Health Evidence Review Commission

November 13, 2014
1:30 PM

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

Section 1.0

Call to Order

Section 1.0

Staff Report

AGENDA
HEALTH EVIDENCE REVIEW COMMISSION
Meridian Park Room 117B&C
November 13, 2014
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 (August 14, 2014)	Som Saha	X
3	1:40 PM	Director's Report	Darren Coffman	
4	1.45 PM	Value-based Benefits Subcommittee Report	Kevin Olson Ariel Smits Cat Livingston	X
5	2:20 PM	Indications for Hyperbaric Oxygen Therapy a. HTAS coverage guidance recommendation b. VbBS Prioritized List recommended changes	Wally Shaffer Alison Little	X
6	3:20 PM	Coverage Guidance Updates	Cat Livingston Alison Little	X
7	3:40 PM	Retreat Follow-up	Som Saha Darren Coffman	
8	4:20 PM	Next Steps • Schedule next meeting – January 8, 2015 Wilsonville CCC Room 111-112	Som Saha	
9	4:30 PM	Adjournment	Som Saha	

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

Minutes

HEALTH EVIDENCE REVIEW COMMISSION
Meridian Park Hospital
Community Health Education Center Room 117B&C
Tualatin, OR 97062
August 14, 2014

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

Members Absent: None.

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

Also Attending:
Alison Little, MD, MPH, OHSU CeBP; Kevin Olson, MD, VbBS Chair; Kent Benner & Kaitlan Benner, The Oregon Clinic; Kerri Fowler, Umpqua Health Alliance; Christie & Eric Riehl; Adrienne Scavera, MHAO; Rebekah Brewis, PDX Trans* Pride; Jo Ann Sowers, Portland State University; Paul Neilson, Astra Zeneca (Medimmune); Ashlen Strong, Health Share of Oregon; Shannon Beatty, Medimmune; Seth Johnstone and Jenn Burleton, TransActive; Eric Larsson, Lovaas Institute; Laura Hill and Becky Reynolds, Abbvie; BJ Cavnor, One in Four Chronic Health; Seth Adams, WVP Health Authority; Cory Bradley, CareOregon; Tobi Rates, Autism Society; Dr. Maria Gilmour, Wynne Solutions; Alex Shebiel, Lindsay Hart; Camille Kerr and Deirdre Monroe, Allergan; Danielle Askini, Maura C. Roche, Alex Lausen, Peter Molof, Ryannah Quigley, Curtis Espinoza, & Amanda Spencer, Basic Rights Oregon; Ellen Miller, CFM/PHS; Lea Forsman, OHA/DMAP; Maria Wynne Gilmour, Wynne Solutions; Stacy Aria, Family Care; Amy Burn, All Care CCO; Jesse Little, OHA Actuarial Services Unit; Lorren Sandt, Caring Ambassadors.

Call to Order

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

Approval of Minutes

MOTION: To approve the minutes of the June 12, 2014 meeting as presented. CARRIES 10-0.

Director's Report

Darren Coffman confirmed there will be an interim modifications Prioritized List published October 1, 2014. The new biennial list will be published January 1, 2015. Going forward, we will produce lists each January and October 1st. The implementation of the next biennial list will be

on either October 1, 2015 or January 1, 2016, depending on CMS's final decision on the implementation of ICD-10.

Coffman reported that he and Saha held conversations with two potential osteopathic physician candidates for the DO HERC vacancy and there has been a strong candidate for the consumer representative who has indicated interest in that vacancy as well. The Governor's Office may hold off making appointments until October for a November Senate confirmation.

Value-based Benefits Subcommittee (VbBS) Report
Meeting materials handout

Treatments for Hepatitis C

Saha announced that the Commission is tabling the discussion of this topic after hearing the recommendation that came out of the VbBS's meeting that morning, along with input from CCOs and legislators and new reports/guidelines that will need to be reviewed.

Miscellaneous recommended changes to the Prioritized List

Ariel Smits, Cat Livingston and Kevin Olson, MD, VbBS Chair, each helped to summarize a number of topics discussed at recent meetings.

Smits reported the recommendations from the May 8, 2014 VbBS meeting not reported at the June HERC meeting:

May 8th recommendations for interim changes, effective 10/1/14 include:

- Add a surgical code to the colon cancer line
- Add a surgical code to the vascular insufficiency of intestines line
- Combine open and closed hip fracture diagnoses on the hip fracture line
- Add transurethral prostatic implants for treatment of benign prostatic hypertrophy
- Remove multiple surgical codes from the covered sleep apnea line
- Revise the rehabilitation guideline to reflect criteria for rehabilitation services rather than limits based on the number of visits
- Revise the sleep apnea guideline to further define daytime sleepiness and to specify that tonsillectomy/adenoidectomy surgical codes on that line are for treatment of children only
- Add a new diagnostic guideline specifying that computer-aided mammography for both screening and diagnostic purposes is not a covered service

August 14th recommendations for interim changes, effective 10/1/14 include:

- Remove certain nerve block procedure codes from the Prioritized List and advise DMAP to place these codes in the Ancillary File
- Add diagnosis codes for diabetic retinopathy to the diabetic retinopathy line
- Add ICD-10 diagnosis codes for certain types of diabetes to the appropriate diabetes lines
- Delete diagnosis codes for chiropractic and osteopathic manipulation from the migraine headache line
- Add a new coding specification to the tension headache line specifying that chiropractic and osteopathic manipulation are on this line only for pairing with cervicogenic headache.

DRAFT

- Add codes for chemodenervation of the anal sphincter to the uncovered chronic anal fissure line
- Delete codes for chemodenervation of extraocular muscles from the covered amblyopia line; those codes will remain on two covered strabismus lines
- Modify the nerve block guideline to include the CPT codes for certain procedures and remake it into an ancillary guideline
- Add a new guideline which specifies that removal of tympanostomy tubes is a covered service
- Modify the spinal disorders guideline to require objective evidence of neurologic injury or radiculopathy
- Modify the rehabilitation guideline to limit the total number of therapy visits for all conditions to 30 per year, except for certain neurological conditions or when in an inpatient rehabilitation facility.
- Modify the lymphedema guideline to specify that compression dressings/garments are covered for treatment of lymphedema even in the absence of complications.
- Delete the Synagis guideline for RSV prophylaxis
- Add several new coding specifications regarding use of botulinum toxin; delete the guideline note regarding botulinum toxin use for bladder indications

August 14th recommendations for interim changes, effective 10/1/14 include:

- Add several surgical codes for sex reassignment surgery to the gender dysphoria line along with new guideline on when hormone therapy and surgical treatment is appropriate

May 8th recommendations for the 2016 biennial list include:

- Move the diagnostic code for unspecified myopathy from the covered dysfunction lines to the uncovered fibromyalgia line.
- Add the diagnostic code for chronic fatigue syndrome to the new fibromyalgia line and retitle it
- Remove the diagnosis codes for injuries to the major blood vessels of the neck from one covered line to a more appropriate covered line
- Create a new lymphedema line and prioritize it in the covered region of the Prioritized List
- Create a new line for miscellaneous conditions requiring no treatment and prioritize it to the last line on the Prioritized List
- Merge the somatization and factitious disorder lines; prioritize into the non-covered region of the Prioritized List
- Combine the two hyperbaric oxygen lines (merge line 373 into line 336)

Other recommendations were developed related to the prioritization of hyperbaric oxygen therapy, but those will be presented for discussion at the November meeting along with the coverage guidance that they were based on.

VbBS Chair Kevin Olson and staff then asked for clarification about incorporating coverage guidances into the List, specifically what to do with weak recommendations *for* and *against*. Saha clarified that VbBS has other considerations to weigh, including cost, public input, etc. They should use the entire document, including the GRADE-informed framework, to make an appropriate recommendation for placement on the Prioritized List of Health Services.

DRAFT

MOTION: To accept the VbBS recommendations on changes to upcoming Prioritized Lists as stated. See the VbBS minutes of 5/8/14, 8/8/14 and 8/14/14 for a full description. Carries: 10-0.

Applied Behavior Analysis (ABA) for Autism Spectrum Disorder (ASD)
Meeting Materials page 143-264

Dr. Cat Livingston reviewed the background on the Commission's evaluation of the evidence of ABA for ASD, which began in August of 2013.

Oregon Senate Bill 365 (2013) requirments.

- Requires state-regulated commercial health plans to approve and manage autism treatment, including ABA therapy and any other medical or mental health services identified in an individualized treatment plan.
    - Law applies to patients who seek care before age nine, minimum coverage of up to 25 hours of ABA per week, continuing as long as medically necessary.
    - Health plans that provide coverage to OEBB and PEBB must begin coverage in 2015
    - Other health plans are required to begin coverage in 2016.
- The bill required HERC to evaluate the evidence for ABA and make a coverage decision for OHP.

EbGS reviewed the evidence and adopted summary conclusions based on the modified GRADE methodology used in the coverage guidance development process. Expert input and public comment was solicited and reviewed. In addition to specific comments, a total of 336 unduplicated citations were provided by public commenters. Each citation was evaluated to determine study design or article type and population characteristics (number and ages of included individuals), the abstract was retrieved and a link to the article provided when available.

Given that the focus of most of the public comment pertained to requesting that ABA be recommended for coverage in individuals over age 12, a detailed review of citations was limited to those studies. A random sample of 10% of single-subject research design (SSRD) study types were reviewed in additional detail. In addition, all systematic reviews and meta-analyses of SSRDs were reviewed in more detail.

EbGS met April 24, 2014, having reviewed the evidence, public written comment, in-person public comment and expert input and approved a modified evaluation of the evidence to send to VbBS.

On further review of what is allowed under the Mental Health Parity and Addiction Equity Act, staff suggested and VbBS agreed to modify the language to be more descriptive of the studies and not include specific hour or duration limits of the treatment.

Proposed scoring would place treatment of autism at approximately line 199, up from the current prioritization of 313.

Coffman added that the implementation date, as determined by OHA leadership, will be January 1, 2015. This coincides with a new CCO contract/rate period and with the date when providers can be licensed/certified to provide this care.

DRAFT

In June 2014, VbBS approved a new guideline on treatment of autistic spectrum disorder with applied behavioral analysis. Many of the studies and discussion centered around self-injurious behavior. There was some concern expressed that the guideline being recommended only impacted patients diagnosed with autism and did not include treatment for non-autistic patients with self-injurious behaviors. This condition responds in the same way to ABA as does a person with an ASD diagnosis.

Public Comment

Christie & Eric Riehl, as a parents of a child with autism and self-injurious behavior, offered their perspective and advocated to allow coverage of ABA for patients outside of an ASD diagnosis. She urged the commission to include codes for inpatient treatment and to include other comorbid conditions.

Tobi Rates, Executive Director of the Autism Society of Oregon and parent of two children on the autism spectrum who receive OHP services, expressed her gratitude to the Commission for taking on this complex issue, for the recommendations presented today and announcing a clear implantation date. She expressed concern with conclusion that the evidence for ABA for children 13 years and older is inconclusive. She said her advocacy group would continue to examine this issue.

Maria Wynne Gilmour, Wynne Solution, an ABA provider and board certified behavior analyst of 15 years from Portland, added some statistics regarding self-injurious behavior. In the last 30 days, she has received 18 referrals for this condition of which 8 were children over 12 or adults.

Gibson asked if ABA for self-injurious behavior, in the absence of an ASD diagnosis, is effective. Saha stated that the subcommittee determined it is effective. Chan, the subcommittee chair, suggested the evidence summary be reframed for clarity. Saha agreed, the subcommittee may look at editing their work but that would not preclude a vote today.

Audience member Christie Riehl, asked additional implementation questions about coding problem behaviors vs. primary diagnosis, citing the guideline that is being replaced. Livingston assured all that ABA treatment will need prior authorization and will be considered by a medical reviewer.

MOTION: To accept the VbBS recommendations to add codes and a guideline to the Prioritized List based on the EbGS evidence evaluation on applied behavior analysis for autism spectrum disorder and approve the staff recommendation to add ABA to Line 442 of the 1/1/15 list including self-injurious behavior (see Attachment A). CARRIES: 10-0.

Cross-Sex Hormone Therapy & Sex Reassignment Surgery for Gender Dysphoria
Meeting Materials pages 265-269

Dr. Ariel Smits explained, the January 1, 2015 Prioritized List includes gender dysphoria as a new, covered line (413).

DRAFT

- Currently, the only treatments approved for inclusion on that line are office visits, psychotherapy and puberty suppression medication for transgender and gender-questioning youth.
- Other treatments include cross-sex hormone therapy and sex reassignment (gender reassignment) surgery.
    - Additional evidence was reviewed about the efficacy of treatment, particularly in reducing suicide attempts, IV drug abuse, and other high-risk behavior.
    - Treatment significantly reduces depression and anxiety in patients.
    - The total cost to OHP of adding additional treatments is expected to be minimal.
    - Evidence supports adding cross-sex hormone therapy and sex reassignment surgery, excluding the more cosmetic-focused procedures (breast augmentation, facial bone reconstruction).
    - Proposed scoring would place treatment of autism at approximately line 312, up from the current prioritization of 413.

At the VbBS meeting earlier in the day, there was considerable discussion about the lack of an age restriction for surgical procedures. Smits confirmed that the Oregon age of consent for surgical procedures is age 15. Dr. Olson explained that these types of procedures should not be singled out for restriction until age 18 or even higher, as many other procedures which have life-long impact can be consented to at age 15.

Tyack explained his position by saying there are so many things a 15-year-old cannot do. They cannot drive, serve in the armed forces, vote, ingest alcohol, smoke, etc. In general, he supports the procedure and feels sympathy for people who need the surgery but cannot get passed the issue of age of medical consent. Ahmann added his agreement and concern.

Saha discussed whether anyone under the age of 18 should be able to consent to any surgery and stated that is a question for lawmakers in Oregon. He thought it would be a dangerous precedent to single out an exception for this one surgery.

Williams discussed her understanding is that surgery itself comes near end of a long treatment plan. No one rushes into this irreversible surgery lightly or without preparation. Smits added the evidence shows there is a very low rate of regret recorded. Saha believes the stipulations in the guideline preclude one making a rash decision.

Public Comment

> *Danielle Askini*, policy director for Basic Rights Oregon, asserted that this invasive, life-altering treatment is only given as part of a lengthy continuum of care. Youth are required to have extensive evaluations by qualified mental health professionals and that the year of hormone therapy required in the guideline acts as another safeguard against rash decisions by youth.
>
> *Jenn Burleton*, Executive Director of TransActive, agreed with Ms. Askini, adding details about the lengthy path to surgery: assessments, reassessment, evaluation, referral and many other steps throughout the growth cycle.

Saha asked if families often support youths with gender dysphoria. Burleton responded affirmatively. Moreover, those living outside the home have advocacy and support as well.

DRAFT

Ahmann wanted to know how many surgeries are completed per year in Oregon. Burleton and Askini stated there are two physicians in Oregon who perform gender-confirming surgeries and estimated a very small percentage would undergo genital reconstruction. Burleton added, with access to puberty suppressing drugs, many procedures will become unnecessary, as the undesired sex characteristics will never fully develop.

Smits added many individuals do well with certain medications and counseling and never pursue surgical interventions. She added, among California government employees, a study showed that 42 surgeries were performed over a 6.5-year period.

Gibson commented that while he shares the concerns about age, we cannot rewrite the state statute about age of medical consent though the HERC process.

MOTION: To approve the line rescoring, updated treatment description, and the addition of cross-sex hormone therapy and various surgical procedures to the gender dysphoria line, and the new guideline as recommended by VbBS (see Attachment B). CARRIES 8-2 (Opposed:Tyack, Abstained: Ahmann).

Retreat Planning

Coffman mentioned the HERC retreat is scheduled for October 30, 2014 at a location TBD.

Some commissioners expressed a wish to have the retreat be a closed meeting, feeling that would foster more open conversation. Coffman explained what constituted a public meeting; in part, a public body with quorum discussing or deliberating towards a decision. Saha advocated for a public meeting, commenting that a core HERC principle is *transparency*. Further, he argued, limiting the discussion to meet the restrictions of a closed meeting would effectively limit the Commission's ability for meaningfully discussion, necessitating another public meeting to rehash topics to allow for public deliberations. All agreed using a facilitator with familiarity with the HERC process and products makes sense.

Staff suggested the possibility of a compromise, with half of the meeting closed, then opened as a public meeting to allow deliberation. Members would like participation in discussion limited to staff, commissioners, subcommittee members and advisory panel members. They clearly expressed their desire to hear *no* public comment that day. Staff will review public meeting laws to see what is possible.

Public Comment

There was no other public comment at this time.

Adjournment

Meeting was adjourned at 3:30 pm. Next scheduled regular meeting – November 13, 2014, Meridian Park Room 117 B&C.

DRAFT

ATTACHMENT A

Changes to Prioritized List Involving Applied Behavior Analysis

Add codes as follows to Line 313 and 442 of 1/1/15 Prioritized List:

Code	Description	Action
0359T	Behavior identification assessment	**Add to 313 & 442**
Follows 0359T 0360T 16-45 min 0361T each additional 30 min	Observational behavioral follow-up assessment	**Add to 313 & 442**
Follows 0359T 0362T 16-45 min 0363T each additional 30 min	Exposure behavioral follow-up assessment	**Add to 313 & 442**
0364T first 30 min 0365T each additional 30 min	Adaptive behavior treatment by protocol	**Add to 313 & 442**
0366T first 30 min 0367T each additional 30 min	Group adaptive behavior treatment by protocol	**Add to 313 & 442**
0368T first 30 min 0369T each additional 30 min	Adaptive behavior treatment with protocol modification	**Add to 313 & 442**
0370T	Family adaptive behavior treatment guidance	**Add to 313 & 442**
0373T first 60 minutes of technicians' time, 0374T each additional 30 minutes of technicians' time	Exposure adaptive behavior treatment with protocol modification	**Add to 313 & 442**

Revise Guideline Note 75 as follows effective 1/1/15:

GUIDELINE NOTE 75, APPLIED BEHAVIOR ANALYSIS FOR AUTISM SPECTRUM DISORDER

Line 313

~~There is limited evidence of the effectiveness of treatment (e.g., Applied Behavioral Analysis) for Autism Spectrum Disorders (ASD). However, effective treatments may be available for co-morbid conditions such as mood disorders. When treating co-morbid conditions, that condition, not an ASD diagnosis, should be the primary diagnosis for billing purposes. The treatment of co-morbid mental health conditions should be consistent with the treatment methods, frequency, and duration normally applied to those diagnoses. Treatment of neurologic dysfunctions that may be seen in individuals with an ASD diagnosis are prioritized according to the four dysfunction lines found on the Prioritized List (Lines 78, 318, 375 and 407). Treatment for associated behaviors, such as agitation, that do not meet the criteria for co-morbid mental health diagnoses should be limited in frequency to a maximum of 8 hours of behavioral health service per month, subject to utilization management review by the mental health organization (MHO) or other relevant payer.~~

Applied behavior analysis (ABA), including early intensive behavioral intervention (EIBI), represented by CPT codes 0359T-0374T, is included on line 313 for the treatment of autism spectrum disorders.

DRAFT

GUIDELINE NOTE 75, APPLIED BEHAVIOR ANALYSIS FOR AUTISM SPECTRUM DISORDER (Cont'd)

ABA services are provided in addition to any rehabilitative services (e.g. physical therapy, occupational therapy, speech therapy) included in guideline note 6, REHABILITATIVE THERAPIES that are indicated for other acute qualifying conditions.

Individuals ages 1-12

Specifically, EIBI (for example, UCLA/Lovaas or Early Start Denver Model), is included on this line.

For a child initiating EIBI therapy, EIBI is included for up to six months. Ongoing coverage is based on demonstrated progress towards meaningful predefined objectives (objectives should be achieved as a result of the EIBI, over and beyond gains that would be expected to arise from maturation alone) using a standardized, multimodal assessment, no more frequently than every six months. Examples of such assessments include Vineland, IQ tests (Mullen, WPPSI, WISC-R), language measures, behavior checklists (CBCL, ABC), and autistic symptoms measures (SRS).

The evidence does not lead to a direct determination of optimal intensity. Studies of EIBI ranged from 15-40 hours per week. Through Oregon's Senate Bill 365, other payers are mandated to cover a minimum of 25 hours per week of ABA. There is no evidence that increasing intensity of therapy yields improves outcomes. Studies for these interventions had a duration from less than one year up to 3 years.

If EIBI is not indicated, has been completed, or there is not sufficient progress toward multidimensional goals, then less intensive ABA-based interventions (such as parent training, play/interaction based interventions, and joint attention interventions) are included on this line to address core symptoms of autism and/or specific problem areas. Initial coverage is provided for six months. Ongoing coverage is based on demonstrated progress towards meaningful predefined objectives, with demonstration of medical appropriateness and/or emergence of new problem behaviors.

Effective interventions from the research literature had lower intensity than EIBI, usually a few hours per week to a maximum of 16 hours per week, divided into daily, twice-daily or weekly sessions, over a period of several months.

Parent/caregiver involvement and training is recommended as a component of treatment.

Individuals ages 13 and older

Intensive ABA is not included on this line.

Targeted ABA-based behavioral interventions to address problem behaviors, are included on this line. The quality of evidence is insufficient to support these

DRAFT

ATTACHMENT A

Changes to Prioritized List Involving Applied Behavior Analysis

GUIDELINE NOTE 75, APPLIED BEHAVIOR ANALYSIS FOR AUTISM SPECTRUM DISORDER (Cont'd)

interventions in this population. However, due to strong caregiver values and preferences and the potential for avoiding suffering and expense in dealing with unmanageable behaviors, targeted interventions may be reasonable. Behaviors eligible for coverage include those which place the member at risk for harm or create significant daily issues related to care, education, or other important functions. Ongoing coverage is based on demonstrated progress towards meaningful predefined objectives, with demonstration of medical appropriateness and/or emergence of new problem behaviors.

Very low quality evidence is available to illustrate needed intensity and duration of intervention. In the single-subject research design literature, frequency and duration of interventions were highly variable, with session duration ranging from 30 seconds to 3 hours, number of sessions ranging from a total of three to 8 times a day, and duration ranging from 1 to 20 weeks. These interventions were often conducted in inpatient or residential settings and studies often included patients with intellectual disabilities, some of which were not diagnosed with autism.

Parent/caregiver involvement and training is encouraged.

Add the following guideline note to the 1/1/15 Prioritized List:

GUIDELINE NOTE 126, APPLIED BEHAVIOR ANALYSIS (ABA) INTERVENTIONS FOR SELF-INJURIOUS BEHAVIOR

Line 442

Targeted ABA-based interventions towards self-injurious problem behaviors are included on this line when meeting criteria as defined in guideline note 75 APPLIED BEHAVIOR ANALYSIS FOR AUTISM SPECTRUM DISORDER.

Rescore the autism spectrum disorder line as shown below for the 1/1/2016 Prioritized List:

- Category: 3
- HL: 5
- Suffering: 4
- Population effects: 2
- Vulnerable population: 0
- Tertiary prevention: N/A
- Effectiveness: 3
- Need for service: 0.7
- Net cost: 1
- Approximate new line placement: 199

DRAFT

ATTACHMENT B

Changes to Prioritized List Involving Treatments for Gender Dysphoria

Make the following changes to the Prioritized List effective 1-1-2015:

1) Change the treatment description of Line 413 GENDER DYSPHORIA to ~~MEDICAL/PSYCHOTHERAPY~~ MEDICAL AND SURGICAL TREATMENT; PSYCHOTHERAPY
2) Add cross-sex hormone therapy to Line 413
3) Add CPT 19301-19304, 53430, 54125, 54400-54417, 54520, 54660, 54690, 55175-55180, 55970, 55980, 56625, 56800, 56805, 56810, 57106-57107, 57110-57111, 57291-57292, 57335, 58150, 58180, 58260-58262, 58275-58291, 58541-58544, 58550-58554, 58570-58573, 58661, 58720 to Line 413
    a. Advise DMAP to remove CPT 55970 and 55980 from the Excluded List
4) Add the following guideline:

GUIDELINE NOTE 127, GENDER DYSPHORIA

Line 413

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

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

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

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

1) have persistent, well documented gender dysphoria
2) have completed twelve months of continuous hormone therapy as appropriate to the member's gender goals unless hormones are not clinically indicated for the individual
3) have completed twelve months of living in a gender role that is congruent with their gender identity unless a medical and a mental health professional both determine that this requirement is not safe for the patient
~~4)~~ have the capacity to make a fully informed decision and to give consent for treatment
5) have any significant medical or mental health concerns reasonably well controlled

DRAFT

GUIDELINE 127, GENDER DYSPHORIA (Cont'd)

6) have two referrals from qualified mental health professionals with experience in working with patients with gender dysphoria who have independently assessed the patient. Such an assessment should include the clinical rationale supporting the patient's request for surgery, as well as the rationale for the procedure(s)

Rescore the gender dysphoria line as shown below for the 1/1/2016 Prioritized List:

- Category: 6
- HL: 6
- Suffering: 4
- Population effects: 0
- Vulnerable population: 0
- Tertiary prevention: 3
- Effectiveness: 2
- Need for service: 1
- Net cost: 2
- Score: 1040
- Approximate new line placement: 312

DRAFT

Value-based Benefits Subcommittee Recommendations Summary

For Presentation to:

Health Evidence Review Commission in November 2014

For specific guideline wording, please see the text of the 8-8-14 VbBS minutes.

ITEMS CONSIDERED BUT NO CHANGES MADE

VbBS considered, but did not accept the proposal to prioritize new treatments for Hepatitis C below the funding line.

GUIDELINE CHANGES

VbBS approved a recommendation for a new guideline on the treatments of Hepatitis C on lines 205 and 360. Staff to prepare draft wording and bring it back to the 8/14/2014 VbBS meeting.

.

DRAFT

VALUE-BASED BENEFITS SUBCOMMITTEE

Meridian Park Health
Community Health Education Center, Room 117B&C
Tualatin, OR
August 8, 2014
1:30 PM – 3:30 PM

Members Present: Kevin Olson, MD, Chair; James Tyack, DMD; David Pollack, MD (arrived 1:40); Susan Williams, MD (via phone); Mark Gibson; Irene Croswell, RPh; Laura Ocker, Lac; Holly Jo Hodges, MD (via phone).

Members Absent: None.

