of SPECT and ECHO.</p>
	7	<ul style="list-style-type: none"> ○ Second, invasive angiography is an anatomic test, whereas MPI and stress echo are physiologic tests. Angiography will often identify a stenosis in the range of 50-70%, which is considered equivocal on anatomic grounds. Multiple studies have shown that MPI is more likely to demonstrate ischemia in such territories, as compared to stress echo. Though fractional flow reserve assessment can be done at the time of angiography, and does provide a functional assessment of whether such lesions are flow limiting, currently we are not aware of any studies which have utilized this technology in comparison to the results obtained with stress echo or MPI. 	Ability to demonstrate ischemia in an area of known stenosis was not specifically addressed in the WA HTA report. However, whether or not this ultimately results in improved patient outcomes is unclear. While commenter states that multiple studies have shown that MPI is more likely to demonstrate ischemia in such territories than stress ECHO, no citations are provided, and no such comparative evidence is presented in the source report.
	8	<p><u>Frequency of incidental findings (outside the heart)</u></p> <ul style="list-style-type: none"> • Research indicates that the incidence of noncardiac findings on nuclear MPI is about 2.5% (Williams 2003). Detection of breast cancer, lung cancer, and abnormalities in the thyroid are not uncommon and may result in early detection of disease and subsequent life-saving treatment. 	Studies reported in the WA HTA report cite a very low rate of extracardiac findings (0-0.3%) for SPECT. While incidental findings can occasionally result in early detection of disease, more often they result in unnecessary additional testing, increased anxiety and potential harms.
	9	<p><u>Relevant Outcome Data</u></p> <ul style="list-style-type: none"> • First, research shows that major adverse cardiac events are better predicted by SPECT than by visually-analyzed coronary angiograms. In addition, there is no incremental prognostic 	The WA HTA report does not address the comparison of SPECT with invasive angiography, or the additional value that SPECT may provide.

HERC Coverage Guidance – Nuclear Cardiac Imaging Disposition of Public Comments

Ident.	#	Comment	Disposition
		<p>value from visually-analyzed coronary angiograms over SPECT perfusion data (Iskandrian 1993).</p> <ul style="list-style-type: none"> • Second, in 2002 a study demonstrated that “ischemia guided angiography” using SPECT was more cost effective than routine angiography in patients with stable chest pain (Shaw 2002). • Further, Hachamovitch et al. (2003) published research that showed patients with a lesser degree of reversible ischemia on SPECT perfusion imaging had higher survival rates with medical therapy than with revascularization. However, those with a greater degree of ischemia were likely to benefit from invasive procedures. A subsequent study demonstrated that women who had a “false positive” noninvasive study and thus had coronary angiography showing “no significant” stenosis often had endothelial dysfunction documented in the catheterization lab. • Finally, the FAME trial affirmed the prognostic value of physiologic assessment to document ischemia before performing revascularization (Tonino 2009). 	<p>Iskandrian 1993 is a case series of 316 medically treated patients with CAD who had undergone both angiography and stress MPI who were followed for a mean of 28 months. Cox regression models were used to determine the prognostic values of clinical, exercise, MPI and angiography data in predicting cardiac death or MI. Authors report that extent of perfusion abnormality had the higher chi-square value of any of the variables (gender, exercise work, cath data).</p> <p>Shaw 2002 was a retrospective cohort study that compared direct referral for angiography to stress myocardial perfusion imaging in women with stable chest pain. Cost per patient was calculated for both strategies and found to be \$2490 for angiography and \$1587 for MPI in low risk patients; for high risk patients, the costs were \$3687 and \$2585 respectively.</p> <p>Hachomovitch 2003 was a retrospective cohort study of patients without prior MI or revascularization who received SPECT. Patients were assigned to groups based on treatment received at 60 days after SPECT (revascularization or medical therapy). Patients were then followed approx. 2 years and outcomes of cardiac death and all-cause death were calculated. Cardiac death was higher in the revascularization group (2.8% vs 1.3%). However, authors state that “with increasing amounts of inducible ischemia, mortality rates progressively increased in patients undergoing medical therapy”, and that in patients with > 20% myocardium ischemic, revascularization had a lower cardiac death rate than medical therapy.</p> <p>Tonino 2009 evaluated fractional flow reserve calculated</p>

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			<p>from angiography; MPI was not utilized.</p> <p>None of these studies would meet the inclusion criteria of the WA HTA review, which included only RCTs or observational studies comparing alternative testing strategies; none of them compare the diagnostic value of ECHO with SPECT.</p> <p>There is evidence demonstrating that the prognostic value of stress echo and MPI are comparable.</p>
	10	<p><u>Summary</u></p> <ul style="list-style-type: none"> Stress echo, MPI and cardiac PET have AUC which have been rigorously developed, endorsed by multiple specialty societies, and utilized by the medical community successfully for years. There are certainly circumstances where patients referred for imaging may meet AUC for both stress echo and MPI. Selecting the appropriate test in these circumstances is generally best left to the ordering physician, using the factors described above, along with their knowledge of the individual patient. 	<p>Selection of the appropriate test is always left to the ordering physician; that does not obviate the need for coverage policy development.</p>
	11	<p>Again, we support the HERC adopting the NCI guidance based on the AUC and the Washington State Health Care Authority Technology Assessment. Thank you for this opportunity to comment on the Health Evidence Review Commission’s Coverage Guidance on Nuclear Cardiac Imaging.</p>	<p>The AUC criteria do not compare MPI to other cardiac imaging technologies. The evidence reviewed in the guidance document that compares stress ECHO and MPI indicates equivalence of the two procedures in most circumstances, and stress ECHO is less costly and is associated with less harm.</p>

HERC Coverage Guidance – Nuclear Cardiac Imaging Disposition of Public Comments

References Provided by Commenters

Commenter	References
A	<p>(1) Hendel, R. C., Berman, D. S., Di Carli, M. F., Heidenreich, P. A., Henkin, R. E., Pellikka, P. A., Williams, K. A., et al. (2009). ACCF/ASNC/ACR/AHA/ASE/SCCT/SCMR/SNM 2009 Appropriate Use Criteria for Cardiac Radionuclide Imaging. A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, the American Society of Nuclear Cardiology, the American College of Radiology, the American Heart Association, the American Society of Echocardiography, the Society of Cardiovascular Computed Tomography, the Society for Cardiovascular Magnetic Resonance, and the Society of Nuclear Medicine Endorsed by the American <i>Journal of the American College of Cardiology</i>, 53(23), 2201-2229.</p>
B	<p>(1) Hendel, R. C., Berman, D. S., Di Carli, M. F., Heidenreich, P. A., Henkin, R. E., Pellikka, P. A., Williams, K. A., et al. (2009). ACCF/ASNC/ACR/AHA/ASE/SCCT/SCMR/SNM 2009 Appropriate Use Criteria for Cardiac Radionuclide Imaging. A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, the American Society of Nuclear Cardiology, the American College of Radiology, the American Heart Association, the American Society of Echocardiography, the Society of Cardiovascular Computed Tomography, the Society for Cardiovascular Magnetic Resonance, and the Society of Nuclear Medicine Endorsed by the American <i>Journal of the American College of Cardiology</i>, 53(23), 2201-2229.</p> <p>(2) Hendel, R. C., Patel, M. R., Allen, J. M., Min, J. K., Shaw, L. J., Wolk, M. J., et al. (2013). Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force. <i>Journal of the American College of Cardiology</i>, 61(12), 1305-1317.</p> <p>(3) Williams, K. A., Hill, K. A., & Sheridan, C. M. (2003). Noncardiac findings on dual-isotope myocardial perfusion SPECT. <i>Journal of nuclear cardiology</i>, 10(4), 395-402.</p> <p>(4) Iskandrian, A. S., Chae, S. C., Heo, J., Stanberry, C. D., & Wasserleben, V. (1993). Independent and incremental prognostic value of exercise single-photon emission computed tomographic (SPECT) thallium imaging in coronary artery disease. <i>Journal of the American College of Cardiology</i>, 22(3), 665-670.</p> <p>(5) Shaw, L. J., Heller, G. V., Travin, M. I., Lauer, M., Marwick, T., Hachamovitch, R., et al. (1999). Cost analysis of diagnostic testing for coronary artery disease in women with stable chest pain. <i>Journal of Nuclear Cardiology</i>, 6(6), 559-569.</p> <p>(6) Hachamovitch, R., Hayes, S. W., Friedman, J. D., Cohen, I., & Berman, D. S. (2003). Comparison of the short-term survival benefit associated with revascularization compared with medical therapy in patients with no prior coronary artery disease undergoing stress myocardial perfusion single photon emission computed tomography. <i>Circulation</i>, 107(23), 2900-2907.</p> <p>(7) Tonino, P. A., De Bruyne, B., Pijls, N. H., Siebert, U., Ikeno, F., vant Veer, M., et al. (2009). Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. <i>New England Journal of Medicine</i>, 360(3), 213-224.</p>