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

Also Attending: Lorren Sandt, Caring Ambassadors; Anne Murray and Brett Marett, BMS; Laura Hill, Becky Reynolds, Cheryl Fletcher and Desi Allen, Abbvie; Kent Benner, The Oregon Clinic; Barry Benson, Merck; Kim Blood, WVCH; Steve Nemirow; Shelly Bailey, Central Drugs; BJ Cavnor, One in Four Chronic Health; Bill Struyk, Johnson & Johnson; Jesse Little & Chelsea Guest, Actuarial Services Unit of DMAP; John Powell, John Powell Associates; Paul Nielsen, Astra Zeneca; Michele Hill, Gilead; Karynn Fish, OHA

DRAFT

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

  The meeting was called to order at 1:35 PM and roll was called. Minutes from the June 12, 2014 VbBS meeting were reviewed and approved. (Passed 7-0, Pollack absent)

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

- **Topic: Hepatitis C Treatments**

  Discussion: Livingston presented an issue summary. She briefly reviewed the MED report and the natural history of hepatitis C. She discussed that new trials are being released every week, and that a Drug Effectiveness Review Project (DERP) report is expected in early 2015. She reviewed the staff recommendation to place treatment for hepatitis C with newer low-value agents low on the Prioritized List with a guideline

referring to the Pharmacy & Therapeutics Committee Prior Authorization Criteria, which was recently adopted for fee-for-service clients. It was discussed that the prior criteria would have led to an estimated one-year cost of $168 million if applied to all OHP clients not a part of the ACA expansion, and with the revised P&T criteria this would limit the expected cost to approximately one-quarter of that amount.

Kent Benner, from the Oregon Clinic offered invited testimony. He is a hepatologist member of the external "Community Advisory Panel" who helped develop the criteria adopted by the P & T Committee for prior authorization. He declared no conflicts of interest. He stated that the prevalence of hepatitis C has not yet reached its peak. He also discussed the costs associated with liver decompensation and this should be considered in a cost-effectiveness analysis, mentioning studies that show a 8-15 fold reduction in endpoints if the virus can be cleared. Studies have typically excluded patients whom are sick with decompensation. He believes there is sufficient data to validate the effectiveness of these new drugs, and that they are game changers. Dr. Benner explained the rationale for treating the patients more urgently needing care represented in the latest P & T criteria, but said that this "triaging" raises major clinical and policy questions.

Public Comment:

Lauren Sant, Director of the Caring Ambassadors program. She acknowledged Caring Ambassadors gets unrestricted funding from every pharmaceutical company. She said that that moving drugs below the funding line is against the law. She discussed that current therapies are toxic, and that keeping telapravir and bocepravir as an option is criminal. She requested public input into the process. She said that she was co-chair of the "Fair Pricing Coalition" for many years and acknowledged the high price of these drugs.

Steve Nemerow, who represented himself and declared no conflicts of interest. He discussed his personal experience with Sovaldi and how this therapy cured him and allowed him to work and be functional. He said the committee shouldn't be saving money, but rather should be saving lives.

BJ Cavnor, Executive Director of One in Four Chronic Health. He acknowledged his organization receives unrestricted education

DRAFT

grants from the pharmaceutical industry,although they have not received funding from Gilead. He argued that the cost of not treating hepatitis C needs to be looked at, not just the cost of treating. He also addressed the need to treat individuals with HIV co-infection. He reports working on price reduction of drugs since 1997.

Dr. Olson asked to clarify what options were available to the subcommittee. Livingston discussed options of placing these treatments above or below a line, with or without a guideline, or to remain silent. Dr. Benner also asked some clarifying questions and stated that some of the studies of these medications have looked at non-treatment naïve patients. Additionally a question was asked about whether patients with decompensation will improve, and the answer was it is unknown. There is the hope that this will remove people from the transplant list but the data is not there yet. There is also the reality that relapse rates are likely higher than in the initial studies.

Mark Gibson discussed concerns about potential different coverage between fee-for-service and CCOs if these treatments a prioritized below the funding line. The subcommittee also discussed issues about price and there being an absolute limit to what can be funded for OHP, also balanced with education, child protective services, and public safety. If money were to be redirected from social supports to health care, then a net health deficit would be created. There was a discussion about price differences between different countries. and how, because of the price set, and the profit being derived from this drug, this is creating very difficult decisions. The moral aspects of the pricing of this drug were discussed. There was discussion about endorsing P&T Committee criteria. The group discussed the challenge that if it does cost ~$40 million dollars, then where is that money going to come from and what other budgets are being put at risk? There was a request for the future to address high cost medications with some sort of standard or consistent guideline.

There was a discussion about the suggested criteria regarding drug and alcohol use and abuse. They decided that 6 months of abstinence from alcohol misuse or hazardous drinking and substance use (or misuse of prescription medication) was appropriate.

Tyack announced a potential conflict of interest that did not require recusal.

DRAFT

There were concerns about currently available economic analyses not showing that this will save costs. There was a discussion that the cost in Oregon should be known, up front, as well as projected costs and savings down the road. It was suggested the legislature would need to find additional funding to work around 2% cap. Another proposal was to not offer the drug and then the effective price may drop, this has been seen in oncology drugs. After discussion, the subcommittee requested that

MOTION: To recommend keeping medical treatments for Hepatitis C on lines 205 and 360 witha guideline note referencing the P & T committee criteria, and to have staff bring back revised wording reflecting today's discussion to the August 14, 2014 VbBS meeting for additional review.

CARRIES 8-0.

Actions:

1) Amend Guideline from the meeting materials and bring it back to the VbBS meeting next week for final review and approval
2) Staff directed to bring back a guideline proposal for handling the prioritization of high cost medications at a later meeting

- **Issues for next meeting:**
  - Nerve blocks
  - Diabetic retinopathy codes
  - Tympanostomy tube removal
  - Spinal manipulation for treatment of migraine and tension headaches
  - Wearable cardiac defibrillators
  - Fibromyalgia related diagnoses
    - General conditions
    - Chronic fatigue syndrome
  - Hyperbaric oxygen
  - Percutaneous intervention for cervical spine
  - Guideline note on spinal disorders with neurologic impairment
  - Rehabilitation guideline
  - Lymphedema guideline
  - Denture guideline
  - Adenoidectomy – revisions to the obstructive sleep apnea guideline and sinusitis surgery guideline
  - RSV guideline
  - Botulinum toxin
  - Gender dysphoria

DRAFT

- Hepatitis C
- The new “non-covered” section of the Prioritized List
- Applied behavior analysis for the treatment of non-autistic self-injurious behavior
- Standardized assessment tools for evaluating progress in the treatment of autism spectrum disorder

- **Adjournment**

The meeting was adjourned at 3:40 pm. The next meeting will be held from 8:30 am to 1:00 pm on Thursday, August 14, 2014 at the Meridian Park Hospital Community Health Education Center in Conference Room 117B&C.

DRAFT

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

For specific coding recommendations and guideline wording, please see the text of the 8-14-14 VbBS minutes.

RECOMMENDED CODE MOVEMENT (effective 10/1/14 unless otherwise noted)

- Make various straightforward coding changes
- Remove various nerve block procedure codes from lines on the Prioritized List and recommend they be returned to the Ancillary List
- Add diagnosis codes for diabetic retinopathy to the diabetic retinopathy line
- Add ICD-10 diagnosis codes for certain types of diabetes to the appropriate diabetes lines (effective 1/1/15)
- Remove diagnosis codes for chiropractic and osteopathic manipulation from the migraine headache line
- Add a new coding specification to the tension headache line specifying that chiropractic and osteopathic manipulation are on this line only for pairing with cervicogenic headache
- Move the diagnostic code for unspecified myopathy from the covered dysfunction lines to the new fibromyalgia line (effective 1/1/16)
- Add the diagnostic code for chronic fatigue syndrome to the new fibromyalgia line (effective 1/1/16)
- Remove diagnosis codes for osteomyelitis from the hyperbaric oxygen therapy line (to be reviewed by HERC in November, 2014)
- Add chemodenervation of the anal sphincter to the uncovered chronic anal fissure line
- Remove chemodenervation of extraocular muscles from the covered amblyopia line but leave on two covered strabismus lines
- Add various surgical codes for sex reassignment surgery to the gender dysphoria line (effective 1/1/15)

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- Did not change the placement of tympanic membrane perforation diagnosis codes
- Leave diagnosis codes for unspecified rheumatism and fasciitis on a very low priority line rather than moving them to the new fibromyalgia line
- Did not change placement for botulinum toxin injections for treatment of neck or lower back pain or chronic daily headaches

RECOMMENDED GUIDELINE CHANGES (effective 10/1/14 unless otherwise noted)

- Eliminate the proposed guideline for treatments for Hepatitis C (which had been approved at the August 8, 2014 meeting)
- Modify the nerve block guideline to include the CPT codes for these procedures and make into an ancillary guideline

DRAFT

- Add a new guideline which specifies that removal of tympanostomy tubes is a covered service
- Modify the hyperbaric oxygen therapy guideline to add diabetic wounds as an indication, with specifics about when hyperbaric oxygen therapy would be appropriate (to be reviewed by HERC in November)
- Modify the spinal disorders guideline to require objective evidence of neurologic injury or radiculopathy
- Modify the rehabilitation guideline to limit the total number of therapy visits for all conditions to 30 per year, except for certain neurological conditions or when in an inpatient rehabilitation facility
- Modify the lymphedema guideline to specify that compression dressings/garments are covered for treatment of lymphedema even in the absence of complications
- Delete the Synagis guideline for RSV prophylaxis
- Add several new coding specifications regarding use of botulinum toxin and delete the guideline note regarding botulinum toxin use for bladder indications
- Modify the gender dysphoria guideline to add specifications for when cross-sex hormone therapy and sex reassignment surgery are appropriate (effective 1/1/15)

DRAFT

VALUE-BASED BENEFITS SUBCOMMITTEE
Meridian Park Health
Community Health Education Center, Room 117B&C
Tualatin, OR
August 14, 2014
8:30 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair; James Tyack, DMD; David Pollack, MD (left at 12:35 PM); Susan Williams, MD; Mark Gibson; Irene Croswell, RPh; Holly Jo Hodges, MD.

Members Absent: Laura Ocker, LAc.

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

Also Attending: Jesse Little, Actuarial Services Unit of DMAP; Laura Hill and Becky Reynolds, Abbvie; Sarah Schmidt, Zoll; Camille Kerr and Deirdre Monroe, Allergan; Amy Burns and Mark Bradshaw, AllCare CCO; Josh Balloch, Pac/West Communications; Seth Adams, WVP Health Authority; Kim Blood, WVCH; Jim Gardner, PhRMA; Bill Struyk, Johnson &Johnson; Paul Neilsen, Astra Zeneca (Medimmune); Lisa Valaika, Genzyme; Rachel Seltzer, OHSU/OHA; Brian Neiubuurt, OHA; John Beckwith and Debbie Christensen, Sacred Heart Hospital; Aubrey Harrison, Danielle Askini, and Alex Lausen, Basic Rights Oregon; Megan Bird, MD, Legacy Health Systems; Ann Murray, BMS; Shannon Beatty, Medimmune; Kathleen Klemann, FamilyCare; Lorren Sandt, Caring Ambassadors; Seth Johnstone and Jenn Burleton, TransActive; Eric Larsson, Lovaas Institute; Jim Murray, Hill-Ray; BJ Cavnor, One in Four Chronic Health; Kent Benner, MD, Oregon Clinic.

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

  The meeting was called to order at 8:35 am and roll was called. Minutes from the June, 2014 VbBS meeting were previously reviewed and approved at the August 8th meeting. The minutes from the August 8th meeting are not yet available and will be reviewed and approved at the November, 2014 VBBS meeting.

  Coffman reviewed the timing of upcoming Prioritized Lists. The HERC retreat has been set for October 30, 2014. There was some discussion about whether this was a public meeting; staff will review the agenda and public meetings law and advise the commission.

  Note: line numbers referenced in these minutes are in the format of *October 1, 2014 line/January 1, 2015 line*

DRAFT

- **Topic: Straightforward/Consent Agenda**

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

MOTION: To approve the consent agenda as presented. CARRIES 7-0.

Recommended Actions:

1) Add 40530 (Resection of lip, more than 1/4, without reconstruction) to line 292/279 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
2) Add 77418 (Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session) and 77421 (Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy**)** to lines 252/242 CANCER OF OVARY and 459/439 CANCER OF GALLBLADDER AND OTHER BILIARY
3) Add 35606 (Bypass graft, with other than vein; carotid-subclavian) to line 440/419 TRANSIENT CEREBRAL ISCHEMIA; OCCLUSION/STENOSIS OF PRECEREBRAL ARTERIES WITHOUT OCCLUSION
4) Add 35452 (Transluminal balloon angioplasty, open; aortic) to line 472/452 ATHEROSCLEROSIS, AORTIC AND RENAL
5) Add 15120 (Split-thickness autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children) and 15121 (each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof) to line 448/427 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
6) Add 14040 (Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10 sq cm or less) to line 459/438 HYPOSPADIAS AND EPISPADIAS
7) Add 62311 (Injection(s), of diagnostic or therapeutic substance(s),including anesthetic, antispasmodic, opioid, steroid, other solution, not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral) to lines 78/75 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES and 318/297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
8) Add 90670 (Pneumococcal conjugate vaccine, 13 valent) to line 3 PREVENTIVE SERVICES, BIRTH TO 10 YEARS OF AGE and 4 PREVENTIVE SERVICES, OVER AGE OF 10 of the October 1, 2014 list and line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS of January 1, 2015 list
    a. Advise DMAP to remove 90670 from the Excluded List.

DRAFT

- **Topic: Nerve blocks**

  Discussion: Smits introduced the summary document regarding nerve blocks. The subcommittee felt that the return of these codes to the Ancillary List was the better of the two proposed staff recommendations. This will allow the nerve blocks to continue to be treated as anesthesia for the peri-operative uses. Additionally, HERC staff could not find previous discussion/rationale for moving these codes from Ancillary to the Prioritized List. The Subcommittee felt that this was likely a mistake and should be corrected. The guideline note is recommended to be changed to an Ancillary Guideline.

MOTION: To recommend the code and guideline note changes as presented. CARRIES 7-0.

Recommended Actions:

1) Remove all nerve block CPT codes (64400-64450) from lines on the Prioritized List
2) DMAP was advices to place CPT codes (64400-64450) on the Ancillary List
3) Make the current nerve block guideline into an Ancillary Guideline and modify to add the CPT codes. See Appendix A for final approved wording.
4) Note: The meeting materials mistakenly listed the code range as 64400-64550

- **Topic: Diabetic retinopathy codes**

  Discussion: Smits presented the staff summary for this topic. Allergan representatives informed staff that GN 116 needs to be considered for modification to allow pairing of intraocular steroids with the new FDA approved indication for limited use in diabetic retinopathy. Staff agreed to look into this possible GN change and bring back for further discussion at the November, 2014 VbBS meeting.

MOTION: To recommend the code changes as presented. CARRIES 7-0.

Recommended Actions:

1) Add the 362.0x codes (diabetic retinopathy, mild/moderate/severe, with or without proliferative retinopathy, and diabetic macular edema) to line 106/100 DIABETIC AND OTHER RETINOPATHY
   a. Advise DMAP to remove the 362.0x codes from the Excluded List
   b. Note: there was a typographical error in the meeting materials. The correct ICD-9 code is 362.0x, not 367.0x
2) Add all codes in the E10.3xx family (Type 1 diabetes mellitus with ophthalmologic complications) to line 100 DIABETIC AND OTHER RETINOPATHY for the January 1, 2015 Prioritized List

DRAFT

3) Add all codes in the E08.3xx family (diabetes due to underlying condition with retinopathy), E09.3xx family (drug or chemical induced diabetes with retinopathy), E11.3xx family (Type 2 diabetes mellitus with ophthalmologic complications), and E13.3xx family (other specified diabetes with retinopathy) to line 30 TYPE 2 DIABETES MELLITUS for the January 1, 2015 Prioritized List
4) Staff will review possible changes to GN116 for the November, 2014 VbBS meeting

- **Topic: Tympanostomy tube removal**

Discussion: Livingston reviewed the material in the packet for this topic. There was minimal discussion.

MOTION: To recommend the guideline note changes as presented. CARRIES 7-0.

Recommended Actions:
1) Make no changes to the placement of tympanic membrane perforation diagnosis codes
2) Add a new guideline specifying that retained tympanostomy tube removal is a covered procedure even if the underlying diagnosis for placement of these tubes was a non-covered diagnosis. See Appendix B for guideline wording.

- **Topic: Spinal manipulation for tension and migraine headaches**

Discussion: Smits reviewed the materials in the meeting packet for this topic. The subcommittee discussed that the evidence for treatment of migraine headache and tension headache showed moderate to good evidence of lack of effectiveness, which is generally a rationale for removing a service from a Prioritized List pairing. There was some discussion about adding a guideline note specifying what is meant by "cervicogenic headache." The group decided that such a guideline note could be added later if the health plans required assistance with this definition.

MOTION: To approve the code changes and coding specification as presented. CARRIES 6-1 (Opposed: Hodges).

Recommended Actions:
1) Remove osteopathic and chiropractic manipulation (CPT 98926- 98929, 98940-98943) from line 435/414 MIGRAINE HEADACHES
2) Add the following coding specifications to line 563/546 TENSION HEADACHES
    i. "OMT and CMT (CPT 98926- 98929, 98940-98943) pair on this line only with cervicogenic headache (R51)."

DRAFT

- **Topic: Wearable cardiac defibrillators**

  Discussion: Smits reviewed the packet materials regarding wearable cardiac defibrillators. Sarah Schmidt, representing Zoll, the company which manufactures Life Vest, gave testimony that the purpose of this device is a temporary use until ICD placement or until the patient has his or her medications optimized and no longer will need an ICD. Ms. Schmidt noted that the studies regarding the effectiveness of Life Vest have difficulties in their methodology, although she was unsure what the issues with the methodology actually were. These methodology issues are the reason that no mortality benefit was seen in these studies. Ms. Schmidt stated that there are studies which show what the therapeutic shock rates were, and noted that she can provide these studies to HERC staff. She noted that in the Zoll studies, 74% of patients who received a shock were alive 6 months later. She noted that the Life Vest allows discharge from hospital sooner. Zoll is currently conducting an RCT of the Life Vest with planned release of the results in fall 2015.

  Subcommittee discussion centered around how successfully the vests stop ventricular fibrillation or ventricular tachycardia, and how often the shocks given by the vests are for these arrhythmias. It was noted that the lethal rhythms treated by this device generally have no symptoms other than sudden death, and so cannot be adequately treated by other means besides a bedside defibrillator. There is increasing numbers of requests for these devices. Hospitals and physicians are hesitant to discharge patients without these devices, as there is not another method in place to treat any fatal arrhythmias which might occur at home. Olson requested data on how often these devices are successfully converting serious arrhythmias. If was noted that the lack of evidence of effective reduction in mortality might stem from lack of patient compliance with wearing the device. Hodges noted that Life Vest use can be monitored, and that her health plan takes back the device if it is not being worn 21 or more hours a day.

  The decision was made to table this topic and have HERC staff find more information on the rate of successful shock of such lethal rhythms as ventricular fibrillation or ventricular tachycardia.

  Action:
  1) This topic was tabled until the November, 2014 VBBS meeting.

- **Topic: Fibromyalgia related diagnoses (general conditions and chronic fatigue syndrome)**

  Discussion: Smits reviewed the materials of general conditions related to fibromyalgia. The subcommittee felt that Rheumatism, unspecified and Fasciitis,

DRAFT

unspecified should not be moved to the fibromyalgia line as this would raise their priority on the Prioritized List.

Smits also reviewed the materials summarizing the research and recommendations regarding chronic fatigue syndrome. There was minimal discussion.

MOTION: To approve the code changes and line name change as amended. CARRIES 7-0.

Recommended Actions:

1) Move ICD-9 359.9 (Myopathy, unspecified) from lines 75,297,349,381 to the new fibromyalgia line
2) Keep ICD-10 G72.9 (Myopathy, unspecified) on the Excluded List.
3) Add chronic fatigue syndrome (ICD-9 780.71/ICD-10 R53.82) to the new fibromyalgia line
    a. Advise DMAP to remove ICD-9 780.71/ICD-10 R53.82 from the Excluded List
4) Change line name to "Fibromyalgia, Chronic Fatigue Syndrome, and Related Disorders"

- **Topic: Coverage guidance—Hyperbaric Oxygen**

Discussion: Smits reviewed the packet materials regarding hyperbaric oxygen coverage. There was minimal discussion.

MOTION: To approve the code and guideline note change as presented. CARRIES 7-0.

Recommended Actions:

For the biennial review (to be reviewed by HERC later in the day)

1) Combine the two hyperbaric oxygen lines (lines 336 and 373) into one line placed at line 336 for the next biennial Prioritized List.

For review by HERC in November, along with the coverage guidance, for potential inclusion in January 1, 2015 list:

1) Add ICD-9 250.7, 250.8 and ICD-10 E11.5x,E11.621,E11.622,E11.628, S07.xxx,S17.xxx,S38.xxx, S57.xxx,S67.xxx, S77.xxx,S87.xxx,S97.xxx,and T79.Axx, to line 336 TOXIC EFFECT OF GASES, FUMES, AND VAPORS REQUIRING HYPERBARIC OXYGEN
2) Remove ICD-9 526.4, 686.00-686.09,709.3 and ICD-10 M46.20-M46.39 and M86.9 from line 336
3) Modify GN 107 as shown in Appendix A

DRAFT

- **Topic: Coverage guidance—percutaneous interventions for cervical spine pain**

  Discussion: The summary document was reviewed. A mistake in the recommendations was found: CPT 64490-64495 was proposed for exclusion as well as for addition to 3 lines on the Prioritized List. The proposed placement on the Excluded list was a mistake.

  Hodges cautioned that there would be a large demand for these types of procedures is coverage is added. Gibson expressed concern that the recommendations from HTAS to cover cervical epidural steroid injections and facet joint neurotomy were weak and based on a weak level of evidence. Shaffer commented that HTAS was led to recommend coverage based on the evidence plus clinical expertise and a desire to avoid more costly alternatives, such as spinal surgery. Gibson noted that the CCOs could elect to cover these procedures for cases in which they would help avoid a surgery, without adding these services to the Prioritized List and requiring coverage in all cases. He was concerned about adding these procedures to the Prioritized List based on weak evidence and provider testimony. The HTAS report was reviewed. The rational for recommending adding coverage for epidural spinal steroid injections was found to be "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." Williams expressed concern over using a retrospective cohort study as the basis for the decision. There was general concern over the low level of evidence and over using other payer policies as a deciding factor for adding a service to the Prioritized List. However, some members noted that these types of procedures may prevent surgery, reduce ER visits, lower narcotic use, and have other beneficial outcomes.

  HERC staff clarified that currently, epidural steroid injections are ancillary. This was felt to give these procedures the same status as procedures already included for coverage on the Prioritized List—such procedures must have evidence of ineffectiveness or evidence of harm or lower cost effectiveness compared to other procedures in order to be taken off the Prioritized List and therefore take away existing coverage. Procedures considered for initial addition to the list have a higher bar—they must have good evidence of effectiveness. The group initially felt that ancillary procedures should have the lower bar of evidence for inclusion on the List. However, this topic was readdressed later in the meeting, and several subcommittee members expressed concern with this policy. It was felt that many ancillary procedures were never formally reviewed and had a formal placement decision. Therefore, these procedures should be fully reviewed before addition to the List, just like new procedures. HERC staff agreed that this policy needed to be discussed further and placed it on the agenda for the VBBS/HERC retreat in October.

DRAFT

Hodges noted that clarification of when epidural steroids should be covered, such as in the proposed guideline, would be very helpful for the CCOs as these procedures are currently covered as ancillary. Shaffer noted that these injections are treatments and do not belong on the Ancillary List. Therefore, some placement decision needs to be made.

The subcommittee members noted that facet joint neurotomy was currently excluded. The evidence summary in the HTAS report stated that the recommendation for addition to coverage was based on the following: "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." There was general agreement that expert opinion was not good enough evidence to justify coverage when the quality of evidence from trusted sources was very low. The group felt that facet joint neurotomy should not be added to the List.

Initially, the subcommittee voted to approve the addition of epidural steroid injections with the appropriate guideline and to not approve the addition of facet joint injections (Vote 6-0 with Pollack abstaining). However, this decision was reopened at a later point in the meeting and voided (Vote 7-0). The subcommittee wished to have this topic returned for further discussion to their November meeting.

Actions:

1) HERC staff will add a discussion about the level of evidence required for adding ancillary procedures to the Prioritized List to the VBBS/HERC agenda for the October retreat
2) This topic was tabled for further discussion in November.

- **Topic: Guideline Note 37, Disorders Of Spine With Neurologic Impairment**

Discussion: Smits introduced the summary document on this topic. There was no discussion.

MOTION: To approve the guideline note changes as presented. CARRIES 7-0.

Recommended Action:

1) GN 37 was modified as shown in Appendix A

- **Topic: Rehabilitation guideline**

Discussion: Smits reviewed the packet materials regarding suggested changes to the rehabilitation guideline. Olson expressed frustration with the medical directors requesting changes to VbBS decisions when they are not coming to

DRAFT

VbBS meetings. Smits noted that there has not been a medical director representative on the VbBS for over a year, since Chris Kirk left. This meeting is the first official meeting for the new medical director representative, Holly Jo Hodges, who promised to bring the medical directors input to the VbBS meetings going forward.

The subcommittee felt that the staff recommended wording, including the suggesting additional wording, for the rehabilitation guideline was acceptable.

MOTION: To approve the guideline note changes as presented with additional optional language in the meeting materials. CARRIES 7-0.

Recommended Action:
1) Modify the rehabilitation guideline wording as shown in Appendix A

- **Topic: Lymphedema guideline**

Discussion: Smits presented the summary on proposed changes to the lymphedema guideline. John Beckwith, PT, testified that he was very concerned that the language in the guideline be very clear that compression dressings/garments were covered even when no complications were present. The subcommittee felt that the wording was sufficient. Hodges requested that clarification be made to the guideline to specify whether compression dressings included compression garments. Smits offered amended wording, adding in the term "garments." Beckwith requested that chronic venous insufficiency (CVI) be covered for compression dressings when appropriate. Smits reviewed her previous findings that CVI includes a range of conditions, from very mild to quite severe. It would be difficult to write a guideline specifying at what stage CVI was covered. The subcommittee requested that HERC staff work with experts to see if some coverage of compression dressings/garments should be done for CVI.

MOTION: To approve the guideline note changes as amended. CARRIES 7-0.

Recommended Actions:
1) GN 43 was modified as shown in Appendix A
2) HERC staff to evaluate potential coverage of compression dressings/garments for chronic venous insufficiency and bring back for subcommittee review at a future date

- **Topic: Denture guideline**

Discussion: This topic was tabled until the November, 2014 VbBS meeting.

DRAFT

- **Topic: Adenoidectomy—revisions to the obstructive sleep apnea guideline and sinusitis surgery guideline**

  Discussion: This topic was tabled until the November, 2014 VbBS meeting.

- **Topic: RSV guideline**

  Discussion: Livingston reviewed the summary document for proposed revisions to the RSV guideline. The CCO representatives testified that referring to P&T criteria would not be acceptable to them. The CCOs have their own committees and develop their own coverage criteria. They do not attend or participate in DMAP's P&T Committee meetings and do not feel that their preferences or opinions are taken into account in the P&T decision making process. If no guideline referring to P&T was adopted, then coverage of Synagis would revert to the individual CCO P&T committee decisions (or DMAP P&T coverage guidance for fee-for-service patients). This was felt to be the preferable alternative.

  There was also public comment received from Paul Nielson, AstraZeneca, who raised concerns about the quality of the new American Academy of Pediatrics guideline on RSV prophylaxis.

  The subcommittee decided to not adopt a new guideline referring to DMAP P&T criteria. However, it was recognized that the current Synagis guideline was out of compliance with national coverage recommendations by the American Academy of Pediatrics. Because DMAP and CCO P&T committee decisions can be much more timely than VbBS/HERC guideline note changes, the subcommittee decided to remove the Synagis guideline and similar drug related guidelines and not add any guidelines referring to DMAP P&T decisions.

MOTION: To approve the guideline note deletion but reject the proposed new guideline note. CARRIES 7-0.

Recommended Action:
1) Delete GN 69

- **Topic: Botulinum toxin**

  Discussion: Smits reviewed the summary document regarding Botox. The VbBS had previously indicated that they did not wish to have guidelines referring to the DMAP P&T coverage criteria (see "RSV guideline" discussion above). The proposed new guideline referring to P&T criteria was therefore not accepted.

MOTION: To approve the coding changes, coding specifications and guideline note deletion but not the proposed new guideline note. CARRIES 7-0.

DRAFT

Recommended Actions:

1) Add 46505 (Chemodenervation of internal anal sphincter) to line 506/532 CHRONIC ANAL FISSURE
2) Remove 67345 (Chemodenervation of extraocular muscle) from line 397/372 AMBLYOPIA
3) Do not add coverage for botulinum toxin injections for treatment of neck or lower back pain or chronic daily headaches
4) Keep the coding specification shown below on line 388/364 DYSTONIA (UNCONTROLLABLE); LARYNGEAL SPASM AND STENOSIS
   a. "Chemodenervation with botulinum toxin injection (CPT 64612, 64616) is included on this line only for treatment of blepharospasm (ICD-9 333.81/ICD-10-CM G24.5), spasmodic torticollis (ICD-9 333.83/ICD-10-CM G24.3), and other fragments of torsion dystonia (ICD-9 333.89/ICD-10-CM G24.9)."
5) Add the coding specification shown below to line 318/297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
   a. "Chemodenervation with botulinum toxin injection (CPT 64642-64647) is included on this line for treatment of upper and lower limb spasticity (ICD-9 333.6x, 333.7x, 340.xx, 341.0, 342.xx, 343.xx, 344.0x, 344.1, 344.2, 344.3x, 344.4x, 344.5, 344.89, 344.9, 359.0-359.2, 438.2x-438.5x/ICD-10 G24.02, G24.1, G35, G36.0, G71.xx, G80-G83, I69.03-I69.06).
6) Add the coding specification shown below to lines 452 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE/354 STRABISMUS DUE TO NEUROLOGIC DISORDER and 398 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN
   a. "Chemodenervation with botulinum toxin injection (CPT 67345) is included on this line for the treatment of strabismus due to other neurological disorders (ICD-9 378.73 /ICD-10 H50.89)."
7) Add the coding specification shown below to line 421 ACHALASIA, NON-NEONATAL/382 ESOPHAGEAL STRICTURE; ACHALASIA
   a. "Chemodenervation with botulinum toxin injection (CPT 43201) is included on this line for treatment of achalasia (ICD-9 530.0/ICD-10 K22.0)."
8) Add the coding specification shown below to line 542/523 DISORDERS OF SWEAT GLANDS
   b. "Chemodenervation with botulinum toxin injection (CPT 64650, 64653) is included on this line for the treatment of axillary hyperhidrosis and palmar hyperhidrosis (ICD-9 705.2 and 780.8/ICD-10 L74.52, R61).
9) Delete GUIDELINE NOTE 103, CHEMODENERVATION OF THE BLADDER

DRAFT

- **Topic: Gender dysphoria**

Discussion: Smits reviewed the summary document in the meeting packet. There was considerable discussion regarding concerns for lack of an age restriction for surgical procedures. Smits reviewed that the Oregon age of consent for surgical procedures is age 15. Olson felt that these types of procedures should not be singled out for restriction until age 18 or even higher, as many other procedures which have life-long impact can be consented to at age 15. Expert testimony by Danielle Askini from Basic Rights Oregon and Jenn Burleton from TransActive indicated that youth are required to have extensive evaluations by qualified mental health professionals and that the year of hormone therapy required in the guideline acts as another safeguard against rash decisions by youth.

There was a minor edit to the proposed guideline to add in a missing word.

MOTION: To approve the line rescoring, updated treatment description, and the addition of cross-sex hormone therapy and various surgical procedures related to sex reassignment to the gender dysphoria line, and the new guideline as amended. CARRIES 5-1 (Opposed: Tyack, Absent: Pollack).

Recommended Actions:

1) Change the treatment description of the gender dysphoria line to ~~MEDICAL/PSYCHOTHERAPY~~ MEDICAL AND SURGICAL TREATMENT; PSYCHOTHERAPY
2) Rescore the gender dysphoria line as shown below:
    a. Scoring proposal
    Category: 6
    HL: 6
    Suffering: 4
    Population effects: 0
    Vulnerable population: 0
    Tertiary prevention: 3
    Effectiveness: 2
    Need for service: 1
    Net cost: 2
    Score: 1040
    Approximate line placement: 312
3) Add cross-sex hormone therapy to the new gender dysphoria line
4) Add CPT 19301-19304, 53430, 54125, 54400-54417, 54520, 54660, 54690, 55175-55180, 55970, 55980, 56625, 56800, 56805, 56810, 57106-57107, 57110-57111, 57291-57292, 57335, 58150, 58180, 58260-58262, 58275-58291, 58541-58544, 58550-58554, 58570-58573, 58661, 58720 to the new gender dysphoria line
    a. Advise DMAP to remove CPT 55970 and 55980 from the Excluded List

DRAFT

5) Modify the guideline for the new gender dysphoria line as shown in Appendix A
6) Note that all of these recommended actions would take effect on January 1, 2015 when the new gender dysphoria line appears on the Prioritized List

- **Topic: Hepatitis C**

Discussion: Livingston reviewed the summary document regarding treatments for hepatitis C in the meeting packet. Written testimony from CCOs, legislators and concerned citizens was received.

The following public testimony was received verbally:

Amy Burns and Mark Bradshaw from AllCare presented a collaborative statement from 9 CCOs. The collective strongly discouraged a guideline note requiring CCOs to adhere to the P&T Committee's drug use criteria. They strongly felt that each CCO manages their own drug use and formularies and this drug class should be no different. They also had specific concerns about the criteria including:

1) Allowing off-label use of simeprevir and sofosburiv
2) Allowing for off-label use for patients who are post transplant. This goes against OARs that do not allow for investigational or experimental practices. There is no outcome data to support this. The liver transplant population has not been studied and is not recommended in the Sovaldi package insert.
3) Subjective language around who can prescribe
4) Important psychosocial and medical factors around treatment that aren't addressed

Jim Gardner, Oregon Council for PhMRA, a paid advocate, recommended not looking at single therapeutic products and raised legal concerns with this approach.

Ann Murray, Bristol Myers Squibb, stated that she thinks this would be the first time HERC would have taken this approach, in which a treatments for a condition appear both on a funded and unfunded line.

Subcommittee members made a request to PhRMA to decrease the cost of the drug, with the answer that they appreciated the comment.

Kimberly Wyatt, Willamette Valley Community Health CCO and Dr. Seth Adams, pharmacist with WVCH, offered public comment. They stated they have their own pharmacy and therapeutics committee and have already created PA criteria for approval of these medications. It is important to the CCOS to have freedom to develop their own criteria. If there was going to be

DRAFT

accountability to another organization (DMAP's P&T Committee) then CCOs would have wanted to be responsible in the development of these criteria.

Subcommittee members asked about the CCOs concerns regarding criteria in the proposed guideline note for drug and alcohol testing. It was clarified that they felt 6 months sobriety was too short of a time. They also require a mental health evaluation to assess readiness to treat and ascertain whether patients are compliant with prescription drugs for other diseases, such as diabetes and hypertension.

Lorren Sandt, from Caring Ambassadors, and BJ Cavnor, 1 in 4 Chronic Disease, testified as well, both stating pharmaceutical funding for their organizations. Sandt requested hepatitis C drug treatments should remain above the funding line and that everyone with hepatitis C should be treated with these drugs. She also pointed to the AASLD/IDSA guideline not requiring abstinence or sobriety. Cavnor requested a workgroup that would follow national guidelines and demanded that all people be allowed to come to the table.

Dr. Kent Benner offered testimony with no current conflicts of interest. He spoke about the community standard that was developed by local hepatologists, and discussed the rationale for this.

Subcommitee members discussed the significant impact of these medications on the budget. There was a proposal to table the decision. Given the concerns CCOs have about the reference to P&T criteria, the need for ongoing dialogue, the new AASLD guidelines, it was felt that a final decision on this policy should be tabled until a future meeting.

It was clarified that there will be a pharmacoeconomic anlaysis available by the November meeting and that an updated DERP report and NICE guidelines may be available later this year or early next year as well.

MOTION: To reject the proposed new guideline regarding treatment of hepatitis C and table the topic until a future meeting. CARRIES 7-0.

Recommended Actions:

1) None

- **Topic: Proposed "Non covered" section of the Prioritized List**

Discussion: Smits introduced this topic and noted that the new "non-covered" table was presented for approval in concept only. There was minimal discussion.

DRAFT

Actions:

1) HERC staff will continue to work on developing the "non-covered" table and will publish it as a new portion of the January 1, 2015 Prioritized List.

- **Topic: Applied behavioral analysis for treatment of non-autistic self-injurious behavior**

  Discussion: This topic was tabled to the August HERC meeting.

  Actions: See minutes from the August HERC meeting.

- **Topic: Standardized assessment tools for evaluating progress for autism spectrum disorder**

  Discussion: This topic was tabled to the August HERC meeting.

  Actions: See minutes from the August HERC meeting.

- **Public Comment:**

  No additional public comment was received.

- **Issues for next meeting:**
  - Wearable cardiac defibrillators
  - Denture guideline
  - Adenoidectomy—revisions to the obstructive sleep apnea guideline and the sinusitis surgery guideline
  - Coverage guidance—percutaneous interventions for cervical spine pain
  - A new breastfeeding supplies guideline
  - Unilateral hearing loss in adults
  - OMT/CMT and the dysfunction lines
  - Tobacco cessation coverage
  - Tobacco smoking and procedures
  - PET scan for fever of unknown origin
  - Unilateral tonsillar hypertrophy
  - Various straightforward coding changes

- **Next meeting:**

  November 13, 2014 at Meridian Park Health Education Center, Tualatin, OR Room 117B&C.

DRAFT

- **Adjournment:**

  The meeting was adjourned at 1:30 PM.

DRAFT

Appendix A

Revised Guideline Notes

~~GUIDELINE NOTE 76~~ ANCILLARY GUIDELINE A3, NERVE BLOCKS *(Effective October 1, 2014)*

~~Lines 1,3,6,8,9,11,20,24,25,28,30,32,37-41,46-55,59-63,65,67,68,70-76,81-100,102-105,107,109-112,115-121,123-125,129-132,134-145,147,148,154,156-164,166-170,172-175,178,180,183-195,197-201,203,204,206,208,209,211-214,216-221,223,225-228,230,232-239,241-251,253-255,257-267,269,273-275,277-280,283-286,289-294,297-306,308-312,314-317,319-324,327,328,330-335,337-341,343,344,346,349,350,352,354-360,362-370,372,374-376,378-384,386,389,391,392,394,397-402,404-408,410,412,417,419-424,426-428,430-436,438-441,443-447,450,452,453,456,458,459,464-466,468-472,474,476,477,480-484,486,487,496,504,519,526,527,532,535,549,568,630~~

The Health Evidence Review Commission intends that single injection and continuous nerve blocks (CPT 64400-64550) should be covered services if they are required for successful completion of, perioperative pain control for, or post-operative recovery from a covered operative procedure when the diagnosis requiring the operative procedure is also covered. Additionally, nerve blocks are covered services for patients hospitalized with trauma, cancer, or intractable pain conditions, if the underlying condition is a covered diagnosis.

GUIDELINE NOTE 6, REHABILITATIVE THERAPIES *(Effective October 1, 2014)*

Lines 37,50-52,64,74-76,78,80,85,89,90,94,95,98-101, 108, 109, 115, 116, 122, 129, 139, 141-143,145,146,158,161,167,179,184,185,189, 190, 192, 194, 195, 201, 202, 208,209,216,226,237,239,270,271,273,274,279,288,289,293,297,302,304,307-309, 318, 336,342,349, 350, 363, 367, 369, 375,376,378, 382,384,385,387, 400,406, 407, 434, 441,443,448,455,467,478,489,493,507,516,535,549,562,580, 597,619,638

A total of 30 visits per year of rehabilitative therapy (physical, occupational and speech therapy, and cardiac and vascular rehabilitation) are included on these lines when medically appropriate. Additional visits, not to exceed 30 visits per year, may be authorized in exceptional circumstances, such as in cases of rapid growth/development. Physical, occupational and speech therapy, and cardiac and vascular rehabilitation are only included on these lines when the following criteria are met:

1) therapy is provided by a licensed physical therapist, occupational therapist, speech language pathologist, physician, or other practitioner licensed to provide the therapy,
2) there is objective, measurable documentation of clinically significant progress toward the therapy plan of care goals and objectives,
3) the therapy plan of care requires the skills of a ~~therapist~~ medical provider, and
4) the client and/or caregiver cannot be taught to carry out the therapy regimen independently.

DRAFT

Appendix A

No limits apply while in a skilled nursing facility for the primary purpose of rehabilitation, an inpatient hospital or an inpatient rehabilitation unit.

Spinal cord injuries, traumatic brain injuries, or cerebral vascular accidents are not subject to the visit limitations during the first year after an acute injury.

GUIDELINE NOTE 37, DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT *(Effective October 1, 2014)*

Lines 374,545

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

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

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

GUIDELINE NOTE 43, LYMPHEDEMA *(Effective October 1, 2014)*

Lines 448,597,598

Lymphedema treatments are included on these lines when medically appropriate. These services are to be provided by a licensed practitioner who is certified by one of the accepted lymphedema training certifying organizations or a graduate of one of the National Lymphedema Network accepted training courses within the past two years. The only accepted certifying organization at this time is LANA (Lymphology Association of North America; http://www.clt-lana.org). Treatments for lymphedema are not subject to the visit number restrictions found in Guideline Note 6 REHABILITATIVE THERAPIES. It is the intent of the HERC that compression dressings/garments and other medical equipment needed for the treatment of lymphedema be covered even in the absence of ulcers or other complications.

GUIDELINE NOTE 43, LYMPHEDEMA *(Effective January 1, 2016)*

Line~~s 427,577,579~~ XXX (new lymphedema line ~427)

Lymphedema treatments are included on this line ~~these lines~~ when medically appropriate. These services are to be provided by a licensed practitioner who is certified by one of the accepted lymphedema training certifying organizations or a graduate of one of the National Lymphedema Network accepted training courses within the past two years. The only accepted certifying organization at this time is LANA (Lymphology

DRAFT

Appendix A

Association of North America; http://www.clt-lana.org). Treatments for lymphedema are not subject to the visit number restrictions found in Guideline Note 6 REHABILITATIVE THERAPIES.-It is the intent of the HERC that compression dressings/garments and other medical equipment needed for the treatment of lymphedema be covered even in the absence of ulcers or other complications.

GUIDELINE NOTE 107, HYPERBARIC OXYGEN *(Effective date pending HERC review of coverage guidance, not to be prior to January 1, 2015)*

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

Hyperbaric oxygen is a covered service 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
    - 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

Appendix A

GUIDELINE XXX GENDER DYSPHORIA *(Effective January 1, 2015)*

Line 413

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

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

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

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

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

DRAFT

Appendix B

New Guideline Notes

GUIDELINE NOTE XXX RETAINED TYMPANOSTOMY TUBES *(Effective October 1, 2014)*

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 383.83 (Retained foreign body of middle ear*).*

DRAFT

MINUTES

Health Technology Assessment Subcommittee
Meridian Park Community Health Education Center
19300 SW 65th Avenue, Tualatin, OR
September 22, 2014
1:00-4:00pm

Members Present: James MacKay, MD, Vice-Chair; Gerald Ahmann, MD, PhD; George Waldmann, MD; Timothy Keenen, MD.

Members Absent: None.

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

Also Attending: Eugene Fuchs, MD (appointed ad hoc expert) Alison Little, MD (CEBP); Suzy Geroux (American Medical Systems), Joanie Cosgrove (Medtronic), Brian Shaffer, MD.

---

1. CALL TO ORDER

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

---

2. MINUTES REVIEW

No changes were made to the June, 2014 minutes.
Minutes approved 3-0 (Keenen not present).

---

3. REVIEW OF DRAFT COVERAGE GUIDANCE

A) Alternatives to Transurethral Resection of the Prostate (TURP)

Wally Shaffer reviewed the draft coverage guidance, noting that there are a large number of different procedures listed in the coverage guidance, some of which are not compared to TURP, which is the reference procedure. This topic will require expert input especialy because the source report is British and some procedures may not be in common use in Oregon. Only procedures which have been compared to TURP are included in the draft coverage recommendation. In addition, new technologies may have become available since the source review which was done in 2010. He introduced Dr. Eugene Fuchs, a Portland urologist who will serve as ad hoc expert for this topic.

Fuchs noted that the TURP procedure used as a reference in the studies is no longer commonly used, as it's been replaced by bipolar TURP which has the advantages of less bleeding and also no risk of water intoxication (a serious side effect). Though the literature mostly compares the older TURP procedure, in practice the subcommittee

DRAFT

needs to compare the other interventions to the bipolar procedure; although there has not been a head-to-head trial, bipolar TURP is much more commonly used.

The committee requested that staff add a footnote to the coverage guidance making clear where the study comparator was monopolar TURP.

Fuchs also said there is little level 1 evidence for these other procedures other than the PVP laser procedure. Ahmann asked wheher the comparisons are still valid, given that there is an improved surgical procedure; Brian Shaffer, an audience member who is a Portland urologist, said that monopolar TURP operations are seldom used. In addition, he said you can't do as good a job with a laser as with bipolar TURP in many cases, and it takes longer, though laser vaporization is preferable when the patient is anticoagulated. Also, when a tumor is excised using electricity, there is tumor tissue for pathology, whereas the laser vaporizes the tumor so it can be hard to know how much tissue has been removed.

Wally Shaffer reviewed the GRADE table, noting that resource allocation was listed as low for outpatient procedures and moderate for inpatient procedures. He also noted that there is not likely to be a lot of patient preference as the variability will be driven largely by provider preference and availability. However, Fuchs noted that patients do request laser procedures after doing Internet research, so patient preference is a factor in his practice.

In the discussion on HoLEP, Fuchs noted the lack of level 1 evidence; however, the subcommittee did not change its recommendation. Fuchs clarified that unlike the other laser techniques listed as laser vaporization, HoLEP is a laser enucleation technique and there is a specimen at the end of the surgery, though it also involves some vaporization as well.

They also noted that the TUVP and TUVRP procedures are often done together (that is, the surgeon does some vaporization and some resection) and are adequately covered by the recommendation for coverage of TUVP, which Wally Shaffer noted should be a weak recommendation based on the low strength of evidence. TUVP is also known as the "button" procedure.

For the laser vaporization techniques, Fuchs and Brian Shaffer said that the newer lasers are higher powered and therefore superior to many of the interventions done in the studies from the literature. One in particular is known as PVP or the "greenlight", and has better evidence to support it compared to bipolar TURP. MacKay suggested that this evidence be incorporated into the draft coverage guidance. The subcommittee noted the distinction between various laser techniques and discussed merging them all into a single recommendation but then decided to merge some lines and keep others separate. Brian Shaffer said there is an older laser coagulation technique that is questionable and no longer in use, but the laser vaporization techniques could be combined. Little confirmed that this wouldn't be problematic, as the distinctions in the evidence aren't all that significant, and the source guideline was based largely on expert opinion. The subcommittee clarified that laser coagulation could remain not recommended and that outdated laser vaporization techniques should not be recommended.

After discussion of the various techniques, the subcommittee settled on classifying the procedures listed with a strong recommendation as follows:

DRAFT

- Bipolar TURP
- Laser vaporization/resection; for example, photoselective vaporization of the prostate (PVP) and thulium laser resection
- Laser enucleation; HoLEP (Holmium Laser Enucleation of Prostate)
- TUVP (Transurethral Electrovaporization of Prostate)
- TUIP (Transurethral Incision of the Prostate)

The subcommittee wanted to list specific procedures under these categories as new technologies may be developed and many will fall into these categories.

Wally Shaffer noted that one procedure seemed to have less evidence, the bipolar TUVP. It shows better results than TURP but but the strength of evidence is lower. After discussion the subcommittee decided to make a weak recommendation for coverage based on expert opinion as well as the evidence. Brian Shaffer suggested that this procedure is often used in conjunction with a TURP to add additional coagulation.

Discussion moved to the remaining topics with a weak recommendation in the draft. Brian Shaffer noted that TUNA and TUMT are in-office procedures. Although they are inferior to some other alternatives they may be appropriate for patients who are not good candidates for the more invasive procedures. There is a role for each of these procedures in different types of patients. After discussion the subcommittee decided to give them a weak recommendation for coverage to ensure availability of these procedures for those who could not tolerate a more invasive procedure.

The subcommittee then discussed the procedures not recommended for coverage in the draft. They determined that the HoLRP is the same as HoLEP, so eliminated that recommendation. For botulinum toxin, HIFU, TEAP and prostatic urethral lifts, the subcommittee affirmed the weak recommendation against coverage. For Transurethral Artery Embolization the subcommittee decided to make a strong recommendation against coverage as it is still investigational in this country. Fuchs said it is being done in highly selected patients at OHSU by interventional radiologists; he had one success but it is considered experimental. Brian Shaffer said he had a position paper from the Society of Interventional Radiologists saying it is a technically challenging procedure with possibility of complications and that they need more data. Shaffer noted that this may be covered for selected patients in CCOs and in the appeals process in the Oregon Health Plan.

The subcommittee heard additional public comment from Suzy Geroux from American Medical Systems, which manufactures a laser device known as the green light laser or PVP or laser vaporization. She said it shows fewer side effects and better cost effectiveness as shown by Medicare data compared to other less invasive techniques used in the United States. PVP uses a KTP crystal or LDO crystal known as a green light which does make a difference. She testified that the wavelength of the laser does matter. The current green light system uses a frequency which was not available for the NICE study. She included some references to studies showing prospective randomized trials sponsored by her company, and said that the 12-month data is in final review to be published in the Journal of Urology soon. She noted that the subcommittee already made the change she is advocating, moving PVP to recommended for coverage. She also noted that HIFU is not approved for use in the U.S. outside of clinical trials.

DRAFT

She also said that TUVP is described several different ways in the coverage guidances. Some places it's described as electrovaporization. In terms of commonly accepted language they describe the TUVP as the roller ball. Fuchs and Brian Shaffer agreed that the roller ball is inferior to the button because of geometry though it is used for coagulation.

After discussion of her comments the subcommittee removed its earlier recommendation against outdated laser vaporizations, and clarified the distinction between electrovaporization and laser vaporization as it could cause confusion. They asked staff to update the GRADE table, removing irrelevant comparisons and services for which there is no recommendation, but to leave the algorithms as they are since they reflect the evidence.

After discussion, the subcommittee approved the draft coverage guidance to be posted for public comment after staff makes changes conforming with the current discussion. **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, or 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
- Laser vaporization/resection; for example, photoselective vaporization of the prostate (PVP) and thulium laser resection
- Laser enucleation; HoLEP (Holmium Laser Enucleation of Prostate)
- TUVP (Transurethral Electrovaporization 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

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

- Prostatic artery embolization

B) ADVANCED IMAGING IN THE STAGING OF PROSTATE CANCER

Wally Shaffer presented the draft coverage guidance. Keenen asked whether ultrasound should be included. Wally Shaffer said it should be part of the workup but is not specifically in scope as advanced imaging. Little pointed out that the scope of the guidance is for patients who have already received a diagnosis, which would include the ultrasound-guided biopsy. The subcommittee elected not to put a strength of recommendation on this initial paragraph since its purpose is to set the context of the other recommendations, and evidence surrounding it was not evaluated.

Shaffer noted that there is some discussion comparing ultrasound to MRI in the guidance, but MRI is superior. Ultrasound is only included as a comparator.

Ahmann said there may be controversy around the draft recommendation regarding MRI, which may be used to determine whether the cancer is extracapsular so that the surgeon could know that before surgery. But MRIs can give false information.

The subcommittee discussed the use of the word routine around radionuclide bone scanning. Shaffer said if someone has back or hip pain and it's not clear whether it is related to the cancer, a bone scan may make sense. After discussion the subcommittee decided to leave the word routine in for this indication.

For PET scan, the subcommittee elected to remove the word routine as there is no evidence of benefit. In addition they decided to delete the paragraph "Imaging is not recommended for [routine] coverage in men with prostate cancer who are not candidates for radical treatment. (weak/strong recommendation)", as it is too vague to implement and the recommendations above are sufficient.

No additional changes to the draft coverage guidance were made.

After discussion, the subcommittee approved the draft coverage guidance to be posted for public comment after staff makes changes conforming with the current discussion. **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)*

DRAFT

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 RESCAN OF TOPICS APPROVED IN 2012

Little explained that these reviews are part of the normal process to consider which coverage guidances may merit an update. It is part of the HERC's process to complete such a review every two years. She reviewed the topics in the meeting packet.