VIA Electronic Mail

November 12, 2014

Oregon Health Policy & Research
Value-based Benefits Subcommittee
Health Evidence Review Commission
1225 Ferry Street, Suite C
Salem, Oregon 97301
Email: HERC.Info@state.or.us

Re: Coverage Guidance for Nuclear Cardiac Imaging

Dear Dr.Coffman,

The American Society of Nuclear Cardiology appreciates the opportunity to comment on the Implementation for the Prioritized List before the Value based Benefits Subcommittee of the Oregon Health Evidence Review Commission. While we appreciate that the diagnostic procedure file designation for the SPECT codes enables a practitioner to perform SPECT in certain circumstances we adamantly oppose the proposed policy due to its implication that SPECT and stress echo are interchangeable tests. ASNC is a 4,500 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology and cardiovascular computed tomography, develops standards and guidelines for training and practice, promotes accreditation and certification within the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology and cardiovascular computed tomography.

We are deeply concerned that this policy suggests that stress echocardiography studies are interchangeable with myocardial perfusion imaging (MPI) in most clinical situations. This is an incorrect assumption and it confuses the proper application of these two essential imaging tools. The perception that stress echo and MPI are interchangeable is clearly erroneous as the determination as to which test is performed is based on many nuanced factors that are specific to the individual patient. **ASNC strongly opposes any policy that forces the substitution of tests and removes the physician's ability to decide what course of care is the most effective for the patient.** Moreover, this position is underscored by American Medical Association (AMA) policy H-320.946 which opposes:

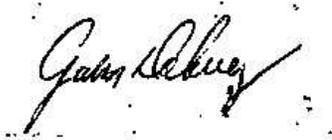
“the intrusion...in to doctor patient interaction (e.g. denying one diagnostic test in favor of another)[and will take action] by (a) studying the prevalence of forced test substitution and

denial of requesting imaging service... payers (b) advocating against such practices (c) supporting the use of appropriate use criteria developed by medical societies and expert physicians....”

Where two tests are clinically appropriate it is the exclusive right of the physician, in consultation with his or her patient, to decide which test is performed. The physician is in the best position to evaluate which test is better for the patient based on the patient’s condition, quality of the imaging available, and which test would most beneficial according to the clinical judgment of the physician.

ASNC appreciates the opportunity to comment on this policy and we welcome any questions or concerns you may have. Should you have any questions or concerns regarding our comments, feel free to Georgia Hearn, Senior Specialist, Regulatory Affairs for ASNC at ghearn@asnc.org.

Sincerely,

A handwritten signature in black ink, appearing to read "E. Gordon Depuey". The signature is written in a cursive style with a prominent flourish at the end.