A) **Artificial disks** Keenen said for lumbar artificial disks that he doesn't understand the controversy as these cost less than the alternatives and have been shown to be equal to a fusion. The unknown is whether it spares future degeneration. They are not failing or falling out. The cervical disk gets better results than lumbar. There is an FDA approval for a 2-level disk. At some point he believes there will be data to show that it's better, particular in the cervical spine. The single level artificial disks were recommended by the previous guidelines. After discussions the subcommittee decided not to update the guidance as it was unlikely the recommendation would change.
B) **MRI for breast cancer screening.** Little said that NICE and Washington state have new reports coming out, so the subcommittee asked to re-evaluate once both of these reports are out.
C) **Lumbar discography** The subcommittee agreed not to re-evaluate this topic as no new information has been published other than the Hayes review.
D) **Hip resurfacing** The subcommittee decided not to initiate a new review.
E) **Viscosupplementation for osteoarthritis of the knee** The subcommittee wants to re-evaluate this topic once the new AHRQ report comes out.

The subcommittee voted 4-0 to say no further reviews are needed at this time. For MRI for Breast Cancer and Viscosupplementation, the subcommittee would like to consider initiating a review when the additional studies noted above are available.

5. NEXT TOPICS

Shaffer proposed three new topics: recombinant human bone morphogenetic protein, genetic tests of cancer tissue for potential response to treatment, and proton beam therapy. After discussion, the subcommittee decided that the recombinant human bone morphogenetic protein was a lower priority than the other two and staff can choose which of these to pursue.

DRAFT

6. ADJOURNMENT

The meeting was adjourned at 4:00 pm. The next meeting is scheduled for November 24, 2014 from 1:00-4:00pm in Room 117B&C of the Meridian Park Hospital Community Health Education Center in Tualatin.

DRAFT

MINUTES

Evidence-based Guidelines Subcommittee
Meridian Park Community Health Education Center, Room 117B&C
19300 SW 65th Avenue, Tualatin, OR
September 4, 2014
2:00-5:00pm

Members Present: Wiley Chan, MD, Chair; Steve Marks, MD, Vice-Chair; Vern Saboe, DC; Leda Garside, RN, MBA; Som Saha, MD, MPH; Bob Joondeph, JD; Eric Stecker, MD, MPH (arrived via teleconference at 4:02pm).

Members Absent: None

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

Also Attending: Alison Little, MD (CEBP); Jessie Little (OHA/ASU); Sharron Fuchs; Sue Miller, Astellas; Leigh Hess (OHSU).

---

1. CALL TO ORDER

Wiley Chan called the meeting of the Evidence-based Guidelines Subcommittee (EbGS) to order at 2:10 pm.

---

2. MINUTES REVIEW

No changes were made to the June 5, 2014 minutes.

Minutes approved 6-0.

---

3. STAFF REPORT

Livingston provided an updated on the Evaluation of evidence for applied behavioral analysis for autism spectrum disorder. There was minimal discussion. A typo was noted and corrected.

Motion approved to accept the revised version, passed 6-0 (Absent: Stecker).

DRAFT

4. COVERAGE GUIDANCE SCANNING

Little discussed the process for reviewing coverage guidances and scanning for new evidence. There was a discussion as to how the update will be documented in the coverage guidances themselves and on the website if there are no changes based on the updated evidence review. The group decided to add the updated citations to within the coverage guidance itself and to add a notation saying that the coverage guidance remains unchanged based on an updated evidence review as of a certain date. The details of the updated citations may be kept separately, and available on the website.

Scanning updates were performed for:

- Management of chronic otitis media in children – there was minimal discussion.
- Indications for planned cesarean section - there was minimal discussion.
- Knee arthroscopy for osteoarthritis - there was minimal discussion.
- Neuroimaging in dementia
    - Subcommittee members discussed a concern about planning and management decisions based on information that could be obtained through neuroimaging. EbGS decided to update the Coverage Guidance once two or three forthcoming reviews are published. Subcommittee members reaffirmed reevaluation every two years but in this particular case since trusted source reviews were found to be in process, these would be evaluated once published. They agreed that occasional variance from the standard two-year timeline would be appropriate in certain circumstances.
- Routine ultrasound in pregnancy - there was minimal discussion.
- Non-pharmacologic interventions for treatment-resistant depression
    - The subcommittee discussed the conflicting conclusions of the updated evidence sources. The fact that there are unpublished completed studies suggests publication bias. Joondeph raised concerns about the issue of quality of life and whether this determines policy decision. Historically this had violated the ADA because of discrimination against people with disabilities. There was a discussion that incremental quality of life is valuable regardless of disability status and that it is usually one of many outcomes considered in determining an intervention's effectiveness. EbGS directed staff to investigate if transcranial magnetic stimulation (and direct subtype) is something that is done frequently and is worthwhile to investigate further given new conflicting assessments of the evidence.
- Advanced imaging for low back pain - there was minimal discussion.
- Low Back Pain: pharmacologic Interventions - there was minimal discussion.
- Low Back Pain: non-pharmacologic, non-invasive interventions - there was minimal discussion.

Recommended Actions to HERC:

1) No changes based on updated evidence review:
    - Management of chronic otitis media in children

DRAFT

- Indications for planned cesarean section
- Knee arthroscopy for osteoarthritis
- Routine ultrasound in pregnancy

2) Revisit once more information available:
   - Non-pharmacologic interventions for treatment-resistant depression – specifically transcranial magnetic stimulation

3) Review once updated trusted sources are available:
   - Neuroimaging in dementia
   - Advanced imaging for low back pain -
   - Low Back Pain: Pharmacologic interventions
   - Low Back Pain: Non-pharmacologic, non-invasive interventions
   - Percutaneous interventions for low back pain

Motion Approved 6-0 (Absent: Stecker).

---

5. REVIEW OF NEW DRAFT COVERAGE GUIDANCES

A. Topic HOME BIRTH

Livingston presented the Draft Coverage Guidance on Home Birth, reviewing the evidence, algorithm and proposed GRADE table. There was a extensive discussion about the quality of evidence available and the extrapolation of the evidence to the U.S. It was concluded that because observational studies are used, there is a major question of selection bias.

Dr. Melissa Cheyney, the appointed midwifery expert, joined via phone conference. Cheyney discussed how the training of midwives in the U.S. is much more variable. She explained that the International Confederation of Midwives lays out standards. In the U.S there are two trajectories for becoming a direct entry midwife. One involves schooling and the other allows credentialing simply through apprenticeship without every going to school. Sixty percent of currently credentialed midwives used the path to licensure without completing midwifery schooling. Thirty percent of certified midwives in the U.S. do not meet international criterial. Unlicensed midwives in Oregon are no longer allowed to practice after January 1, 2015. She also addressed how data is skewed because most of it is not about intended place of delivery (resulting in pregnancies related to planned home births which transfer to a hospital being counted as hospital births). She addressed high transfer rates, especially of nulliparous women.

Based on the available evidence it was agreed that it appears home birth is safe when performed by highly trained people in a system set up for normative home births. The education of midwives who participated in the studies (performed outside of the United States) is remarkably different than in the U.S. It was

DRAFT

clarified that the choice of home birth appears to be safe if we assume the intervention is the same in the United States as to the other studies., However, it was acknowledged that training and systems of care are significantly different (and weaker) in the U.S. than in the studied countries. Subcommittee members also recognized that there are strong values and preferences that need to be respected.

Subcommitee members reviewed the GRADE table. As a result of discussions the following changes were made:

- Quality of evidence rating was downgraded to low because of the issues of selection bias and external validity
- Balance of benefits and harms: "possible" was added to qualify that the potential benefit can not be proven based on the low quality of evidence
- Intervention language was changed to "Planned home birth"
- Values and preferences was discussed and changed to "low" variability for planned home birth.
- The recommendation for planned home birth among low risk women was downgraded to "weak" based on the revised changes.
- The Coverage Guidance Development Framework pathway for low risk women was changed to 2a1b, and in unselected women was changed to 2A2.

Action:

Due to time constraints, the draft coverage guidance box language was not reviewed. Changes to the GRADE table and algorithm were made as described. The draft coverage guidance will be revisited at the November meeting and submitted for public comment at that time.

---

6. REVIEW OF PUBLIC COMMENTS

A) Topic NUCLEAR CARDIAC IMAGING

Little reviewed the public comment disposition document. Dr. Steve Heitner participated as the invited expert. He shared the importance of adding the word "asymptomatic" to clarify noncoverage for screening. There was a concern about lack of geographic access to stress echo. The coverage guidance box language was amended to include unavailability of stress echo.

It was stated that there was evidence supporting equal efficacy, lower cost, and lower harm for stress echo as compared to SPECT. Subcommittee members recommend that the public comment disposition be updated to reflect this succinctly. There was an extensive discussion about the benefits of theorectically superior physiologic information, but which has unknown implications for health outcomes when compared to stress echo. Heitner shared

DRAFT

that ischemia as assessed by echo prognosticates in the same manner as by SPECT. They also discussed how viability assessment is included in the exceptions (e.g. pre-existing cardiomyopathy). They agreed that it is important to maintain access to diagnostic testing for clinicians, but the weight of evidence does not support superiority of SPECT at this time. SPECT would be indicated in select circumstances when stress echo would not provide optimal results.

They agreed the following changes should be made to the draft Coverage Guidance:

1) Modify the box to allow SPECT coverage when stress echo is unavailable
2) Add "asymptomatic" to clarify screening populations
3) Edit the public comment disposition to clarify the evidence and decision-making

A motion was made to approve the revised draft coverage guidance and forward to HERC. **Motion approved 7-0.**

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*

B) Topic ABLATION FOR ATRIAL FIBRILLATION

Little reviewed the public comments disposition document. There was minimal discussion. The subcommittee agreed to delete the sentence referring to the risk of stroke being up to 8% per year based on the public comment that had concerns about this number.

A motion was made to approve the revised draft coverage guidance and forward to HERC. **Motion approved 7-0.**

DRAFT

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*).

7. PUBLIC COMMENT

No additional public comment was received.

8. ADJOURNMENT

The meeting was adjourned at 5:00 pm. The next meeting is scheduled for November 6, 2014 from 2:00-5:00 pm in Room 117B&C of the Meridian Park Hospital Community Health Education Center in Tualatin.

DRAFT

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: PRENATAL GENETIC TESTING

Approved 3/2014 with DRAFT corrections for November 13, 2014 HERC meeting

HERC COVERAGE GUIDANCE

The following are recommended for coverage *(weak recommendation)*:

- Genetic counseling for high risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, or elevated risk of neural tube defect
- Genetic counseling prior to consideration of CVS, amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening
- Validated questionnaire to assess genetic risk in all pregnant women
- Screening high risk ethnic groups for hemoglobinopathies
- Screening for aneuploidy with any of five screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, and contingency]
- Ultrasound for structural anomalies between 18 and 20 weeks gestation
- CVS or amniocentesis for a positive aneuploidy screen, maternal age >34, fetal structural anomalies, family history of inheritable chromosomal disorder or elevated risk of neural tube defect.
- Array CGH when major fetal congenital anomalies apparent on imaging, and karyotype is normal
- FISH testing only if karyotyping is not possible due a need for rapid turnaround for reasons of reproductive decision-making (i.e. at 22w4d gestation or beyond)
- Screening for Tay-Sachs carrier status in high risk populations. First step is hex A, and then additional DNA analysis in individuals with ambiguous Hex A test results, suspected variant form of TSD or suspected pseudodeficiency of Hex A
- Screening for cystic fibrosis carrier status once in a lifetime
- Screening for fragile X status in patients with a personal or family history of
    - fragile X tremor/ataxia syndrome
    - premature ovarian failure
    - unexplained early onset intellectual disability
    - fragile X intellectual disability
    - unexplained autism through the pregnant woman's maternal line
- Screening for spinal muscular atrophy once in a lifetime
- Screening those with Ashkenazi Jewish heritage for Canavan disease, familial dysautonomia, Tay-Sachs carrier status and cystic fibrosis carrier status.
- Expanded carrier screening only for those genetic conditions identified above

The following are recommended for coverage *(strong recommendation)*:

- Cell free fetal DNA testing for evaluation of aneuploidy in women who have an elevated risk of a fetus with aneuploidy (maternal age >34, family history or elevated risk based on screening)

The following are not recommended for coverage *(weak recommendation)*:

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

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 Heath 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

Little, A., Vandegriff, S., Zoller, E., Pettinari, C., Mayer, M., Kriz, H., & King, V. (2013). *Prenatal genetic testing: Evidence and guideline summary of select tests and conditions* [Produced for the Medicaid Evidence-based Decisions (MED) Project]. Portland, OR: Center for Evidence-based Policy, Oregon Health and Science University.

Key Sources Cited in MED Report:

Akkerman, D., Cleland, L., Croft, G., Eskuchen, K., Heim, C., Levine, A., et al. (2012). *Routine prenatal care.* Bloomington, MN: Institute for Clinical Systems Improvement (ICSI). Retrieved August 2, 2012, from https://www.icsi.org/_asset/13n9y4/Prenatal-Interactive0712.pdf

Department of Veterans Affairs, & Department of Defense. (2009). *VA/DoD clinical practice guideline for pregnancy management*. Washington, DC: Department of Veterans Affairs, Department of Defense. Retrieved June 19, 2012, from http://www.healthquality.va.gov/pregnancy.asp

National Collaborating Centre for Women's and Children's Health, & National Institute for Health and Clinical Excellence (NICE). (2008). *Antenatal care: Routine care for the healthy pregnant woman.* London: RCOG Press. Retrieved June 19, 2012, from http://www.nice.org.uk/guidance/CG62

Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). (2013). Sequencing-based tests to determine fetal trisomy 21 from maternal plasma DNA. *TEC Assessment Program, 27*(10). Retrieved September 20, 2013 from http://www.bcbs.com/blueresources/tec/vols/27/sequencing-based-tests-to.html

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

SUMMARY OF EVIDENCE

Clinical Background

Genetic testing detects alterations in DNA or chromosomes. Human genetic testing requires laboratory analyses of DNA, which is isolated from biologic samples, including cells, blood, or amniotic fluid. Tests for more than 1,300 genetic conditions are available. Genetic tests can be used to diagnose, predict risk for a future disease, inform reproductive decision-making, and manage patient care. There are eight categories of genetic testing: diagnostic, predictive, pharmacogenomic, prenatal, carrier, preimplantation, newborn, and research testing. This guidance document will focus only on recommendations for prenatal, carrier and diagnostic genetic testing. Prenatal testing is used to identify a fetus's genes or chromosomes before birth and is offered during pregnancy based on the risk that the baby will have a genetic or chromosomal disorder. Carrier testing is used to identify people who carry one copy of a gene mutation, which can cause a genetic disorder if two copies are present. Carrier testing is primarily offered to those with a family history of a specific genetic disorder and high-risk ethnic groups. Diagnostic testing is used to identify a specific genetic or chromosomal condition, and to confirm a diagnosis when a particular condition is suspected.

Evidence Review

General Prenatal Testing

A search of guideline databases (MED core sources plus the American College of Medical Genetics and the Canadian College of Medical Geneticists) was conducted from 2008 to present and identified 28 guidelines, three of which addressed general prenatal care [NICE (2008), VA/DoD (2009), and ICSI (Akkerman [ICSI] 2012)]. All three were rated good quality and provided detailed guidance on general prenatal care, with specific recommendations related to genetic testing. All three recommend screening

measures and testing indications for aneuploidy screening, general risk assessment and screening options for hemoglobinopathies, cystic fibrosis, and structural abnormalities. One guideline addresses screening for Tay-Sachs disease. Recommendations from all three guidelines are consistent with a few exceptions:

- Ultrasound screening for structural anomalies is recommended only by NICE (optional for ICSI and VA/DoD); and
- Method of aneuploidy screening is specified only by NICE, which recommends the combined test in the first trimester as the most desirable strategy. The other two guidelines do not recommend one strategy for testing over another.
- NICE does not recommend carrier testing for cystic fibrosis

Prenatal genetic testing recommendations are summarized and compared in the table below:

Indication/Test	NICE (2008)	VA/DoD (2009)	ICSI (2012)
Genetic risk assessment	Validated questionnaire	Validated questionnaire	Validated questionnaire
Hemoglobinopathies	Screen all high-risk ethnic groups[1], complete blood count test, hemoglobin electrophoresis test.	Screen all high-risk ethnic groups, complete blood count test, hemoglobin electrophoresis test.	Screen all high-risk ethnic groups, complete blood count test, hemoglobin electrophoresis test.
Cystic fibrosis	Addressed in separate guideline – testing not recommended	Carrier test/counseling	Carrier test/ counseling
Tay-Sachs disease	-	-	Leukocyte hexosaminidase A test for high-risk ethnic groups
Aneuploidy screening	**First choice (for women who enter care in the first trimester)**: nuchal translucency (NT), beta-human chorionic gonadotropin (beta-hCG), and	**Any of the following, based on the woman's choice**: First- or second-trimester serum marker assessment, first-trimester NT measurement, basic and comprehensive second-trimester	Any of four screening strategies (integrated, serum integrated, stepwise sequential, and contingency)[4].

[1] Women of African, Southeast Asian (excluding Japanese and Korean) or Mediterranean descent
[4] See below for description of these screening strategies

Indication/Test	NICE (2008)	VA/DoD (2009)	ICSI (2012)
	pregnancy-associated plasma protein A (PAPP-A) (11 weeks 0 days and 13 weeks 6 days); **Second choice (for women who present later in the pregnancy)**: triple[2] or quadruple[3] test (15 weeks 0 days and 20 weeks 0 days).	ultrasound assessment, first-trimester chorionic villus sampling and second-trimester amniocentesis. **If first trimester screening is elected:** second-trimester serum AFP screening and/or US should be offered to screen for open neural tube defects. **For second trimester serum screening:** Quad Marker Screen should be used rather than the Triple Marker Screen.	
Structural abnormality screen	Between 18 weeks 0 days and 20 weeks 6 days	Optional - only as needed	Optional 18-20 weeks
Chorionic Villus Sampling (CVS) or Amniocentesis	Provide information at first visit Offer if positive aneuploidy screening (details not provided) Offer if both parents are sickle cell or thallasemia carriers	Maternal request Offer CVS in first trimester if: • Age over 34 • Abnormal first trimester screen (risk estimate similar to that of 35 year old woman [1/270]) • Fetal structural anomalies • Positive family history for metabolic/genetic disorder Offer amniocentesis if: • Abnormal first or second	Three different screening algorithms provided, with no recommendation for which to use Perform risk assessment using first trimester strategy (nuchal translucency, serum PAPP-A, patient age) and/or second trimester strategy (triple or quad screen) High, intermediate and low risk not specified, but examples given

[2] Serum AFP, estriol and beta-hCG
[3] Serum AFP, estriol, beta-hCG and dimeric inhibin A

Indication/Test	NICE (2008)	VA/DoD (2009)	ICSI (2012)
		trimester screen (risk estimate similar to that of 35 year old woman [1/270]) • Fetal ultrasound anomalies • Positive family history for metabolic/genetic disorder • Elevated risk of open neural tube defect	(1/50, 1/200) CVS or amniocentesis offered if screening suggests “high risk”, depending on gestational age

Screening strategies as outlined in the ICSI guideline:

- Integrated screening**:** The patient is scanned for nuchal translucency determination and has a serum PAPP-A analysis performed between 10 and 13 weeks. The results of these tests are held, and the patient then has a quadruple screen test performed between 15 and 19 weeks. At that time, the results of all the studies, combined with risk assessment due to the patient's age, are used to present a single-risk figure. Patients at “high risk” are offered amniocentesis (Trisomy 21 detection rate = 94-96%). “High risk” is not defined, but qualified with the following language: “Each clinician/health care organization will establish cutoff values for low and high risk based on laboratory and patient particulars. One system used is 1 in 200 as the cutoff.”
- Serum integrated screening: A variation in which the first-trimester PAPP-A test result is combined with a second-trimester quad test to provide a single-risk figure is called a serum integrated screening. (Trisomy 21 detection rate = 85-88%).
- Stepwise sequential screening: The patient is scanned for nuchal translucency determination and has a serum PAPP-A analysis performed between 10 and 13 weeks. The results of these studies are combined with the patient's age-associated risk, and the patient is given a risk assessment for aneuploidy. The patient may choose at this time to undergo invasive testing (i.e., CVS), or a triple or quad screen at 15-19 weeks. If the patient has the second-trimester test, a new risk is assessed based on the results of her age and both the first- and second-trimester screening test results (Trisomy 21 detection rate = 95%). Those at “high risk” are offered amniocentesis. “High risk” is not defined, but qualified with the following language: “Each clinician/health care organization

will establish cutoff values for low and high risk based on laboratory and patient particulars. One system used is 1 in 200 as the cutoff."

- Contingency screening: The patient has the same first-trimester study described for the stepwise sequential test and is told the results. If the results are above an arbitrary cutoff, such as 1 in 50, she is offered CVS. If her results are below another arbitrary cutoff, such as 1 in 1,000, she is advised that no further testing is necessary. If the patient's risk falls between these two cutoffs, she is offered a quad screen after 15 weeks, and a new risk assessment is determined as in the stepwise sequential test (Trisomy 21 detection rate = 88-94%). Those at "high risk" are offered amniocentesis. "High risk" is not defined, but qualified with the following language: "Each clinician/health care organization will establish cutoff values for low and high risk based on laboratory and patient particulars. One system used is 1 in 200 as the cutoff."

Genetic Counseling

The NICE guideline does not address women with a family history of a genetic disorder, or specify indications for genetic counseling. The ICSI guideline does not specify indications for genetic counseling with the exception of women with a family history of Fragile X disease or mental retardation. The VA/DoD guideline recommends that genetic counseling be provided to any woman identified as high risk, defined as advanced maternal age, personal or family history of genetic disorder or positive screening test result.

Specific Prenatal Tests or Testing Techniques

A search of clinical evidence sources and guideline databases (MED core sources plus the American College of Medical Genetics and the Canadian College of Medical Geneticists) was conducted from 2003 to present (2008 to present for guidelines). Twenty-four evidence reviews and 28 guidelines were identified, all of which addressed specific genetic tests with the exception of the three general prenatal guidelines discussed above. No quality assessment of the guidelines was done.

Fetal Aneuploidy

Prenatal diagnosis of aneuploidy is suggested by use of maternal screening tests, as reviewed above. All such tests have less than perfect sensitivity and require definitive fetal testing if abnormal. Definitive testing for aneuploidy has historically been an invasive procedure, accomplished by amniocentesis or chorionic villus sampling. However, recently, other methods to detect common aneuploidies have been developed. Four of these are outlined below.

Quantitative Fluorescent-Polymerase Chain Reaction (QF-PCR)

This is a PCR-based technique that consists of amplifying polymorphic markers located on the chromosomes of interest (generally, chromosomes 13, 18, 21, X or Y) to determine the number of copies of those chromosomes present per cell. The advantages of QF-PCR are that it requires a small sample (culture of amniocytes is not required), and the procedure can be automated, providing a rapid turnaround time at a lower cost than conventional cytogenetics. Moreover, diagnostic testing with QF-PCR eliminates the unexpected or incidental identification of rare chromosomal abnormalities of uncertain significance.

No evidence was identified that addressed this test. One guideline was identified, produced by collaboration of the Genetics Committee of the Society of Obstetricians and Gynaecologists of Canada (SOGC) joined with the Prenatal Diagnosis Committee of the Canadian College of Medical Genetics in 2011. They state that "*QF-PCR is a reliable method to detect trisomies and should replace conventional cytogenetic analysis whenever prenatal testing is performed solely because of an increased risk of aneuploidy in chromosomes 13, 18, 21, X or Y."*

Microarray Testing

Microarray testing generally refers to array comparative genomic hybridization (array CGH), which uses a high resolution analysis of the genome to identify losses or duplications to the chromosome. These deletions and duplications are referred to as copy number variations (CNV). Conventional chromosome analysis using G-banding will detect chromosome anomalies such as trisomies 21, 18 and 13, and monosomy X, along with many structural rearrangements. However, it only detects anomalies to a resolution of 5-10 Mb (million base-pairs). Array CGH, on the other hand, is capable of detecting changes to a resolution of 1 kb (thousand base-pairs) which is smaller than the average gene, and customized arrays designed for prenatal diagnosis have been developed.

One of the challenges of the application of CGH microarrays in the clinical setting is determining whether a copy number imbalance is *de novo* and likely to be causative, or inherited and likely to be benign. Copy number variants (CNVs) are categorized into those that are likely to be 'benign,' those that are likely to be 'pathogenic' and those of 'unknown clinical significance.' Copy number variants that overlap critical regions of established microdeletion or microduplication syndromes are likely to be pathogenic, but there is a high incidence of CNVs in the normal population, making the significance of many CNVs uncertain. Although array CGH has higher resolution to detect these small chromosomal changes, it cannot detect balanced rearrangements such as transformations or inversions. Identifying CNVs of uncertain significance increases parental anxiety and makes genetic counseling more challenging.

For microarray testing, a systematic review found that array CGH detected 3.6% additional genomic imbalances when conventional karyotyping was normal, regardless of the reason for performing the study, and increased to 5.2% when the indication for performing the study was a structural malformation on ultrasound. Three guidelines were identified that address array CGH and make similar recommendations. None of the three recommend array CGH testing for pregnancies at low risk of chromosome abnormalities. All three recommend this technology when fetal structural abnormalities are identified on ultrasound or MRI, although one recommends that it be utilized only if conventional karyotyping is normal. All three also recommend genetic counseling for all patients utilizing the technology.

Fluorescent In Situ Hybridization (FISH) DNA Testing

This is a rapid technique that relies on fluorescent in situ hybridization (FISH) that provides results in one to two days, in which fluorescently labeled DNA probes are bound to fetal cell DNA in a highly selective manner, allowing detection of changes in the number of specific chromosomes by detecting the fluorescence. To detect the most common disorders involving chromosome number, fluorescent probes are used that bind to chromosomes 13, 18, 21, X, and Y. However, this technique fails to detect many other potentially harmful changes in chromosomes that can be detected by conventional karyotyping, such as certain rearrangements of segments of chromosomes.

One TA was identified that addressed this topic. It included three large studies that compared results obtained with FISH with those obtained with conventional karyotyping. Results suggest that FISH is a highly accurate test for detection of most, but not all, potentially harmful chromosomal abnormalities, with sensitivity and specificity for detection of the targeted abnormalities exceeded 99.5%. However, it is unable to detect 7% to 11% of potentially harmful chromosomal disorders that can be detected by karyotyping.

Cell Free Fetal DNA Testing

Fetal DNA circulates in maternal blood during pregnancy, making up approximately 10% of all circulating DNA. Recently, cell free DNA testing has been used to identify common aneuploidies. These tests utilize maternal blood, from which fetal DNA can be isolated as early as ten weeks gestation. Repeated parallel sequencing can then detect an excess of the chromosome of interest of fetal origin, indicating the specific aneuploidy.

No evidence was identified in the MED report. One guideline recommends that cell free DNA testing be offered to patients at increased risk of aneuploidy[5]. They recommend that it NOT be a part of routine prenatal laboratory measurements or be offered to low risk women.

The Blue Cross TEC Assessment Program analyzed this technology and identified eight studies that reported on the performance of cff-DNA for trisomy 21 screening in singleton high-risk pregnancies. They found that cff-DNA testing reduced the number of invasive confirmatory procedures needed and consequent associated miscarriages, while improving the number of detected cases of trisomy 21, compared to standard screening procedures in high-risk populations of pregnant women. They therefore concluded that ccf-DNA meets the TEC criteria.

Tay-Sachs Disease

Tay-Sachs disease is an autosomal recessive lysosomal storage disease caused by a deficient activity of the enzyme hexosaminidase A (Hex A). It occurs in 1 in 2500 children of Ashkenazi Jewish parents, and is most common among people who are Ashkenazi Jewish, French-Canadian, or Cajun. Hex A activity can be measured in serum, white blood cells, or fetal trophoblastic cells, and is used as the initial screening test for TSD mutation carriers. However, in some cases, the enzyme test may not be diagnostic, and DNA analysis may be necessary to clarify ambiguous enzyme test results or to diagnose variant forms of the disease.

One review that included four studies and a retrospective analysis found that hexoaminidase A testing is accurate and impacts both pre and post-conception reproductive decision making. The review concludes that the evidence is sufficient to support the use of screening by Hex A enzyme testing individuals at high risk (Ashkenazi Jewish, French-Canadian or with positive family history) or partners of known carriers. It is also sufficient to support additional DNA analysis in individuals with ambiguous Hex A test results, suspected variant form of TSD or suspected pseudodeficiency of Hex A. The one guideline identified recommends that Hex A screening be offered to all pregnant Jewish patients if they or their partners have not yet been tested.

Cystic Fibrosis

Cystic Fibrosis is an autosomal recessive disease of the exocrine glands that is characterized by early onset of severe intestinal malabsorption, failure to thrive and recurrent chest infections and pneumonia which, if untreated, leads to death from malnutrition and respiratory failure in infancy or early childhood. The identification of the

[5] Maternal age ≥ 35, suggestive US findings, history of prior trisomy pregnancy, positive aneuploidy screen or parental balanced robertsonian translocation with increased risk for fetal trisomy 13 or 21

gene responsible for CF, *CFTR,* and its major mutations, allow for the identification of couples at risk who can be offered genetic counseling and prenatal CF diagnosis, and who can use the information to inform reproductive decision-making. Since heterozygotes are asymptomatic, carrier status assumes clinical significance only in the context of reproduction.

A review of 10 population-based studies found carrier testing was 80% to 96% sensitive in Caucasians and 58% to 76% sensitive in Hispanics. Uptake rates for testing ranged from 68% to 95%. The evidence was sufficient to support the use of CF carrier screening if results will be used to guide decisions regarding childbearing or need for fetal diagnosis. A second review reported analytic sensitivity of 97.9% and analytic specificity of 99.4%, but clinical sensitivity of only 75%. Uptake rates in this review were reported as 85% to 100%, and of the affected fetuses identified, 83% were terminated. Four guidelines were identified, three of them addressing general prenatal care and offering differing recommendations. Two recommend that CF carrier screening be offered to all couples who desire it and have not been previously screened, while the third does not recommend screening. The one guideline that addressed CF carrier screening outside the context of general prenatal care recommends carrier testing in individuals and their partners with a positive family history, and prenatal diagnosis for pregnancies at 25% or greater risk of CF, and those with an echogenic bowel identified in the fetus.

Fragile X Syndrome

Fragile X Syndrome is the most common inherited cause of mental retardation, and results from a dynamic mutation (those that can change as they are passed down to future generations). In normal individuals there are six to 50 repeats of the CGG sequence of DNA at the Fragile X site. When the number of repeats ranges between 50 and 200, this is known as a premutation (PM); more than 200 repeats is considered a full mutation (FM). Full mutations inactivate the gene resulting in the Fragile X phenotype in all males (who only have one copy of the gene) and a proportion of females (all will be carriers, some will have the phenotype). A female with a PM or a FM may pass on a larger mutation than her own, resulting in offspring affected by Fragile X syndrome. Meanwhile, men with a PM may pass this onto their daughters, who will be of normal intellect, but may pass a larger mutation onto their offspring. The larger the size of the premutation repeat, the more likely is the expansion to a full mutation.

A systematic review that compared antenatal screening of low risk versus high risk women identified no studies, while a health technology assessment that compared different screening strategies for Fragile X syndrome found that population-based prenatal screening is more efficacious but significantly more costly than active cascade

screening[6], with the incremental cost per Fragile X birth avoided being £8494 for active cascade screening and £284,779 for population-based screening. Three guidelines address testing for Fragile X and offer generally consistent recommendations. These include genetic counseling of all testing recipients, carrier screening of women with a positive personal or family history of fragile X-rated disorders, unexplained mental retardation or premature ovarian failure, and prenatal fetal DNA testing for known carriers.

Heritable Thrombophilia

Pregnancy is associated with an increased risk of venous thromboembolism, as are inherited thrombophilias. However, it is controversial whether there is an association between inherited thrombophilias and adverse pregnancy outcomes such as fetal loss, preeclampsia, fetal growth restriction, and placental abruption. This possible association has resulted in increased screening for thrombophilias in pregnancy, although there has been no confirmation of treatment benefits.

For heritable thrombophilia, one systematic review resulted in a recommendation to not screen for heritable thrombophilia in any group. One guideline was identified that addresses inherited thrombophilias in pregnancy. Regarding screening, it recommends against testing in women with recurrent fetal loss or placental abruption, and finds insufficient evidence to support testing in women with previous preeclampsia or intrauterine growth restriction. For women diagnosed with hereditary thrombophilia and/or with a history of thromboembolism, the guideline provides specific recommendations for which tests to perform, and for antepartum and postpartum management.

Fetal Skeletal Dysplasia

Skeletal dysplasias may present in the prenatal period when demonstrated by abnormalities on ultrasound. Differentiating these disorders in the prenatal period can be useful to distinguish known lethal disorders from nonlethal disorders and to assist with determining post-delivery management plans. One guideline was identified that provides specific recommendations for management based on abnormal findings of a second trimester ultrasound. Those recommendations include a determination of lethality based on ultrasound measurements, and molecular testing of pregnancies identified as at-risk for skeletal dysplasias.

Spinal Muscular Atrophy

Spinal muscular atrophy (SMA) is an autosomal recessive neurodegenerative disease that results from degeneration of spinal cord motor neurons leading to atrophy of skeletal muscle and overall weakness. The incidence of SMA is approximately 1 in

[6] Testing relatives of Fragile X patients to determine carrier status

10,000 live births, and it is reported to be the leading genetic cause of infant death, although milder forms allow survival into adulthood. Two guidelines were identified, with conflicting recommendations. One did not recommend screening for SMA in the general population, but did recommend carrier screening for those with a family history of SMA-like disease. The other recommends that carrier testing be offered to all couples.

Ethnicities with Elevated Genetic Risk

For ethnicities at increased genetic risk, two guidelines were identified with conflicting recommendations for screening those of Ashkenazi Jewish descent. Both recommend carrier screening for Tay-Sachs disease, Canavan disease, cystic fibrosis, and familial dysautonomia. One also recommends screening for Fanconi anemia, Bloom syndrome, Mucolipidosis IV, Niemann-Pick type A and Gaucher disease type I, while the other only recommends that patient education materials be made available to patients concerning these conditions. Both groups also recommend carrier screening for Tay Sachs disease for individuals of French Canadian and Cajun origin.

Genetic Counseling

All three guidelines pertaining to microarray testing recommend that it be accompanied by genetic counseling. Guidelines addressing other specific genetic tests recommend genetic counseling be provided in the following situations: a positive cell free fetal DNA testing result, any cystic fibrosis carrier, women with risk factors for Fragile X or who request testing for Fragile X and women with a family history of, or who request testing for, spinal muscular atrophy.

Evidence Summary

Evidence-based guidelines for routine prenatal care are generally consistent regarding their recommendations related to genetic testing, recommending aneuploidy screening and screening options for hemoglobinopathies, cystic fibrosis, and structural abnormalities. Recommendations on specific tests were generally not based on trusted sources due to lack of availability of evidence and are derived from guidelines of variable quality.

There are four options available for aneuploidy testing in addition to the traditional method of karyotyping, which requires an invasive procedure (amniocentesis or chorionic villus sampling) and amniocyte culture. Three of the four do not require the culture of amniocytes, allowing a more rapid turnaround time, but at the expense of a less accurate or complete diagnosis. They include QF-PCR, FISH testing and cell free fetal DNA testing. No evidence was identified for QF-PCR. The evidence for FISH suggests that it is a highly accurate test for detection of most potentially harmful chromosomal abnormalities, although it is unable to detect 7% to 11% of chromosomal disorders that can be detected by karyotyping. Cell free DNA testing reduces the

number of invasive confirmatory procedures needed while improving the number of detected cases of trisomy 21, compared to standard screening procedures, in high-risk populations of pregnant women.

The fourth method, array CGH testing, is limited by difficulty determining whether a copy number imbalance is likely to be causative or benign, as well as the inability to detect balanced rearrangements. Evidence suggests that array CGH detects approximately 5% additional genomic imbalances when conventional karyotyping is normal, if the indication for performing the study is a structural malformation on ultrasound. None of the three identified guidelines recommend array CGH testing for pregnancies at low risk of chromosome abnormalities, but all recommend it when fetal structural abnormalities are identified.

For Tay-Sachs disease, the evidence is sufficient to support the use of screening by Hex A enzyme testing for individuals at high risk (Ashkenazi Jewish, French-Canadian or with positive family history) or partners of known carriers. It is also sufficient to support additional DNA analysis in individuals with ambiguous Hex A test results, suspected variant form of TSD or suspected pseudodeficiency of Hex A.

For cystic fibrosis, the evidence is sufficient to support the use of CF carrier screening if results will be used to inform decisions regarding childbearing or need for fetal diagnosis.

For Fragile X Syndrome, three guidelines recommend carrier screening of women with a positive personal or family history of Fragile X-rated disorders, unexplained mental retardation or premature ovarian failure, and prenatal fetal DNA testing for known carriers.

For heritable thrombophilia, evidence supports and one guideline recommends not screening for heritable thrombophilia in any group.

For fetal skeletal dysplasia, one guideline recommends determining lethality based on ultrasound measurements and molecular testing of at-risk pregnancies.

For spinal muscular atrophy, two guidelines had conflicting recommendations, with one recommending carrier screening to all couples and the other recommending only for those with a family history of SMA-like disease.

For ethnicities at increased genetic risk, two guidelines recommend screening those of Ashkenazi Jewish descent for Tay-Sachs disease, Canavan disease, cystic fibrosis, and familial dysautonomia, but disagree about screening for four additional conditions.

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	Balance between desirable and undesirable effects	Quality of evidence	Resource Allocation	Values and preferences	Coverage Recommendation
Use a validated questionnaire to assess genetic risk in all pregnant women	Likely beneficial without known risks	Low	Limited	Limited variability	Administration of a validated questionnaire to assess genetic risk is recommended for coverage *(weak recommendation)*
Screen high-risk ethnic groups for hemoglobinopathies	Likely beneficial, minimal risks	High	Limited	Limited variability	Screening high risk ethnic groups for hemoglobinopathies is recommended for coverage *(weak recommendation)*
Aneuploidy screening in first or second trimester	Likely beneficial, minimal risks	Moderate	Moderate	Moderate variability	Screening for aneuploidy with any of the four screening strategies (integrated, serum integrated, stepwise sequential, and contingency) is recommended for coverage *(weak recommendation)* Serum triple screen is not recommended for coverage *(weak recommendation)*

Indication	Balance between desirable and undesirable effects	Quality of evidence	Resource Allocation	Values and preferences	Coverage Recommendation
Perform an US for structural anomaly screen at 18-20 weeks	Possibly beneficial, minimal risks	Low	Moderate	Limited variability	Ultrasound for structural anomalies between 18-20 weeks gestation is recommended for coverage *(weak recommendation)*
Offer CVS or amnio for + aneuploidy screen, maternal age > 34, fetal structural anomalies, + FH, elevated risk of neural tube defect or maternal request	Mixed – Moderate benefit depending on patient preferences, small risk (pregnancy loss 1/300-500)	Mixed	High	High variability	CVS and amniocentesis are recommended for coverage for a positive aneuploidy screen, maternal age >34, fetal structural anomalies, positive family history, elevated risk of neural tube defect, or maternal request *(weak recommendation)* Genetic counseling is recommended for coverage prior to CVS/amniocentesis *(weak recommendation)*
Aneuploidy testing with QF-PCR	Similar risk to karyotyping, may be more beneficial when rapid turnaround is required	None	Moderate	High variability	*Test not available in the US – no recommendation made*
Array CGH testing when karyotype normal and structural anomaly on US	Similar risk to karyotyping, similar benefits (detection of more chromosomal anomalies, but also more anomalies of no clinical significance, resulting in increased maternal anxiety	Low	Moderate	Limited variability (because anomalies already identified)	Recommended for coverage when major fetal congenital anomalies apparent on imaging and karyotype is normal *(weak recommendation)*

Indication	Balance between desirable and undesirable effects	Quality of evidence	Resource Allocation	Values and preferences	Coverage Recommendation
Aneuploidy testing with FISH	Similar risk to karyotyping, may be more beneficial when rapid turnaround is required	Moderate	High	High variability (because use for pregnancy decision making only)	Karyotyping is first line test. If a rapid turnaround (i.e. at 22w4d or beyond) is required for reproductive decision-making, FISH is recommended for coverage *(weak recommendation)*
Cell free fetal DNA testing	High level of accuracy (98% detection rate with false positive < 0.5%). Less risk than karyotyping but less information provided (current tests only identify trisomy 13, 18 and 21)	~~None~~ Moderate	High	Moderate variability (many women would choose a noninvasive highly accurate test)	Cell free fetal DNA testing is ~~not~~ recommended for coverage in women with elevated risk (maternal age>34, family history or elevated risk based on screening) *(~~weak~~strong recommendation)*
Screening for Tay-Sachs carrier status using Hex A in high risk populations[7]	Benefits exceed harms	Moderate	Low	Limited variability (most would choose to terminate)	Screening for Tay-Sachs carrier status in high risk populations is recommended for coverage. First step is Hex A, and then additional DNA analysis in individuals with ambiguous Hex A test results, suspected variant form of TSD or suspected pseudodeficiency of Hex A *(weak recommendation)*

[7] Ashkenazi Jewish, French Canadian and Cajun

Indication	Balance between desirable and undesirable effects	Quality of evidence	Resource Allocation	Values and preferences	Coverage Recommendation
Screening for CF carrier status	Potential benefit, minimal harm	Moderate	Moderate	Moderate variability	Screening for cystic fibrosis status is recommended for coverage once in a lifetime *(weak recommendation)*
Screening for fragile X carrier status in women with +FH or risk factors[8]	Small benefit, depending on values of parents, minimal harm	Low	Moderate	Moderate variability	Screening for fragile X status in patients with a personal or family history of • fragile X tremor/ataxia syndrome • premature ovarian failure • unexplained early onset intellectual disability • fragile X intellectual disability • unexplained autism through the pregnant woman's maternal line adult
Screening for thrombophilia	No definite benefit, possible harm if prophylactic treatment undertaken (bleeding risks from anticoagulation)	Low	Moderate (if treatment undertaken)	Limited	Screening for thrombophilia is not recommended for coverage for recurrent pregnancy loss or in the general population (*weak recommendation*)
Fetal genetic analysis of fetuses at risk for fetal skeletal dysplasia based on US	Mixed – Moderate benefit depending on patient preferences, small risk	Low	Moderate (cascade of testing)	Moderate variability	*No recommendation made*

[8] Personal or family history of fragile X tremor/ataxia syndrome, unexplained mental retardation, autism or premature ovarian failure (before age 40)

Indication	Balance between desirable and undesirable effects	Quality of evidence	Resource Allocation	Values and preferences	Coverage Recommendation
Spinal muscular atrophy carrier screening	Small benefit, depending on values of parents, minimal harm	None	Low	Moderate variability	Screening for spinal muscular atrophy is recommended for coverage once in a lifetime *(weak recommendation)*
Screening of Ashkenazi Jewish population for specific genetic diseases	Likely beneficial, minimal risks	Low	Moderate	Moderate variability	Screening is recommended for coverage for those of Ashkenazi Jewish heritage for Tay-Sachs disease, Canavan disease, cystic fibrosis, and familial dysautonomia *(weak recommendation)*
Expanded carrier screening	Components likely beneficial, however, there is a risk of cascade testing, clinically unimportant results	None	Moderate. There is a cascade of testing. However, compared to individual diagnostic tests, this type of testing is much less expensive	High variability	Coverage is recommended for expanded carrier screening only for those genetic conditions previously identified with enough evidence or guidelines to support a recommendation for coverage *(weak recommendation)* Coverage is not recommended for an unlimited variety of tests offered as part of expanded carrier screening *(weak recommendation)*
Genetic counseling	Beneficial in greater understanding of risks and benefits	Moderate	Cost of appointment may be balanced by optimizing appropriate test utilization	Low variability (most women would choose to see a genetic counselor)	Pretest genetic counseling is recommended for coverage prior to CVS, amniocentesis, Fragile X, microarray, and spinal muscular atrophy screening *(weak recommendation)*

Note: GRADE framework elements are described in Appendix A

POLICY LANDSCAPE

There were no quality measures pertaining to prenatal genetic testing identified when searching the National Quality Measures Clearinghouse.

COMMITTEE DELIBERATIONS –EBGS

In its review of this topic at its meetings April 4, June 6 and September 7, 2013, EbGS reviewed the initial draft coverage guidance and made the following decisions (some decisions from early meetings were later reversed; the final decisions are reflected here):

- Did not include coverage for CVS/Amniocentesis for the indication of 'on maternal request' as a weak recommendation.
- Made no recommendation on QF-PCR as the test is not available in the United States.
- Recommended coverage for genetic counseling for women with certain risk factors.
- In Array CGH testing when the karyotype is normal and there is a structural anomaly on ultrasound, the subcommittee decided to remove the recommendation for genetic counseling, as counseling would already have occurred before the CVS/amniocentesis. For Array CGH with stillbirth at >20 weeks gestation, the subcommittee decided to strike the recommendation, as none of the evidence reviewed supports its use in improving future pregnancy outcomes.
- Decided to recommend coverage for Cell Free Fetal DNA testing for high risk pregnancies based on new evidence from trusted sources which was submitted during public comment.
- Changed the recommendation for thrombophilia screening to clarify that it is not recommended for screening, or for women with a history of recurrent pregnancy loss.
- Recommended coverage for spinal muscular atrophy only once in a lifetime with pretest genetic counseling.
- Recommended coverage for carrier screening in the Ashkenazi Jewish population for only four conditions rather than eight.

COMMITTEE DELIBERATIONS – VBBS

VbBS discussed the draft coverage guidance at its meeting 10/10/2013, reviewing a guideline note based on the draft coverage guidance. The subcommittee asked staff to consult with experts to incorporate the correct procedure codes into the guideline note, and added wording to allow a broader, but less expensive, test panel for additional

testing specific to patients of Ashkenazi Jewish heritage. However, with regard to expanded carrier screening, the subcommittee chose not to make a similar statement, as some test panels currently available include traits such as eye color, and could be clinically irrelevant or inappropriate.

COMMITTEE DELIBERATIONS – HERC

The Health Evidence Review Commission reviewed the draft coverage guidance on March 13, 2014. The commission modified the criteria for coverage of genetic counseling prior to CVS, amniocentesis, microarray testing, Fragile X and spinal muscular atrophy screening to include patients considering those tests.

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 of evidence across studies for the treatment/outcome

High = Further research is very unlikely to change our confidence in the estimate of effect.

Moderate = Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low = Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low = Any estimate of effect is very uncertain.

Appendix B. Applicable Codes

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
V18.4	Family history of intellectual disabilities
V18.9	Family history of genetic disease carrier
V26.31	Testing of female for genetic disease carrier status
V26.32	Other genetic testing of female
V26.33	Genetic counseling
V26.34	Testing of male for genetic disease carrier status
V26.35	Encounter for testing of male partner of female with recurrent pregnancy loss
V26.39	Other genetic testing of male
V28.0	Antenatal screening for chromosomal anomalies by amniocentesis
V28.1	Antenatal screening for raised alpha-fetoprotein levels in amniotic fluid
V28.2	Other antenatal screening based on amniocentesis
V28.3	Encounter for routine screening for malformation using ultrasonics
V28.89	Other specified antenatal screening
V28.9	Unspecified antenatal screening
ICD-9 Volume 3 (Procedure Codes)	
None	
CPT Codes	
~~81161~~76805	~~DMD (dystrophin) (eg, Duchenne/Becker muscular dystrophy) deletion analysis, and duplication analysis, if performed~~Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (> or = 14 weeks 0 days), transabdominal approach; single or first gestation
76810	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (> or = 14 weeks 0 days), transabdominal approach; each additional gestation
76811	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach; single or first gestation
76812	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach; each additional gestation
76813	Ultrasound, pregnant uterus, real time with image documentation, first trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach; single or first gestation
76814	Ultrasound, pregnant uterus, real time with image documentation, first trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach; each additional gestation
76817	Ultrasound, pregnant uterus, real time with image documentation, transvaginal
81200	*ASPA (aspartoacylase)* (eg, Canavan disease) gene analysis, common variants (eg, E285A, Y231X)
~~81205~~	~~*BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide)* (eg, Maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X)~~
81209	*BLM (Bloom syndrome, RecQ helicase-like)* (eg, Bloom syndrome) gene analysis, 2281del6ins7 variant)

CODES	DESCRIPTION
81220	*CFTR (cystic fibrosis transmembrane conductance regulator)* (eg, cystic fibrosis) gene analysis; common variants (eg, ACMG/ACOG guidelines)
81221	known familial variants
81222	duplication/deletion variants
81223	full gene sequence
81224	intron 8 poly-t analysis (eg, male infertility)
~~81225~~	~~*CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19)* (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)~~
~~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)~~
~~81227~~	~~*CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9)* (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)~~
81228	~~Cytrogenomic~~Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (eg, Bacterial Artificial Chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis)
81229	interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities
~~81240~~	~~*F2 (prothrombin, coagulation factor II)* (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant~~
~~81241~~	~~*F5 (coagulation Factor V) (eg, hereditary hypercoagulability)* gene analysis, Leiden variant~~
81242	*FANCC (Fanconi anemia, complementation group C)* (eg, Fanconi anemia, type C) gene analysis, common variant (eg, IVS4+4A>T)
81243	*FMR1 (Fragile X mental retardation 1)* (eg, fragile X mental retardation) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
81244	characterization of alleles (eg, expanded size and methylation status)
~~81250~~	~~*G6PC (glucose-6-phosphatase, catalytic subunit)* (eg, Glycogen storage disease, Type 1a, von Gierke disease) gene analysis, common variants (eg, R83C, Q347X)~~
81251	*GBA (glucosidase, beta, acid)* (eg, Gaucher disease) gene analysis, common variants (eg, N370S, 84GG, L444P, IVS2+1G>A)
~~81252~~	~~*GJB2 (gap junction protein, beta 2, 26kDa, conexin 26)* (eg, nonsyndromic hearing loss) gene analysis; full gene sequence~~
~~81253~~	~~known familial variants~~
~~81254~~	~~*GJB6 (gap junction protein, beta 6, 30kDa, connexin 30)* (eg, nonsyndromic hearing loss) gene analysis, common variants (eg, 309kb [del(GJB6-D13S1830)] and 232kb [del(GJB6-D13S1854)])~~
81255	*HEXA (hexosaminidase A [alpha polypeptide])* (eg, Tay-Sachs disease) gene analysis, common variants (eg, 1278insTATC, 1421+1G>C, G269S)
~~81256~~	~~*HFE (hemochromatosis) (eg, hereditary hemochromatosis)* (eg, hereditary hemochromatosis) gene analysis, common variants (eg, C282Y, H63D)~~
81257	*HBA1/HBA2 (alpha globin 1 and alphaglobin 2)* (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis, for common deletions or variant (eg, Southeast Asian, Thai, Filipino, Mediterranean, alpha3.7, alpha4.2, alpha20.5, and Constant Spring)

CODES	DESCRIPTION
81260	*IKBKAP (inhibitor of kappa light polypeptide gene enhancer in B-cells, kinase complex-associated protein)* (eg, familial dysautonomia) gene analysis, common variants (eg, 2507+6T>C, R696P)
~~81280~~	~~Long QT syndrome gene analyses (eg, *KCNQ1, KCNH2, SCN5A, KCNE1, KCNE2, KCNJ2, CACNA1C, CAV3, SCN4B, AKAP, SNTA1, and ANK2*); full sequence analysis~~
~~81281~~	~~known familial sequence variant~~
~~81282~~	~~duplication/deletion variants~~
81290	*MCOLN1 (mucolipin 1)* (eg, Mucolipidosis, type IV) gene analysis, common variants (eg, IVS3-2A>G, del6.4kb)
~~81291~~	~~*MTHFR (5,10-methylenetetrahydrofolate reductase)* (eg, hereditary hypercoagulability) gene analysis, common variants (eg, 677T, 1298C)~~
~~81292~~81507	~~*MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2)* (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis~~Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as risk score for each trisomy
~~81293~~	~~known familial variants~~
~~81294~~	~~duplication/deletion variants~~
~~81295~~	~~*MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1)* (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis~~
~~81296~~	~~known familial variants~~
~~81297~~	~~duplication/deletion variants~~
~~81298~~	~~*MSH6 (mutS homolog 6 [E. coli])* (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis~~
~~81299~~	~~known familial variants~~
~~81300~~	~~duplication/deletion variants~~
~~81301~~81508	~~Microsatellite instability analysis (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repair deficiency (eg, BAT25, BAT26), includes comparison of neoplastic and normal tissue, if performed~~Fetal congenital abnormalities, biochemical assays of two proteins (PAPP-A, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score
~~81302~~	~~*MECP2 (methyl CpG binding protein 2)* (eg, Rett syndrome) gene analysis; full sequence analysis~~
~~81303~~	~~known familial variant~~
~~81304~~	~~duplication/deletion variants~~
~~81317~~	~~*PMS2 (postmeiotic segregation increased 2 [S. cerevisiae])* (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis~~
~~81318~~	~~known familial variants~~
~~81319~~	~~duplication/deletion variants~~
~~81321~~	~~*PTEN (phosphatase and tensin homolog)* (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full sequence analysis~~
~~81322~~	~~known familial variant~~
~~81323~~	~~duplication/deletion variants~~