E. Gordon Depuey, MD

President, American Society of Nuclear Cardiology

Section 5.0

Retreat follow-up January

2015

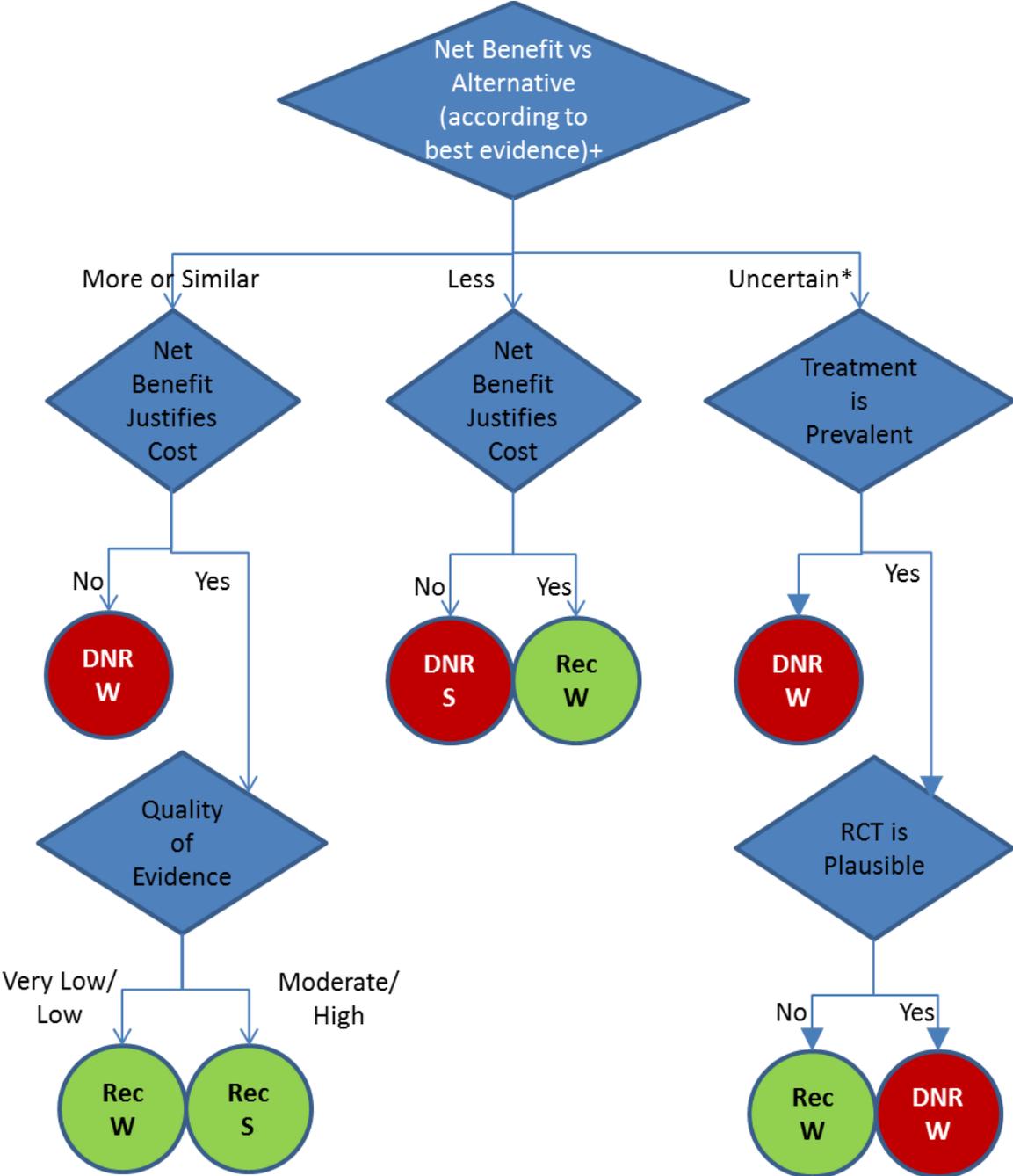
HERC Process improvements, initial plan for 2015 (DRAFT)

ID	Description	Next step/completed status	Rationale (CeBP report or other)	Timing	(Estimated) Completion date
1	Engage experts earlier	New policies are in place allowing HERC medical directors to engage experts prior to public meetings.	Stakeholders would like to be more involved... ...address delays and inefficiencies...	December, 2014	New policy is now in place
2	Engage stakeholder groups earlier	New policy in place of notifying relevant stakeholder groups (professional societies, etc.) at 30-day notice of initial meeting and at public comment.	Stakeholders would like to be more involved... ...address delays and inefficiencies...	December, 2014	New policy is now in place
3	Remove 2 month delay between VbBS and HERC	Approved November, 2014	...address delays and inefficiencies...	January, 2015	New policy is now in place
4	Revised CG Topic Identification and selection process	New policy is in effect now for twice-a-year open nomination process. Staff will conduct outreach.	Revise current meeting processes...create new, explicitly-defined meeting processes	December, 2014	New policy is now in place
5	Incorporate flexible/non-medical services	Staff is working on some topics to bring to VbBS and is considering these topics for coverage guidances. Low back pain group is looking at non-medical interventions	(Related to HERC retreat discussion, not report)	Ongoing	Staff will bring topics as they are identified.
6	Clarify how to introduce experts and what their role is	Finalize draft, encourage use by chairs	Clearly define and communicate the HERC's decision-making process	December, 2014	Template is now ready for use by chairs
7	Services recommended for noncoverage table	Finalize and publish	Optimize HERC website ...expand dissemination...	January, 2015	January, 2015
8	Changes to coverage guidance development framework (algorithm)	Discuss with HERC in January	Revise current meeting processes to optimize use of time (w/Initiative from Dr. Chan)	January, 2015	January, 2015, though it could be delayed
9	Explain cost impacts of decisionmaking in fixed budget/frozen line environment, give cost a higher role;	Staff is working on a collaboration plan with actuarial services, budget, MAP and Pharmacy to obtain cost data sooner in the process and better understand budget impact.	(Feedback from HERC retreat, OHA leadership)	Now	February, 2015
10	Add "clinical bottom line" to coverage guidances	Staff developing examples to review with QHOC.	Translate and disseminate HERC evidence products, and customize to specific audiences.	Staff has started; for Jan. QHOC then March HERC.	March, 2015