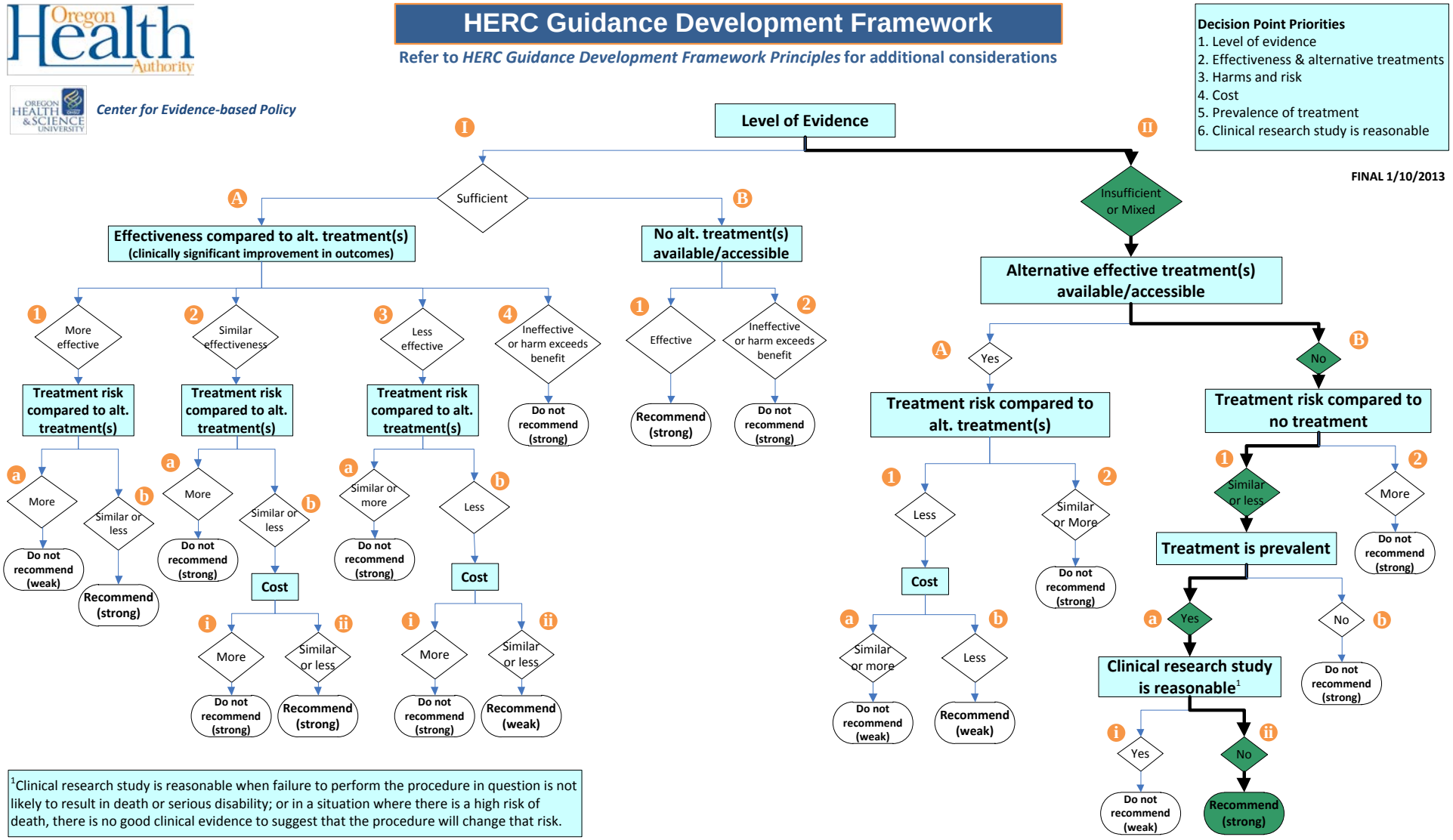
CODES	DESCRIPTION
~~81324~~	~~*PMP22 (peripheral myelin protein 22)* (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; duplication/deletion analysis~~
~~81325~~	~~full sequence analysis~~
~~81326~~	~~known familial variant~~
~~81330~~81509	~~*SMPD1 (sphingomyelin phosphodiesterase 1, acid lysosomal)* (eg, Niemann-Pick disease, Type A) gene analysis, common variants (eg, R496L, L302P, fsP330)~~Fetal congenital abnormalities, biochemical assays of three proteins (PAPP-A, hCG [any form], DIA), utilizing maternal serum, algorithm reported as a risk score
~~81331~~81510	~~*SNRPN/UBE3A (small nuclear ribonucleoprotein polypeptide N and ubiquitin protein ligase E3A)* (eg, Prader-Willi syndrome and/or Angelman syndrome), methylation analysis~~Fetal congenital abnormalities, biochemical assays of three analytes (AFP, uE3, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score
~~81332~~81511	~~*SERPINA1 (serpin peptidase inhibitor, cladeA, alpha-1-antiproteinase, antitrypsin, member 1)* (eg, alpha-1-antitruypsin deficiency), gene analysis, common variants (eg, *S and *Z)~~Fetal congenital abnormalities, biochemical assays of four analytes (AFP, uE3, hCG [any form], DIA), utilizing maternal serum, algorithm reported as a risk score (may include additional results from previous biochemical testing)
88267	Chromosome analysis, amniotic fluid or chorionic villus, count 15 cells, 1 karyotype, with banding
88269	Chromosome analysis, in situ for amniotic fluid cells, count cells from 6-12 colonies, 1 karyotype, with banding
88271	Molecular cytogenetics; DNA probe, each (eg, FISH)
88272	chromosomal in situ hybridization, analyze 3-5 cells (eg, for derivatives and markers)
88273	chromosomal in situ hybridization, analyze 10-30 cells (eg, for microdeletions)
88274	interphase in situ hybridization, analyze 25-99 cells
88275	interphase in situ hybridization, analyze 100-300 cells
88280	Chromosome analysis; additional karyotypes, each study
88283	additional specialized banding technique (eg, NOR, C-banding)
88285	additional cells counted, each study
88289	additional high resolution study
88291	Cytogenetics and molecular cytogenetics, interpretation and report
HCPCS Level II Codes	
S0265	Genetic counseling, under physician supervision, each 15 minutes
~~S3841~~	~~Genetic testing for retinoblastoma~~
~~S3842~~	~~Genetic testing for von hippel-lindau disease~~
~~S3844~~	~~DNA analysis of the connexin 26 gene (gjb2) for susceptibility to congenital, profound deafness~~
S3845	Genetic testing for alpha-thalassemia
S3846	Genetic testing for hemoglobin e beta-thalassemia
S3849	Genetic testing for Niemann-Pick disease
S3850	Genetic testing for sickle cell anemia
~~S3852~~	~~DNA analysis for apoe epsilon 4 allele for susceptibility to Alzheimer's disease~~

CODES	DESCRIPTION
~~S3853~~	~~Genetic testing for myotonic muscular dystrophy~~
~~S3861~~	~~Genetic testing, sodium channel, voltage-gated, type v, alpha subunit (scn5a) and variants for suspected brugada syndrome~~
~~S3865~~	~~Comprehensive gene sequence analysis for hypertrophic cardiomyopathy~~
~~S3866~~	~~Genetic analysis for a specific gene mutation for hypertrophic cardiomyopathy (HCM) in an individual with a known HCM mutation in the family~~
S3870	Comparative genomic hybrization (CGH) microarray testing for developmental delay, autism spectrum disorder and/or mental retardation

Note: Inclusion on this list does not guarantee coverage

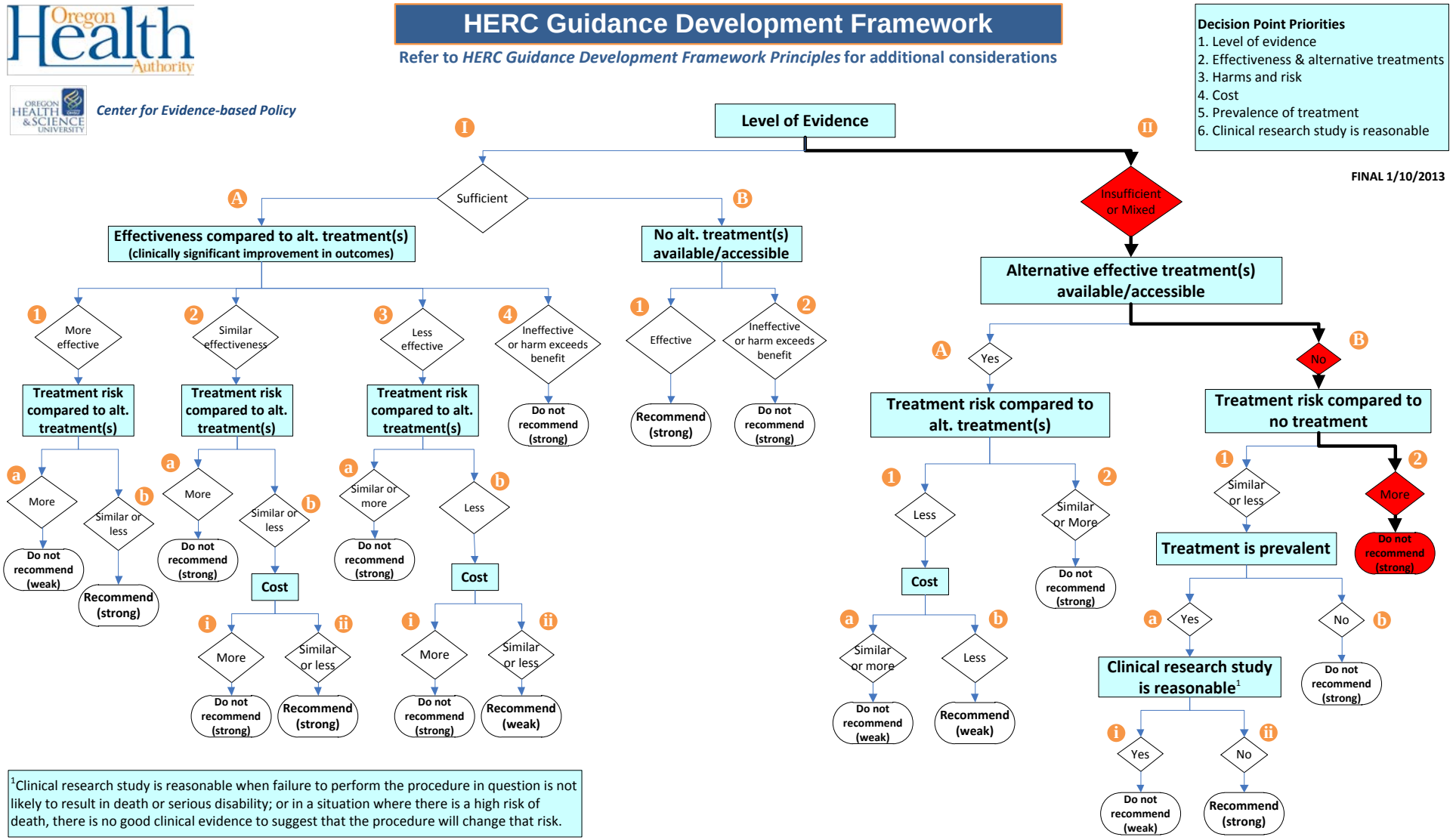
Appendix C. HERC Guidance Development Framework

Validated questionnaire to assess genetic risk in all pregnant women



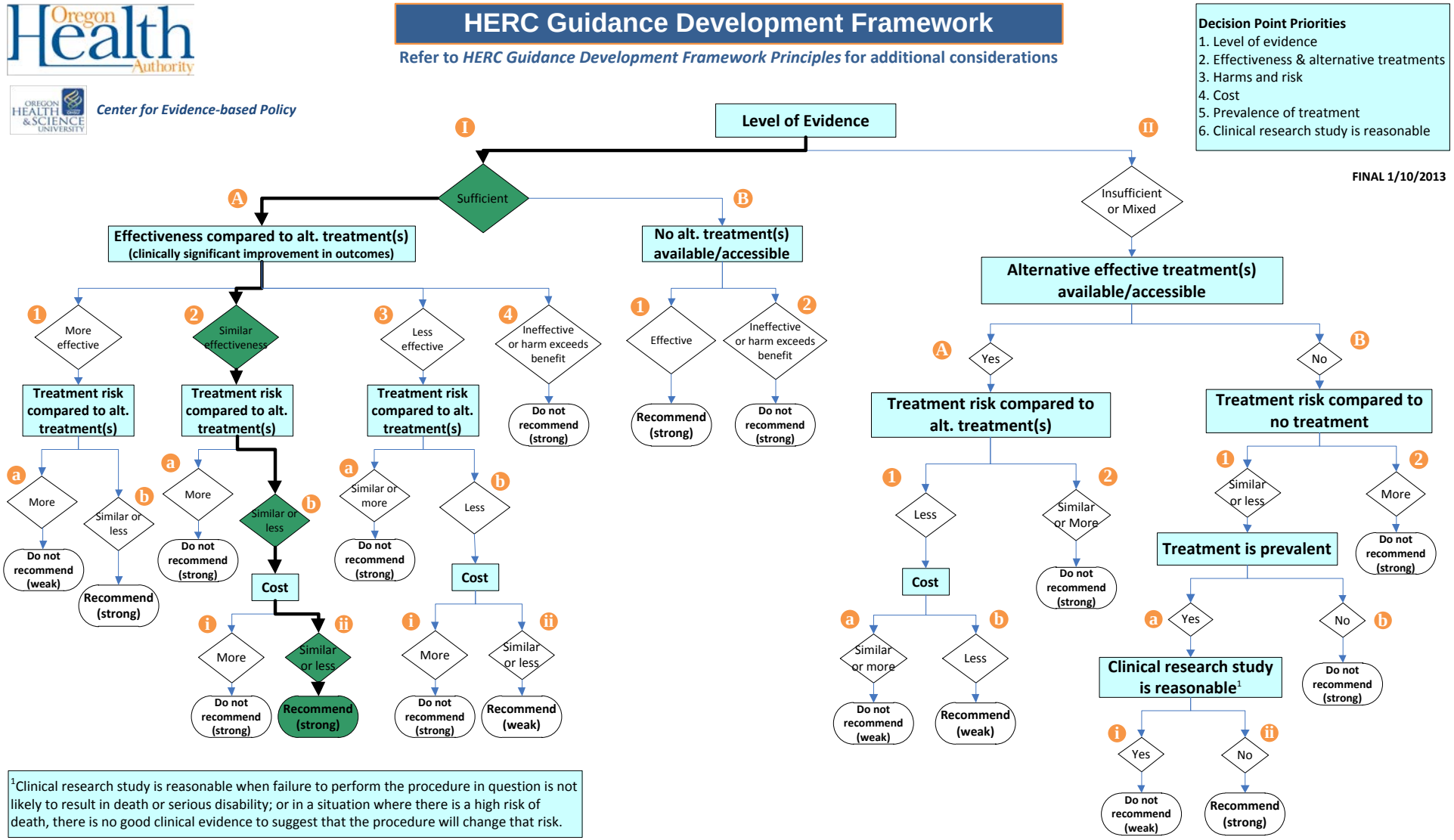
[1]Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

Screening for thrombophilia

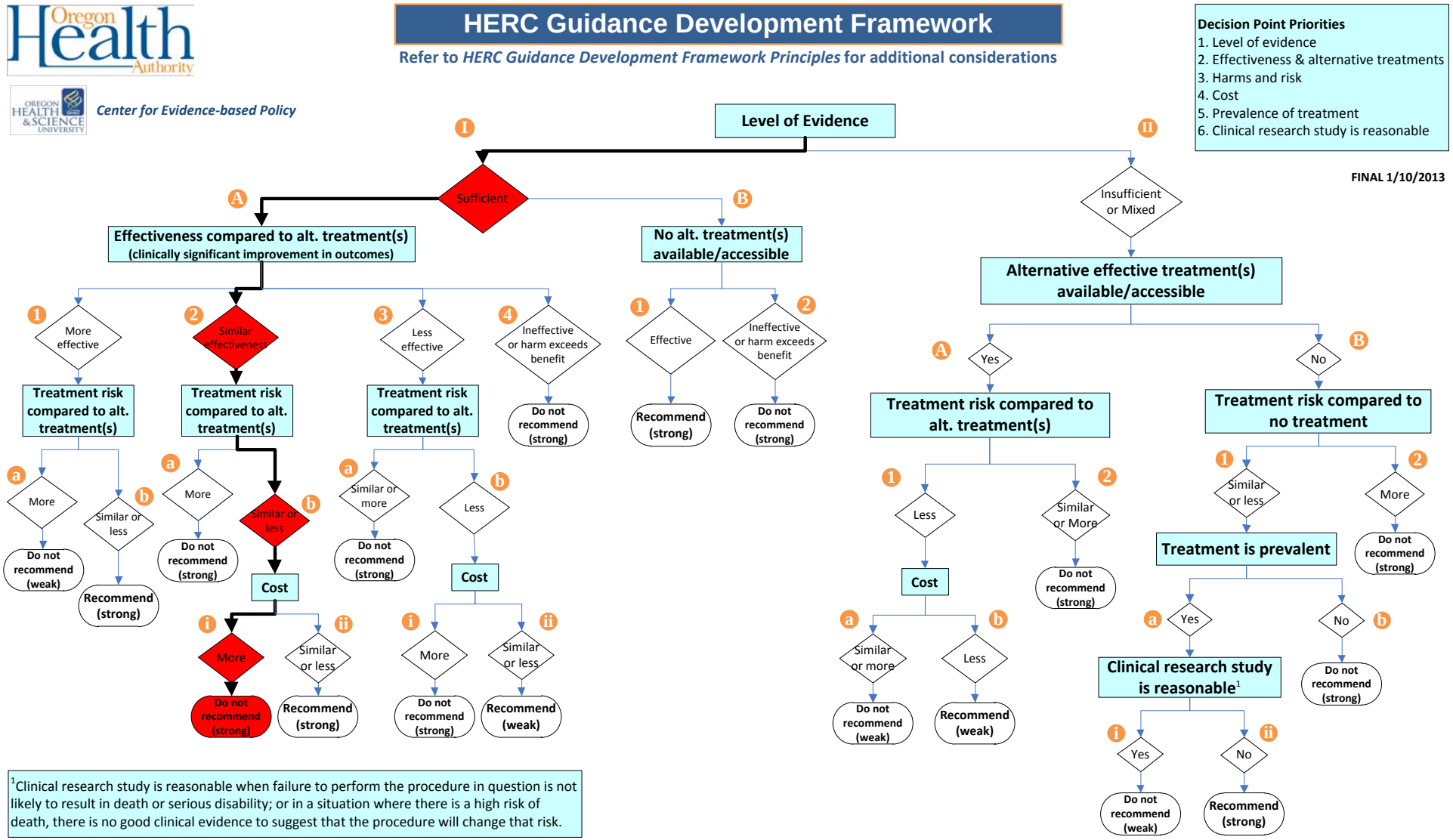


[1]Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

Array CGH testing when karyotype normal and structural anomaly on US; Screen high-risk ethnic groups for hemoglobinopathies; Aneuploidy screening in first or second trimester; CVS or amnio for + aneuploidy screen, maternal age > 34, fetal structural anomalies, + FH, elevated risk of neural tube defect or maternal request; Screening for Tay-Sachs carrier status using Hex A in high risk populations; Screening for CF carrier status; Screening for fragile X carrier status in women with +FH or risk factors; Screening of Ashkenazi Jewish population for specific genetic diseases; Expanded carrier screening

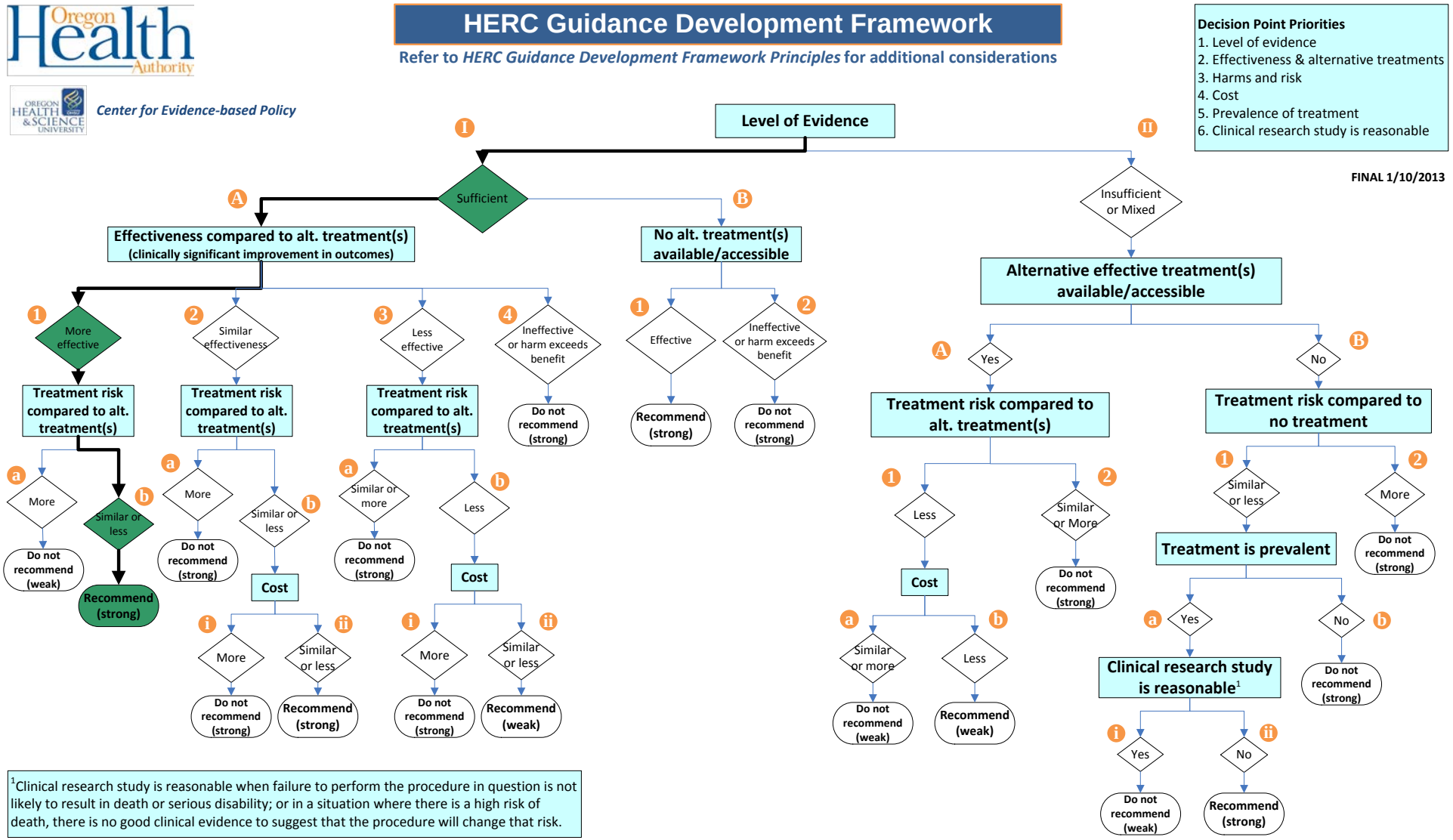


[1]Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.



[1]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.

Cell free fetal DNA testing



[1]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.

Ultrasound for structural anomaly screen at 18-20 weeks; Fetal genetic analysis of fetuses at risk for fetal skeletal dysplasia based on US; Spinal muscular atrophy carrier screening

Oregon Health Authority

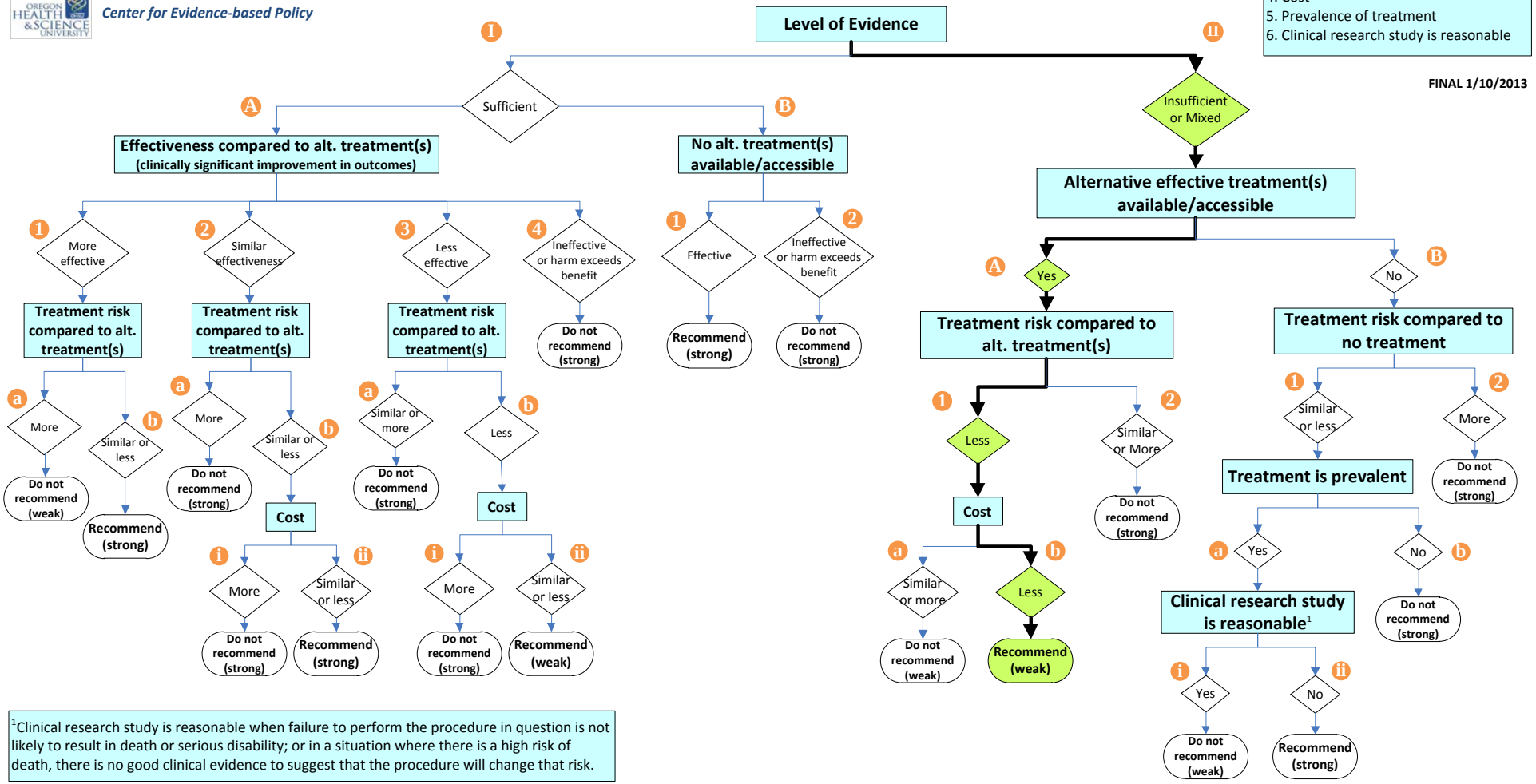
Center for Evidence-based Policy

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

FINAL 1/10/2013



[1]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.