HERC Process improvements, initial plan for 2015 (DRAFT)

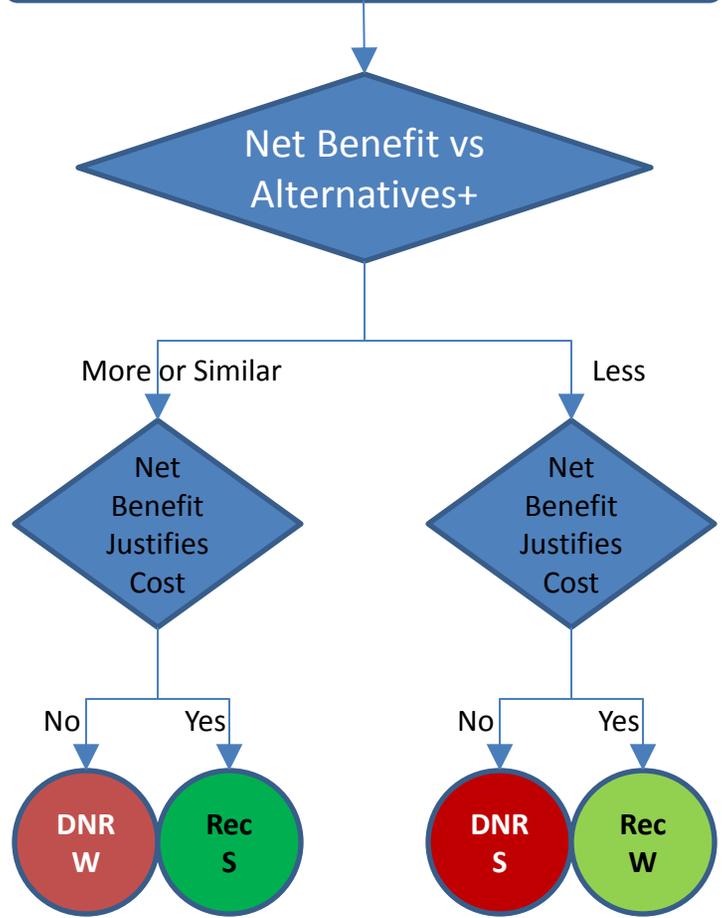
ID	Description	Next step/completed status	Rationale (CeBP report or other)	Timing	(Estimated) Completion date
11	Restructure HTAS/EbGS	Leadership meeting December 17, 2014, then hopefully HERC January 2015.	(Ensure balanced membership for both groups)	Began December, 2014	March, 2015
12	Consider an additional meeting of Commission/subcommittee leaders when subcommittees disagree	Proposal to be discussed at Jan. 2015 HERC	Revise current meeting processes to optimize use of time and resources, and create new, explicitly defined meeting processes	January, 2015	March, 2015
13	Improve HERC's orientation materials and approach	Staff is exploring potential approaches and preparing information.	Develop clear documentation of roles, responsibilities, expectations, processes, org. structure and workflow	Began December, 2014	Spring, 2015
14	Searchable web site	Staff to finalize format and add keywords	Feedback from QHOC Translate and disseminate HERC products Optimize HERC website	Began July, 2014	October 1, 2015 prioritized list
15	Improve expert input process by collaborating with other similar groups	Staff to initiate outreach to Washington HTA.	Revise current meeting processes (by learning from other groups)	January, 2015	By end of 2015
16	Patient decision tools	Initial work is starting up with CeBP and Transformation Center. Funding through SIM grant.	Translate and disseminate HERC evidence products, and customize to specific audiences.	Began in September, 2014	December, 2015

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.

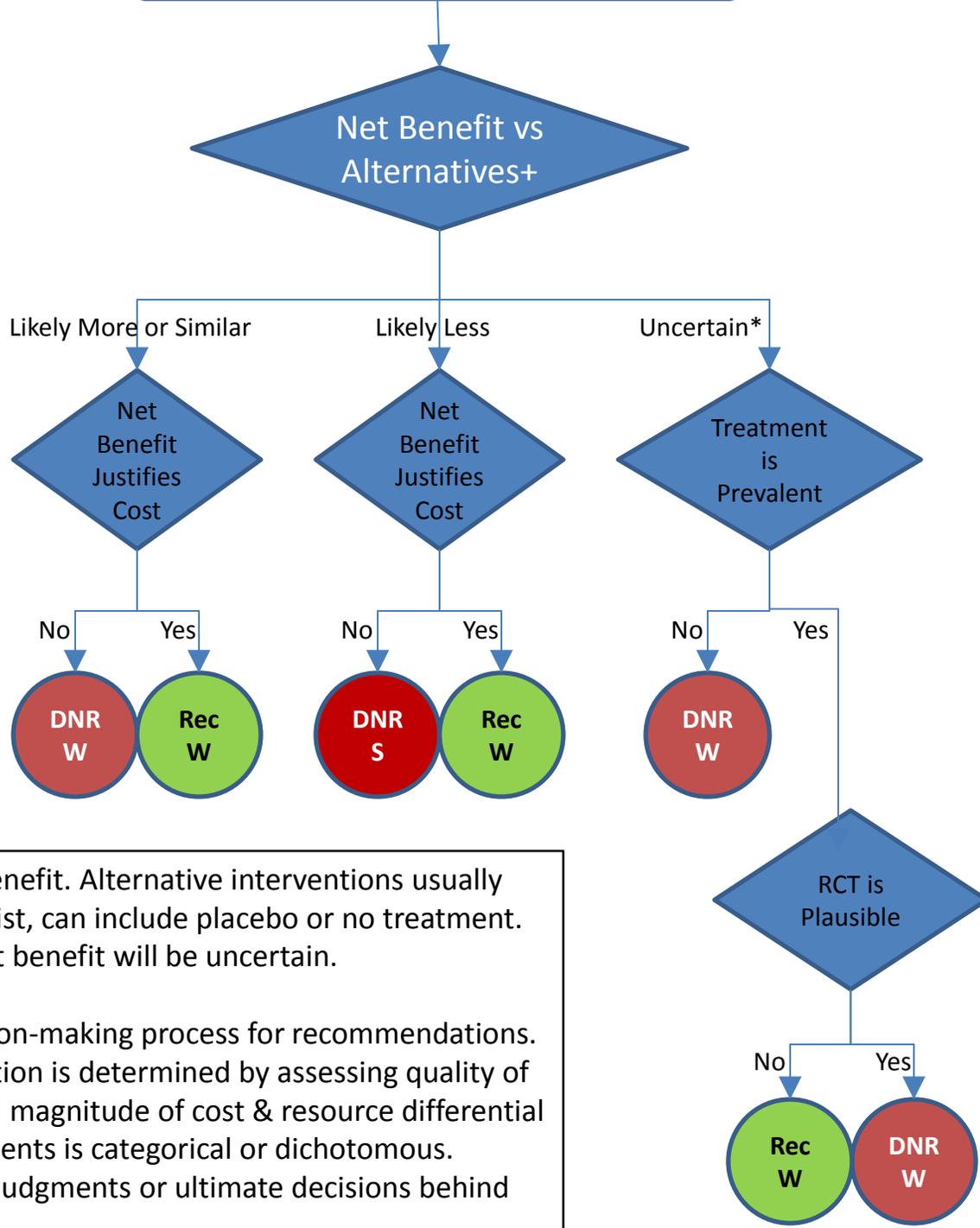


+Values & preferences are integral in the assessment of net benefit. Alternative interventions usually have proven net benefit and cost-effectiveness, but if none exist, can include placebo or no treatment.
 *In most cases of very low quality evidence, assessment of net benefit will be uncertain.

High or Moderate Quality of Evidence



Low or Very Low Quality of Evidence



+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.