Section 2.0

VbBS report

Straightforward Issues—November, 2014

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
61782	Stereotactic computer-assisted (navigational) procedure; cranial, extradural	**391** ACUTE SINUSITIS **498** CHRONIC SINUSITIS **532** NASAL POLYPS, OTHER DISORDERS OF NASAL CAVITY AND SINUSES **548** BENIGN NEOPLASM OF NASAL CAVITIES, MIDDLE EAR AND ACCESSORY SINUSES **600** DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT	OHP medical director has requested that 61782 be paired with sinus surgery. This code is a standard add-on code when there is complex anatomy, previous surgery in the sinus area, scarring, etc. 61782 is currently on lines 137, 162, 201, 266, 320, 342, 359.	Add 61782 to lines 391, 498, 532, 54, and 600
		360 DISEASES OF PULMONARY ARTERY	Line 360 includes both injury and disease diagnosis codes. HERC staff suggest renaming line to reflect this range of diagnoses.	Rename Line 360 ~~DISEASES~~ CONDITIONS OF PULMONARY ARTERY
44620-44626	Closure of enterostomy, large or small intestine	**75** NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES	DMAP requested that 44620 pair with V55.2 Attention to ileostomy. 44620 is currently on 10 lines on the Prioritized List.	Add 44620-44626 to line 75
61500	Craniectomy; with excision of tumor or other bone lesion of skull	**204** CANCER OF BONES	DMAP requested that 61500 pair with 238.0 Neoplasm of uncertain behavior of bone and articular cartilage. 61500 is currently on lines 130,299,600.	Add 61500 to line 204
32673	Thoracoscopy, surgical; with resection of thymus, unilateral or bilateral	**266** CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS	DMAP requested that 32673 pair with 235.8 Neoplasm of uncertain behavior of pleura, thymus, and mediastinum. 32673 is currently on lines 144, 263, 376.	Add 32673 to line 266

VbBS Issue Summaries 11/13/14

Straightforward Issues—November, 2014

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
32663	Thoracoscopy, surgical; with lobectomy (single lobe)	**51** DEEP ABSCESSES, 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	DMAP requested that 32663 be added to line 266 to pair with 162.3 Malignant neoplasm of upper lobe, bronchus, or lung. On OHP medical director also requested additional pairings. 32663 is current on line 201 CONGENITAL LUNG ANOMALIES. The CPT code for the equivalent open procedure (32480) is on 7 lines	Add 32663 to lines 51, 62, 266, 288, 360, and 376
31645 31646	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with therapeutic aspiration of tracheobronchial tree, initial (eg, drainage of lung abscess) Subsequent	**62** BRONCHIECTASIS	DMAP requested that 31645 be paired with 494.1 Bronchiectasis with acute exacerbation. 31645 is currently on lines 51,208,237,266,469.	Add 31645 and 31646 to line 62
64455	Injection(s), anesthetic agent and/or steroid, plantar common digital nerve(s) (eg, Morton's neuroma)	**544** LESION OF PLANTAR NERVE; PLANTAR FASCIAL FIBROMATOSIS	64455 is currently on 350+ lines. Morton's neuroma (ICD-9 355.6) is on line 544. 64455 is not on line 544	Add 64455 to line 544 and remove from all other lines on the Prioritized List.

VbBS Issue Summaries 11/13/14

Straightforward Issues—November, 2014

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
99363-99364	Anticoagulant management for an outpatient taking warfarin,	**579** LYMPHEDEMA	99363-4 are on the current low lymphedema line, but are scheduled to be removed from the biennial review lymphedema line. HERC staff requests that they be removed from the January 1, 2014 List line as well.	Remove 99363-4 from line 579
69717, 69718	Replacement (including removal of existing device), osseointegrated implant, with or without mastoidectomy	**283** SENSORINEURAL HEARING LOSS - AGE 5 OR UNDER; COCHLEAR IMPLANT **317** HEARING LOSS - AGE 5 OR UNDER; MEDICAL THERAPY INCLUDING HEARING AIDS **423** SENSORINEURAL HEARING LOSS – OVER AGE 5; COCHLEAR IMPLANT **450** HEARING LOSS – OVER AGE 5; MEDICAL THERAPY INCLUDING HEARING AIDS	CPT 69717 and 69718 code for replacement of BAHA type hearing aids. They are incorrectly on the cochlear implant lines and should be on the hearing aid lines with other codes for placement of BAHA type units.	Add 69717 and 69718 to lines 317 and 450 Remove 69717 and 69718 from lines 283 and 423
			The following coding specification is on line 564 for the January 1 ICD-10 List. It is not needed. "R49.0 is located on the Diagnostic List for use for the work-up of hoarseness."	Delete the coding specification regarding R49.0 from line 564.

VbBS Issue Summaries 11/13/14

Straightforward Issues—November, 2014

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
26426	Repair of extensor tendon, central slip, secondary (eg, boutonniere deformity); using local tissue(s), including lateral band(s), each finger	**211** DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT **290** COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT **380** DISRUPTIONS OF THE LIGAMENTS AND TENDONS OF THE ARMS AND LEGS, EXCLUDING THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT **391** DEFORMITY/CLOSED DISLOCATION OF MINOR JOINT AND RECURRENT JOINT DISLOCATIONS	DMAP requested that 26426 pair with 736.21 (boutonniere deformity), which is on lines 381 (dysfunction line) and 391. 26426 is on lines 211,290,380. Boutonniere deformity is a condition of the finger. 26426 involves surgery on a finger, which is inappropriate for line 380	Remove 26426 from line 380 Add 26426 to line 391
64721	Neuroplasty and/or transposition; median nerve at carpal tunnel	**211** DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT	DMAP requested that 64721 pair with 955.1 (Injury to median nerve). 64721 is on lines 420,511,534,430.	Add 64721 to line 211
57287	Removal or revision of sling for stress incontinence (eg, fascia or synthetic)	290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	DMAP requested that 57287 pair with 996.39 (Other mechanical complication of genitourinary device, implant, and graft). 57287 is currently on lines 331,459,471.	Add 57287 to line 290
34203	Embolectomy or thrombectomy, with or without catheter; popliteal-tibio-peroneal artery, by leg incision	**290** COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	DMAP requested that 34203 pair with 996.74 (Other complications due to other vascular device, implant, and graft). 34203 is on lines 239,257,352.	Add 34203 to line 290

VbBS Issue Summaries 11/13/14

Straightforward Issues—November, 2014

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
10061	Incision and drainage of abscess (eg, carbuncle, suppurative hidradenitis, cutaneous or subcutaneous abscess, cyst, furuncle, or paronychia); complicated or multiple	**290** COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	DMAP requested that 10061 pair with 998.59 (Other postoperative infection). 10061 is on lines 51, 209, 383, 405, 487, 528, 632, 377.	Add 10061 to line 290
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)	**519** ESOPHAGITIS AND GERD; ESOPHAGEAL SPASM; ASYMPTOMATIC DIAPHRAGMATIC HERNIA	DMAP requested that 43229 pair with 530.82 (Barrett's esophagus). 43229 is on lines 319,382,600,647.	Add 43229 to line 519
		300 APLASTIC ANEMIAS	GN7 ERYTHROPOIESIS-STIMULATING AGENT (ESA) GUIDELINE is not referenced on line 300, which contains the diagnosis for anemia due to chronic kidney disease.	Add line 300 to GN7

VbBS Issue Summaries 11/13/14

Determination of Refraction Code 92015

Question: Where should eye exams for determination of refraction (CPT 92015) be located on the Prioritized List?

Question source: DMAP, HERC staff

Issue: 92015 (DETERMINATION OF REFRACTIVE STATE) is included on 55+ lines of the prioritized list. However, this service is intended to be used for the purpose of prescribing lenses/spectacles. While there is value and medical justification for an ophthalmological exam for medical conditions such as diabetes and MS, the medical conditions other than visual acuity disorders do not support the need for the determination of refractory state. The prioritized list has line 455 DISORDERS OF REFRACTION AND ACCOMODATION which includes 92015.

Despite the funded condition on line 455 for the treatment of disorders of refraction, the OHP benefit plan limits the coverage of lenses and spectacles as follows:

Current OAR:
410-140-0140(4)(d)Visual services for the purpose of prescribing glasses/contact lenses, fitting fees, or glasses or contact lenses for:
(A) Pregnant adult women are covered, and a complete examination and determination of refractive state is limited to once every 24 months;
(B) Non-pregnant adults are not covered, except when the client:
(i) Has a medical diagnoses of aphakia, pseudoaphakia, congenital aphakia, keratoconus; or
(ii) Lacks the natural lenses of the eye due to surgical removal (e.g. cataract extraction) or congenital absence; or
(iii) Has had a keratoplasty surgical procedure (e.g. corneal transplant) with limitations described in OAR 410-140-0160 Contact Lens Services and Supplies; and
(iv) Is limited to one complete examination and determination of refractive state once every 24 months.

VBC Issue Summaries 11/13/14

HERC staff recommendation:

1) Remove 92015 from all lines except line 455 DISORDERS OF REFRACTION AND ACCOMODATION

Diagnosis Codes on Current DMAP Excluded List Suggested for Placement on the Prioritized List

Question: Should certain codes now in the DMAP excluded file be placed on the Prioritized List?

Question source: DMAP and HERC staff

Issue: Coverage for services in OHP benefit plan is define by either prioritized funded or non-funded condition/ treatment pairs or non-prioritized conditions managed by DMAP Lists. HERC makes recommendations for placement of non-prioritized diagnosis codes into any one of the four DMAP Lists (Excluded, Exempt, Ancillary, Diagnostic Workup).

Historically, the DMAP lists have not been published, are poorly defined, and inconsistently utilized to the intent of the Oregon Administrative Rules. Those lists that include diagnosis codes have been revised in an effort to improve access to healthcare by making transparent the management of those diagnosis codes not included on the Prioritized List, provide more precise and useful information to providers about benefit coverage, and improve the accuracy of claims processing.

WBS Issue Summaries 11/13/14

Old DMAP groups:
Excluded = never covered/ not eligible for exception
Exempt = Always covered
Ancillary = always covered when the CPT code is above the funded line (could not find any definition of an ancillary diagnosis code)
Diagnostic Workup File = always paid when paired with procedure codes above the funded line

The new DMAP lists replace the use of the Excluded, Exempt, and Ancillary lines for diagnosis codes and are defined as follows:

1. Conditions Not Covered (never covered/no exceptions) – This list is for the diagnosis codes that are specifically excluded by Oregon Administrative Rule and not eligible to be reviewed for coverage;
    a. Infertility
    b. Cosmetic
    c. Unrelated to improving health status
    d. Participation in experimental/ research programs

2. Undefined (usually not covered but eligible for review) – This list includes diagnosis codes that are unspecified. Some unspecified diagnosis codes are appropriately placed on the Prioritized List. Some unspecified codes may be used for both covered and uncovered diagnoses and are not placed on the List; these codes are eligible for review and for coverage if a more definitive diagnosis is not known. This list includes diagnosis codes that are

a. not definitive enough to determine line placement and ranking of the condition on the Prioritized List, or
b. other coding is available to more specifically define and support treatment.

3. Informational (not covered/informational only) – This list is for diagnosis codes that are not valid to determine reimbursement or benefit plan coverage and may include diagnosis codes that are
    a. External Causes of Mortality
    b. Personal/ Family History not relevant to covered preventative services
    c. Health status codes
    d. Health Care Encounter codes (non-specific or redundant)
    e. Not eligible as a primary diagnosis

4. Diagnostic Workup File (payable when paired with procedure codes)– Diagnosis codes included on this list are only reimbursable with non-prioritized procedure codes that are in the Diagnostic Procedure List. It is intended to allow for diagnostic services to more definitively diagnose
    a. Signs & symptoms
    b. Conditions requiring further evaluation to better define the primary diagnosis

In reviewing these lists, DMAP and HERC staff have identified ICD-9 diagnosis codes that can appropriately be placed on the Prioritized List.

<u>HERC Staff Recommendations</u>:

1) Add the ICD-9 diagnosis codes on the following spreadsheet to the indicated lines on the Prioritized List and advise DMAP to remove them from their current DMAP lists

VbBS Issue Summaries 11/13/14

Code	Code Descriptions	Proposed Placement	Notes
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	See arthrocentesis document
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**	See arthrocentesis document
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	See arthrocentesis document
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**	See Issues document
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	
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	22520-22522 (Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body,unilateral or bilateral injection;...) were on line 507 (became line 484). These codes were deleted with 2015 CPT codes. The new codes include the radiologic supervision which were previously separate codes
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	See 22510
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	See 22510
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	22523-22525 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty)...) were on line 507 (became line 484). Previous separate radiologic interpretation CPT codes are now included in these codes.

VBBS Issue Summaries 11/13/14

Code	Code Descriptions	Proposed Placement	Notes
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	See 22513 above
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	See 22513 above
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy 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	22856 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical) is on lines 374,545
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	27280 (Arthrodesis, sacroiliac joint (including obtaining graft)) was on line 189 (became 187), deleted with 2015 CPT codes
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	Other implantable defibrillator systems on 103, 115, 286, 290
33271	Insertion of subcutaneous implantable defibrillator electrode	**103, 115, 286, 290**	See 33270
33272	Removal of subcutaneous implantable defibrillator electrode	**103, 115, 286, 290**	See 33270
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode	**103, 115, 286, 290**	See 33270
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	mitral valve repair open procedures are on lines 73, 86, 94, 115, 190, 193, 261, 290, 368
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**	See 33418 above

VoBS Issue Summaries 11/13/14

Code	Code Descriptions	Proposed Placement	Notes
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	Lines with diagnoses of respiratory failure (11, 237), cardiac failure lines with treatments including VAD procedures (86, 102), cardiogenic shock (73), septic shock (186), persistant fetal circulation (81), congenital heart disease (48, 71, 74, 89, 90, 93, 94, 109, 110, 115, 123, 132, 134, 138, 142, 180, 192, 236), cardiac transplant and complications thereof (244, 267) Current CPT codes 33960, 33961 (Prolonged extracorporeal circulation for cardiopulmonary insufficiency) are Exempt (always covered). These codes are deleted with 2015 CPT code set. Exempt (always covered) would be another option; however, virtually all diagnoses for which ECMO is used should be on these lines.
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above

VBPS Issue Summaries 11/13/14

Code	Code Descriptions	Proposed Placement	Notes
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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**	See 33946 above
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	Endovascular aortic graft procedures (CPT 34841-34848) are on line 84,257,280,289,330
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	Similar code 37217 (Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery by retrograde treatment, open ipsilateral cervical carotid artery exposure) is on lines 322, 419
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	530.6 (Diverticulum of esophagus, acquired) is on lines 384,519

VBBS Issue Summaries 11/13/14

Code	Code Descriptions	Proposed Placement	Notes
44381	Ileoscopy, through stoma; with transendoscopic balloon dilation	**32** REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE **46** INTUSSCEPTION, 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	Similar code 44379 (Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, including ileum; with transendoscopic stent) is on lines 46,105 Add 44379 to lines 32, 161, and 647
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** INTUSSCEPTION, 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	See 44381 above
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** INTUSSCEPTION, 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	Simlar code 44394 (Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique) is on lines 46,105,161,170,647 Similar code 45384 (Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps) is on lines 46,60,105,161,170,647
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** INTUSSCEPTION, 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	45327 (Proctosigmoidoscopy, rigid; with transendoscopic stent placement (includes predilation)) is on lines 46,105,647 Lines 32, 161 are also appropriate Add 45327 to lines 32 and 161
44403	Colonoscopy through stoma; with endoscopic mucosal resection	**Diagnostic Procedures List**	Similar code 43254 is Diagnostic
44404	Colonoscopy through stoma; with directed submucosal injection(s), any substance	**32** REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE **46** INTUSSCEPTION, 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	45381 (Colonoscopy, flexible; with directed submucosal injection(s), any substance) is on lines 32,46,60,105,161,170,189,480,647,629 480 and 629 are not appropriate for colonoscopy through stoma
44405	Colonoscopy through stoma; with transendoscopic balloon dilation	**32** REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE **46** INTUSSCEPTION, 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	Similar code 45386 (Colonoscopy, flexible; with transendoscopic balloon dilation) is on lines 32,46,105,161 Add 45386 to line 647
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**	

VbBS Issue Summaries 11/13/14

Code	Code Descriptions	Proposed Placement	Notes
44408	Colonoscopy through stoma; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed	**46** INTUSSCEPTION, 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	Megacolon and volvulus diagnoses are on line 46 Hirschsprung's disease is on line 105
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** INTUSSCEPTION, 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	Simlar code 44394 (Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique) is on lines 46,105,161,170,647 Similar code 45384 (Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps) is on lines 46,60,105,161,170,647
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** INTUSSCEPTION, 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	45327 (Proctosigmoidoscopy, rigid; with transendoscopic stent placement (includes predilation)) is on lines 46,105,647 Lines 32, 161 are also appropriate
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	Similar code 46947 (Hemorrhoidopexy) is on lines 480, 629
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** INTUSSCEPTION, 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	Similar code 45384 (Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps) is on lines 46,60,105,161,170,647
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** INTUSSCEPTION, 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	45327 (Proctosigmoidoscopy, rigid; with transendoscopic stent placement (includes predilation)) is on lines 46,105,647 Lines 32, 161 are also appropriate
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** INTUSSCEPTION, 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	Megacolon and volvulus are on line 46 Hirschsprung's disease is on line 105
45398	Colonoscopy, flexible; with band ligation(s) (eg, hemorrhoids)	**480** THROMBOSED AND COMPLICATED HEMORRHOIDS **629** UNCOMPLICATED HEMORRHOIDS	Similar code 46947 (Hemorrhoidopexy) is on lines 480, 629
45399	Unlisted procedure, colon	**Ancillary Codes File**	Will require manual review
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**	See Issues document

VbBS Issue Summaries 11/13/14

Code	Code Descriptions	Proposed Placement	Notes
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant	**331** FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION	Similar HCPCS codes C9739-C9740 (Cystourethroscopy with transprostatic implant; 1 to 3 implants or 4 or more implants) care on line 331 **NICE 2014**: Current evidence on the efficacy and safety of insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia is adequate to support the use of this procedure
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	See 52441
62302	Myelography via lumbar injection, including radiological supervision and interpretation; cervical	**Diagnostic Procedures List**	Other myelography codes (62284, 72240, 72255, etc.) are Diagnostic
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**	See Issues document
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**	See Issues document
64488	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by injections (includes imaging guidance, when performed)	**Ancillary Codes File**	See Issues document
64489	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by continuous infusions (includes imaging guidance, when performed)	**Ancillary Codes File**	See Issues document
66179	Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft	**143** GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE **247** PRIMARY ANGLE-CLOSURE GLAUCOMA	66180 (with graft) is on lines 143,247
66184	Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft	**143** GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE **247** PRIMARY ANGLE-CLOSURE GLAUCOMA	66185 (with graft) is on line 143 Add 66185 to line 247
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**	
77061	Digital breast tomosynthesis; unilateral	**Non-Covered List**	See Issues document
77062	Digital breast tomosynthesis; bilateral	**Non-Covered List**	See Issues document
77063	Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)	**Non-Covered List**	See Issues document
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**	Similar code 77080 and 77081 are diagnostic
77086	Vertebral fracture assessment via dual-energy X-ray absorptiometry (DXA)	**Diagnostic Procedures List**	Similar code 77080 and 77081 are diagnostic
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, 218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,32 0,321,333,359,376, 401, 402, 424, 439,533,600,611**	Current teletherapy CPT codes (77305, 77310, 77315) have been deleted and replaced with 77306 and 77307. The old CPT codes for teletherapy planning where on the radiation therapy lines.

VBBS Issue Summaries 11/13/14

Code	Code Descriptions	Proposed Placement	Notes
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, 218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,32 0,321,333,359,376, 401, 402, 424, 439,533,600,611**	See 77306
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**	Current brachytherapy CPT codes (77326, 77327, 77328) have been deleted and replaced with CPT 77316-77318. The old CPT codes for brachytherapy were on these 19 radiation therapy lines
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**	See 77316
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**	See 77316
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, 218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,32 0,321,333,359,376, 401, 402, 424, 439,533,600,611**	These codes replace CPT 77418 (Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session) which was on the radiation therapy lines
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, 218,219,233,238,241,242,262,263,265,266,274,279,291,292,299,319,32 0,321,333,359,376, 401, 402, 424, 439,533,600,611**	See 77385
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 ,214,162,218,219,233,238,241,242,262,263,265,266,274,279,291,292,29 9,319,320,321,333,359,376, 401, 402, 424, 439,533,600,611**	Radiation therapy lines
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**	
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**	

VbBS Issue Summaries 7/13/14

Code	Code Descriptions	Proposed Placement	Notes
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**	
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**	
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**	

VbBS Issue Summaries 11/13/14

Code	Code Descriptions	Proposed Placement	Notes
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**	
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	See Issues document
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	Test done on a tumor , may affect treatment or surveillance
81313	PCA3/KLK3 (prostate cancer antigen 3 [non-protein coding]/kallikrein-related peptidase 3 [prostate specific antigen]) ratio (eg, prostate cancer)	**Non-Covered List**	See Issues document
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**	Genetics review
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**	Genetics review
81415	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis	**Diagnostic List**	Genetics review
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**	Genetics review
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**	Genetics review
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	Prenatal testing guideline applies
81425	Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis	**Non-Covered List**	Genetics review
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**	Genetics review
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**	Genetics review

VoBS Issue Summaries 11/13/14

Code	Code Descriptions	Proposed Placement	Notes
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**	Genetics review
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**	Genetics review
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**	Genetics review
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**	Genetics review
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**	Genetics review
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**	ALK, BRAF, KRAS, EGFR, PTEN appear to be standard testing
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**	NPMI, BRAF, IDH, KRAS, FTL3 appear to be standard testing
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**	ALK, BRAF, KRAS, EGFR, NPM1, FTL3 appear to be standard testing
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**	Genetics review
81465	Whole mitochondrial genome large deletion analysis panel (eg, Kearns-Sayre syndrome, chronic progressive external ophthalmoplegia), including heteroplasmy detection, if performed	**Diagnostic List**	Genetics review
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**	Genetics review
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**	Genetics review
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	See issues document
83006	Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)	**Non-Covered List**	See issues document
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**	

MBS Issue Summaries 11/13/14

Code	Code Descriptions	Proposed Placement	Notes
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**	Non-oncogenic, or low-risk HPV types, such as HPV 6 or 11, can cause (1) benign or low-grade abnormalities of cervical cells, (2) anogenital warts, and (3) a disease of the respiratory tract called recurrent respiratory papillomatosis (RRP).
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**	G0123 (pap smear) is diagnostic
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**	G0123 (pap smear) is diagnostic
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**	FISH is often used for finding specific features in DNA for use in genetic counseling, medicine, and species identification.[2] FISH can also be used to detect and localize specific RNA targets (mRNA, lncRNA and miRNA) in cells, circulating tumor cells, and tissue samples.
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**	In situ hybridization (ISH) is a type of hybridization that uses a labeled complementary DNA or RNA strand (i.e., probe) to localize a specific DNA or RNA sequence in a portion or section of tissue
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**	In vitro fertilization is an excluded procedures
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	**Non-Covered List**	See Issues document

VbBS Issue Summaries 11/13/14

Code	Code Descriptions	Proposed Placement	Notes
92145	Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report	**Non-Covered List**	See Issues document
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**	DMAP will need to manually review
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**	DMAP will need to manually review
93355	Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg,TAVR, transcathether 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	All congenital heart defect lines, valvular disorder lines and major heart structural defect lines Alternative: Diagnostic Procedures File
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	Implantable defibrillator systems on 103, 115, 286, 290
93702	Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)	**Non-Covered List**	See Issues document
93895	Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral	**Non-Covered List**	See Issues document
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**	Alcohol/drug use assessment tools (SBIRT; CPT 99408, 99409) are on all 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**	See Negative Pressure Wound Therapy document
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**	See Negative Pressure Wound Therapy document
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	D1206 (Topical application of fluoride varnish) is on lines 3 and 57

VBS Issue Summaries 11/13/14

Code	Code Descriptions	Proposed Placement	Notes
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**	

VbBS Issue Summaries 11/13/14

2015 Genetic Testing CPT Codes Recommendations

Date: 10/16/14

		Recommendation		Impact of detecting a mutation				Limitations & Comments
CPT Code	Descriptor	Cover	Don't Cover	Change treatment	Change health monitoring	Provide Prognosis	Provide genetic counseling	
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,	X		X	X	X	X	
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	X		X	X	X	X	
81415	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis	X		X		X	X	
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)	X		X		X	X	
81417	Exome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence (eg, updated knowledge or unrelated condition/syndrome)		X					

VbBS Issue Summaries 11/13/14

		Recommendation		Impact of detecting a mutation				Limitations & Comments
CPT Code	**Descriptor**	**Cover**	**Don't Cover**	**Change treatment**	**Change health monitoring**	**Provide Prognosis**	**Provide genetic counseling**	
81425	Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis		X					
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)		X					
81427	Genome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (eg, updated knowledge or unrelated condition/syndrome)		X					
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	X		X	X	X	X	
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	X		X	X	X	X	
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	X			X			

VbBS Issue Summaries 11/13/14

		Recommendation		Impact of detecting a mutation				Limitations & Comments
CPT Code	Descriptor	Cover	Don't Cover	Change treatment	Change health monitoring	Provide Prognosis	Provide genetic counseling	
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	X			X			
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	X		X	X	X	X	
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	X		X	X	X	X	
81465	Whole mitochondrial genome large deletion analysis panel (eg, Kearns-Sayre syndrome, chronic progressive external ophthalmoplegia), including heteroplasmy detection, if performed	X		X	X	X	X	
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,		X					

VbBS Issue Summaries 11/13/14

		Recommendation		Impact of detecting a mutation				Limitations & Comments
CPT Code	**Descriptor**	**Cover**	**Don't Cover**	**Change treatment**	**Change health monitoring**	**Provide Prognosis**	**Provide genetic counseling**	
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,		X					

VbBS Issue Summaries 11/13/14

2015 Genetic Testing CPT code review

81410-81411

1) Aortic dysfunction or dilation (eg, Marfan syndrome, Loeys Dietz syndrome, Ehler Danlos syndrome type IV, arterial tortuosity syndrome); genomic sequence analysis pane
2) Used for diagnosing both symptomatic patients and asymptomatic family members
3) **American College of Medical Genetics (2012)–**evaluation of a patient with possible Marfan's Syndrome
    a. Consider *FBN1* gene sequencing
    b. Searching for mutations in *FBN1*continues to have a circumscribed role in the diagnosis of equivocal cases. Said differently, MFS remains, by and large, a clinical diagnosis.
    c. Does not address screening asymptomatic family members
4) **American College of Cardiology/American Heart Association (2010)** guidelines for diagnosis and management of patients with thoracic aortic disease
    a. Test for genes associated with aortic aneurysm and/or dissection in patients and family members (*FBN1, TGFBR1, TGFBR2,COL3A1, ACTA2, MYH11*)
    b. Use test results to limit aortic imaging to relatives with the genetic mutation. *(LOE: C)*
1) **Canadian Cardiovascular Society (2014)** opinion
    a. We recommend clinical and genetic screening for suspected Marfan syndrome to clarify the nature of the disease and provide a basis for individual counselling (Strong Recommendation, High-Quality Evidence).
    b. Affects monitoring—recommend echocardiographic screening at diagnosis to measure aortic root and ascending aorta diameters, and repeated 6 months thereafter to determine rate of progression. If aortic diameters remain stable, annual imaging is recommended. (Strong Recommendation, High-Quality Evidence).
2) Recommendation:
    a. **Diagnostic** List

VBS Issue Summaries 11/13/14

81415-81417

1) Exome testing
2) The human exome comprises only 1–2% of the whole genome, it is this portion that codes for proteins, and was thought to contain 85% of all pathogenic mutations causing Mendelian disorders. The exome can be sequenced in only 48 h at roughly a third of the cost, with far fewer data to store and analyse compared to whole genome testing
3) GAP comments:

a. May find other genetic mutations that do not address the specific reason for the tests (i.e. BRCA1 mutation, etc.); therefore, need careful genetic counseling prior to testing
b. Used when there are multiple anomalies in a child, or when other specific testing has not found a diagnosis. 20-30% chance of finding a genetic cause for a syndrome or developmental delay in a population of children who already had non-revealing testing
c. Cost is about $5000 for a test, may be cost effective rather than doing a series of single gene tests
d. Recommended change to non-prenatal genetic testing guideline: "A genetic counseling/geneticist visit is required prior to ordering test."
e. From Cary Harding: Regarding 81417: If any validation of an exome result is necessary, that should be done by another method rather than repeating an exome analysis

4) OHP medical director feedback:
   a. My main concerns are these: it appears that there is a great likelihood of identifying lots of "noise" mutations—things that may or may not have anything to do with the actual problem at hand…many [of the] genetic syndromes don't have any specific treatments that improve their outcome, so it might not alter treatment. It is possible that health monitoring might be changed, because we are basically screening for any genetic mutation. Depending on whether a specific diagnosis is reached, prognosis may change; further testing of parents would probably be needed to answer questions regarding family risk. So an argument could be made that it meets guideline D1, although it really is not clear.
   b. I would need CLEAR documentation how the genetic consultant believes the testing will treat the member. I do get provider feedback with a confirmed diagnosis would allow health plan benefits for the member otherwise not received and this is a majority of our current requests. Our CCO rarely approves this request on the basis it appears to be an investigation and is not assisting on a treatment plan.
   c. Until mutations are better known and we know which ones truly would materially benefit treatment/outcome, I concur testing would be investigational and hence not be covered by OHP plan. There also is the ethics concern raised…of uncovering incidental mutations that may be alarming to members and/or their blood relatives with uncertainty in what it means and whether any prophylactic treatment is indicated. I recommend testing be focused based on strong scientific findings for which recommendations include well-reasoned consideration risks vs. benefits.
5) Other expert input (Alison Adams Martinez, Ph.D., Geneticist Oklahoma Health Care Authority)
   a. The published policies of most private payers indicate that they do not cover WES. However, once you get past testing more than 2-3 whole genes, it actually becomes more cost effective to do the WES up front and prevent the parade of single-gene test requests. So, I felt that the literature/other policies would support

VbBS Issue Summaries 11/13/14

us if we wanted to take a hardline stance against covering WES, but at the same time we could justify covering it in cases where the member's clinical features would make them eligible for genetic testing of multiple genes…we agreed that we would reimburse for WES in select cases…[but] if we got too many claims that we would have to revisit the decision and not cover it at all. So far, we have paid for maybe 10 WES claims over the past year. In all cases, they met the criteria outlined by the ACMG. We've paid between $5-7K per WES claim

6) Evidence
    a. **TEC 2013**
        i. Has an algorithm indicating when testing may be indicated
        ii. Diagnostic yield 10-50%
        iii. Concern for many mutations found that have no or unknown clinical significance or are unrelated to the reason for testing
        iv. Medical management decisions, including initiation of new treatment or discontinuing inappropriate treatment, may result for only a subset of those diagnosed.
        v. Reproductive decisions for parents considering an additional pregnancy may be informed by determining the mode of inheritance.
        vi. Appropriate use of exome sequencing requires considerable genetic, clinical, and genetic counseling expertise.
7) Other coverage policies
    a. **Aetna 2014**
        i. Exome testing is experimental
    b. **Anthem BCBS 2014**
        i. Diagnostic genetic testing using panels of genes (with or without next generation sequencing), including but not limited to whole genome and whole exome sequencing, is considered **investigational and not medically necessary** unless all components of the panel have been determined to be medically necessary based on the criteria above. .
8) Recommendations:
    a. 81415, 81416 (whole exome testing, sequence analysis and comparator genome sequencing): **Diagnostic List**
    b. 81417 (re-evaluation): **Non-covered List**
        i. Note: exclusion of 81417 was based on expert testimony that was not reviewed by the entire GAP.
    c. See changes to the non-prenatal genetic testing guideline
        i. Requirement for genetic consultation prior to covering test (81415, 81416)
        ii. Statement that 81417 is non-covered

MoBS Issue Summaries 11/13/14

81425-81427

1) Genome testing
2) Sequencing of an entire human genome to test for genetic mutations. The human genome can now be sequenced in 2 weeks for approximately £4000 (€4700, US$6200) in many laboratories.

3) GAP comments: "not ready for clinical prime time"; "premature for use in clinical practice"; "need for data/experience." Decision was to delay coverage until more research has been done to clarify the role of these tests in clinical practice
4) Recommendation: **Non-covered List**
    a. Notation made in the non-prenatal genetic testing guideline

81430-81431

1) 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
2) 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
3) Similar code placement:
    a. GJB2 and GJB6 gene analysis assays for nonsyndromic hearing loss are on the diagnostic list (81252, 81253)
4) **American College of Medical Genetics 2014,** guideline for evaluation of hearing loss
    a. If nonsyndromic hearing loss is suspected, consider single-gene tests such as *GJB2* and *GJB6*, gene panel tests, or NGS testing based on history and findings
5) GAP comments: Start with the two most likely tests, if normal, use panels. GJB2 and 6 tests find about 50% of genetic problems. GJB2/6 testing costs $500, panels $3-5,000
    a. Recommend adding clause to guideline: GJB2 and GJB6 need to be tested first and be negative in non-syndromic patients prior to panel being covered
6) Recommendation—**Diagnostic List**
    a. See recommended changes to the non-prenatal genetic testing guideline

VbBS Issue Summaries 11/13/14

81435, 81436

1) 81435-6: Hereditary colon cancer syndromes (eg, Lynch syndrome, familial adenomatosis polyposis); duplication/deletion gene analysis panel, must include analysis of at least 7 genes, including APC, CHEK2, MLH1, MSH2, MSH6, MUTYH, and PMS2
2) Similar Prioritized List placements:
    a. Testing for Lynch syndrome (hereditary nonpolyposis colon cancer) (CPT 81292-81300) with a guideline
        i. MLH1, MSH2, MSH6 individual gene tests (81292-81300)
            1. Current MLH1 tests include full sequence analysis, known familial variants, and duplication/deletion variants (81292-81294)
        ii. PMS2 individual gene tests (81317-81319)

3) **National Comprehensive Cancer Network (NCCN) 2014** screening guideline for colon cancer
    a. Recommends screening for MLH1, MSH2, MSH6, FMS2 and EPCAM for high risk family members
    b. Test results change screening frequency and age to begin screening for affected persons
4) Recommendation: **Diagnostic** List
    a. See recommended changes to the Non-Prenatal Genetic Testing Guideline

81440, 81460, 81465

1) Mitochondrial genome testing
2) Mutations of mitochondrial DNA can lead to a number of illnesses including exercise intolerance and Kearns-Sayre syndrome (KSS). Some evidence suggests that they might be major contributors to the aging process and age-associated pathologies. Recently a mutation in mtDNA has been used to help diagnose prostate cancer in patients with negative prostate biopsy.
3) Evidence
    a. **Falk 2010**, review of mitochondrial disease
        i. Recommends whole mitochondrial DNA genome sequencing when a strong suspicion exists based on the symptom constellation and family history.
        ii. Panel testing of approximately a dozen "common" mtDNA point mutations that cause well-characterized disorders…has historical significance but current utility primarily in adults. Indeed, the high cost of such limited point mutation panel testing currently approximates that of sequencing the entire 16,569 basepair mitochondrial DNA genome…it is typically more cost-efficient and ultimately informative to complete whole mitochondrial DNA genome sequence analysis to evaluate individuals (particularly children) with strong maternal pedigrees
        iii. It is important to realize that mtDNA may harbor other genetic abnormalities that are not detectable by whole genome sequence analysis.
4) GAP comments: "May avoid muscle biopsy or other diagnostic studies." Dr. Cary Harding, a metabolic specialist, thought this test was appropriate in certain clinical situations. He recommended putting in a guideline requiring a genetics or metabolic consult prior to ordering the test.
5) Recommendation: **Diagnostic List**
    a. See recommended changes to the Non-Prenatal Genetic Testing Guideline
        i. Requires genetic or metabolic consult prior to ordering test

81470, 81471

1) X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); genomic sequence analysis panel

VBS Issue Summaries 11/13/14

2) Refers to forms of intellectual disability which are specifically associated with X-linked recessive inheritance. As with most X-linked disorders, males are more heavily affected than females. Females with one affected X chromosome and one normal X chromosome tend to have milder symptoms. Unlike many other types of intellectual disability, the genetics of these conditions are relatively well understood. It has been estimated there are ~200 genes involved in this syndrome; of these ~100 have been identified. X-linked intellectual disability accounts for ~16% of all cases of intellectual disability in males.
3) The panel testing would include multiple of these known genes
4) Similar code coverage:
    a. CPT 81243, 81244 (Fragile X genetic testing) is covered with the following notation in the genetic testing guideline:
        i. "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."
5) GAC input: do not cover. The labs consulted on this question report a pick up rate for significant mutations is quite low, <5%
6) Recommendation: **Non-covered List**
    a. Notation made in the non-prenatal genetic testing guideline

VbBS Issue Summaries 11/13/14

GAC Recommended Changes to the Diagnostic Guideline D1, Non-Prenatal Genetic Testing Guideline
October 16, 2014

Issues:

1) The Non-Prenatal Genetic Testing Algorithm has modifications suggested by the Genetics Advisory Committee. These suggestions have arisen out of the review of the 2015 CPT codes regarding specific genetic tests.

Recommendations:

1) Adopt the amended Diagnostic Guideline 1 as below

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
      a) 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
         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

WBS Issue Summaries 11/13/14

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:
   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,

Voting Issue Summaries 11/13/14

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 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 anpha-1 phenotype test is appropriate is 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 81415-81417, 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.

VoBS Issue Summaries 1/1/13/1/A

Definition of High Risk for Breast Cancer

Question: How should high risk of breast cancer be defined?

Question source: Genetics Advisory Panel

Issue: GN3 defines which patients are at high risk for breast cancer, and therefore eligible for prophylactic procedures such as mastectomy or oophorectomy. The specifications in GN3, and referred to in the non-prenatal genetic testing guideline, are based on USPSTF criteria in place at the time the guideline was created. In 2013, the USPSTF changed their criteria for defining high risk to a recommendation for using one of several screening tools (see below). The NCCN published their own criteria for defining high risk in their 2014 guideline Genetic/Familial High Risk Assessment: Breast and Ovarian. Both the revised USPSTF and NCCN risk groups vary from the current GN3 definition. Additionally, NCCN has published an extensive guideline regarding what procedures should be offered to women based on an algorithm of their risk, which includes genetics as well as multiple other factors.

As staff reviewed this topic, it was identified that the current guideline inappropriately allows prophylactic mastectomy and other treatments based on criteria for further genetic testing, not treatment.

VbBS Issue Summaries 11/13/14

The NCCN 2014 guideline regarding treatment of breast cancer contains this statement:

> Except as outlined in the NCCN Guidelines for Genetic/Familial High-Risk Assessment: Breast and Ovarian and the NCCN Guidelines for Breast Cancer Risk Reduction, prophylactic mastectomy of a breast contralateral to a known unilateral breast cancer is discouraged.

Contralateral mastectomy is still recommended for consideration in cases of invasive lobular carcinoma.

From the USPSTF 2014 recommendations for genetic testing for breast cancer:

> For women who have at least 1 family member with breast, ovarian, or other types of BRCA-related cancer, primary care providers may use 1 of several brief familial risk stratification tools to determine the need for in-depth genetic counseling.
>
> Although several risk tools are available, the tools evaluated by the USPSTF include the Ontario Family History Assessment Tool, Manchester Scoring System, Referral Screening Tool, Pedigree Assessment Tool, and FHS-7. The Referral Screening Tool and FHS-7 are the simplest and quickest to administer. All of these tools seem to be clinically useful predictors of which women should be referred for genetic counseling due to increased risk for potentially harmful BRCA mutations (most sensitivity estimates were >85%), although some models have been evaluated in only 1 study. To determine which patients would benefit from BRCA risk assessment, primary care providers should not use general breast cancer risk assessment models (for example, the National Cancer Institute Breast Cancer

Risk Assessment Tool, which is based on the Gail model) because they are not designed to determine which women should receive genetic counseling or BRCA testing.

In general, these tools elicit information about factors that are associated with increased likelihood of BRCA mutations. Family history factors associated with increased likelihood of potentially harmful BRCA mutations include breast cancer diagnosis before age 50 years, bilateral breast cancer, presence of breast and ovarian cancer, presence of breast cancer in 1 or more male family members, multiple cases of breast cancer in the family, 1 or more family members with 2 primary types of BRCA-related cancer, and Ashkenazi Jewish ethnicity. The USPSTF recognizes that each risk assessment tool has limitations and found insufficient comparative evidence to recommend one tool over another. The USPSTF also found insufficient evidence to support a specific risk threshold for referral for testing.

Definition of who should be offered genetic testing for breast cancer syndrome rom the 2014 NCCN guideline for genetic testing for breast cancer:

An unaffected individual with a family history of one or more of the following:
-A known mutation in a breast cancer susceptibility gene within the family
-≥2 breast primaries in single individual
-≥2 individuals with breast primaries on the same side of family
-≥1 ovarian cancer primary from the same side of family
-First or second degree relative with breast cancer ≤45 y
-≥1 family member on same side of family with a combination of breast cancer and ≥1 of the following: pancreatic cancer, prostate cancer, sarcoma, adrenocortical carcinoma, brain tumors, endometrial cancer, leukemia/lymphoma; thyroid cancer, dermatologic manifestations and/or macrocephaly, hamartomatous polyps of GI tract; diffuse gastric cancer
-male breast cancer

WBS Issue Summaries 11/13/14

Current guideline

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

Line 195

Bilateral prophylactic breast removal is included on Line 195 for women without a personal history of invasive breast cancer who are at high risk for breast cancer. Prior to surgery, women without a personal history of breast cancer must have a genetics consultation. 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.

VbBS Issue Summaries 11/13/14

Expert input:

Dr. Andy Higgens, breast surgeon, Bend

Growing trend nationwide to have contralateral mastectomy for decreasing patient anxiety and decreasing surveillance, despite lack of evidence of improved survival. Commercial insurers are not regulating contralateral mastectomy. The main benefit is peace of mind and symmetry, not medical survival or disease reduction. OHP will be an outlier if contralateral mastectomy is not covered by patient preference. Using risk groups to determine who should have contralateral mastectomy covered is problematic, as this is a rapidly developing area. Someone without a genetic abnormality or a 20% or greater risk of breast cancer would have contralateral mastectomy denied. This is not logical as this patient has more risk than the woman who has never had cancer but meets the NCCN requirement for bilateral prophylactic mastectomy.

Recommends coverage for contralateral mastectomy unless medically contraindicated. Would remove the second paragraph of the proposed new guideline.

Cost effective to do contralateral mastectomy in younger women given cost savings of avoiding years of mammograms and MRIs.

VbBS Issue Summaries 11/13/14

HERC staff recommendation:

1) Modify GN3 as shown below
   a) Wording in green is proposed for possible deletion/non-inclusion based on expert surgical input

[without track changes]

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

Line 195

Bilateral prophylactic breast removal and/or oophorectomy 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***. 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.

Contralateral prophylactic mastectomy is included on Line 195 for women with a personal history of breast cancer and 1) a hereditary breast and/or ovarian cancer syndrome or 2) a lifetime risk of breast cancer >20%. In addition, contralateral prophylactic mastectomy of the unaffected breast is indicated for women with invasive lobular carcinoma.

WbBS Issue Summaries 11/13/14

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 1) a hereditary breast and/or ovarian cancer syndrome or 2) a lifetime risk of breast cancer >20%. 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.

VbBS Issue Summaries 11/13/14

CDT Code	Code description	Proposed Placement	Comments
D0171	re-evaluation – post-operative office visit	**Excluded**	Service should be bundled into the original treatment code
D0351	3D PHOTOGRAPHIC IMAGE-This procedure is for dental or maxillofacial diagnostic purposes. Not applicable for a CAD-CAM procedure	**Excluded**	Experimental
D1353	SEALANT REPAIR-PER TOOTH	**57** PREVENTIVE DENTAL SERVICES	D1351 Sealant is on line 57. Rule limits sealants to every 5 yrs unless they fail, then sealant can be redone. Monitor use to ensure not abused.
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	Includes ultrasonic cleaning of dentures. DMAP to create rule to limit frequency to once per year and can not be billed with a prophylactic cleaning.
D9936	missed appointment	**Excluded**	Specifically excluded in OAR from being billed
D9987	Cancelled appointment	**Excluded**	Specifically excluded in OAR from being billed
D9219	evaluation for deep sedation or general anesthesia	**Exempt**	Anesthesia codes are all Exempt

ssue Summaries 11/13/14

Dentures Guideline and Rule Conflict

Question: What should be done about a conflict between the removable prosthodontics guideline and rule?

Question source: Katie Noah, Willamette Dental; DMAP

Issue:
Katie Noah noticed a discrepancy between DMAP rules and Guideline Note 62. Under the Dental Services Program Rulebook, 410-123-1260, the rule shows that under 21 is 4 missing posterior teeth but over 21 is 6 missing posterior teeth for the benefit.
http://www.dhs.state.or.us/policy/healthplan/guides/dental/123rb010112.pdf

However, Guideline note 62 states that **4** or more posterior missing teeth per arch are required, not **6**.

On 1/1/2012, DMAP changed the coverage rules so adults age 21+ could only receive coverage of a partial dentures if they are missing 6 or more posterior or one or more anterior teeth. This was a benefit reduction and made coverage different for adults versus children. The guideline did not change at the same time. The rationale for this was:
"Limits on some dental services for adult clients (age 21 and older) due to reduced payments to managed Dental Care Organizations (DCOs) to comply with budget limitations required by the 2011 Legislative Assembly in SB 5529. This will help assure access to services through sufficient provider networks will be maintained following this approximate 11% reduction in capitation rates."

Prioritized List Status:

Line:	**477**
Condition:	DENTAL CONDITIONS (EG. MISSING TEETH, PROSTHESIS FAILURE) (See Guideline Note 62)
Treatment:	REMOVABLE PROSTHODONTICS (E.G. FULL AND PARTIAL DENTURES, RELINES)
HCPCS:	D5110-D5212,D5520-D5761,D5820,D5821

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).

Expert input:
OHAP reviewed this guideline and felt that deletion of the guideline would provide the most clarity to the dental community.

Web Issue Summaries 11/13/14

Dentures Guideline and Rule Conflict

HERC staff recommendation:

1) Delete guideline note 62 REMOVEABLE PROSTHODONTICS

VbBS Issue Summaries 11/13/14

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?

VbBS Issue Summaries 11/13/14

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.

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 11/13/14

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.

VHBS Issue Summaries 11/13/14

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).

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	**Ancillary**

VBS Issue Summaries 11/13/14

HERC staff recommendations:

1) Add 228.09 (Hemangioma of other sites) to line 636 BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES
    a. Advise DMAP to remove 228.09 from the Ancillary list
    b. Will match the ICD-10 equivalent (D18.09) placement
2) 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
3) Make the changes shown below to GN13

GUIDELINE NOTE 13, ~~H~~HEMANGIOMAS, COMPLICATED

Line 326,636

Dermatologic ~~H~~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.

Intraocular Steroid Implants

Question: what conditions should be paired with intraocular steroid implants?

Question source: Allergan, Inc.

Issue: Dexamethasone intravitreal implants (brand name Ozurdex) has recently been FDA approved for a new indication: the treatment of diabetic macular edema in patients who are pseudophakic or are phakic and scheduled for cataract surgery. Allergan Inc. is requesting that the HERC re-review coverage of dexamethasone intravitreal implants for this new indication.

Psuedophakic refers to having an artificial lens in place in the eye (i.e. previously having had cataract removal surgery). Phakic and scheduled for cataract surgery refers to patients with cataracts severe enough to require surgery who are planning to undergo cataract removal surgery in the near future. These two groups have been singled out as they do not suffer from one of the major adverse effects and increased costs of intraocular steroid implants, which is the formation of cataracts and the subsequent increased cost of cataract removal/lens implantation surgery. Previous studies have found that intraocular steroid implants are somewhat effective at treatment macular edema in the short term, but lead to long term complications (cataracts, glaucoma) which make the implants less effective and cost-effective than alternative treatments such as systemic steroid therapy.

Current FDA approved indications for dexamethasone intravitreal implants:

Retinal Vein Occlusion
OZURDEX® (dexamethasone intravitreal implant) is a corticosteroid indicated for the treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).

Posterior Segment Uveitis
OZURDEX® is indicated for the treatment of noninfectious uveitis affecting the posterior segment of the eye.

Diabetic Macular Edema
OZURDEX® is a corticosteroid indicated for the treatment of diabetic macular edema in patients who are pseudophakic or are phakic and scheduled for cataract surgery.

VhBS Issue Summaries 1/13/14

At several VBBS and HERC meetings in 2013, dexamethasone intravitreal implants (Ozurdex) and fluocinolone intraocular implants (brand name Retisert) were reviewed for various indications.

1) Uveitis: P&T reviewed this indication in January, 2013 and concluded “There is low quality evidence that there is no difference in visual acuity outcomes between fluocinolone acetonide intravitreal implant and standard of care with systemic corticosteroids for the treatment of noninfectious uveitis. There is also low quality evidence that fluocinolone intravitreal implant may control inflammation in the eye faster and more frequently than standard of care, although both approaches decrease inflammation.” These treatments were added to the line 106 DIABETIC AND OTHER RETINOPATHY with a guideline specifying that they appeared on this line for pairing with uveitis which was “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.” Line 106 is due to split into 3 lines in January, 2015. The CPT codes will only be included on line 363

CHORIORETINAL INFLAMMATION for the ICD-10 List. HERC staff was also charged with finding more information on the effectiveness of treatment on intermediate uveitis, which is a non-FDA approved indication for implantable steroids.

2) Diabetic macular edema: P&T reviewed this indication in January, 2013 and found "There is low quality evidence demonstrating potential benefit of fluocinolone acetonide intravitreal implant and dexamethasone implant for the treatment of diabetic macular edema, however significant complications have also been reported. There is insufficient evidence to support the use for diabetic macular edema or other off-label indications." Intravitreal steroid implants were not added as a treatment for diabetic macular edema.
3) Central retinal vein occlusion: P&T reviewed these treatments in January, 2013 and concluded "There is moderate quality evidence demonstrating efficacy of dexamethasone intravitreal implant following central retinal vein occlusion." At the October, 2013 meeting VBBS/HERC added CPT 67028 only to line 445 VENOUS TRIBUTARY (BRANCH) OCCLUSION; CENTRAL RETINAL VEIN OCCLUSION with a guideline specifying coverage was only for those individuals who have failed anti-VEGF therapy.
4) Branch retinal vein occlusion: This condition was not included in the P&T review conclusions. It was included in a NICE review that recommended coverage in certain limited situations. At the VBBS/HERC meetings, the commission felt that there was not enough evidence presented to make a decision on coverage, and HERC staff was directed to search for more evidence of effectiveness of intravitreal steroids for this condition.
5) Other conditions: the CPT code used for intravitreal steroid injections appears on line 387 CENTRAL SEROUS CHORIORETINOPATHY, but no evidence was found for use for intravitreal steroids for any condition on that line. A coding specification was added to line 387: "CPT 67027 (Implantation of intravitreal drug delivery system) is included on this line for use with medications other than intraocular steroid implants."

VbBS Issue Summaries 11/5/14

Current Prioritized List status:
CPT 67027 (Implantation of intravitreal drug delivery system) and 67028 (Intravitreal injection of a pharmacologic agent) are found on lines

100 DIABETIC AND OTHER RETINOPATHY
284 RETINAL DETACHMENT AND OTHER RETINAL DISORDERS
290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
323 PURULENT ENDOPHTHALMITIS
387 CENTRAL SEROUS CHORIORETINOPATHY
445 VENOUS TRIBUTARY (BRANCH) OCCLUSION; CENTRAL RETINAL VEIN OCCLUSION (67028 only)
453 DEGENERATION OF MACULA AND POSTERIOR POLE (67028 only)

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

Line 100

Intraocular steroid implants (CPT 67027, 67028) are only included on Line 100 for pairing with uveitis (ICD-9-CM codes 363.0x, 363.1x, 363.20 and 363.22), 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 central retinal vein occlusion (ICD-10-CM code H34.81x) in those individuals who have failed anti-VEGF therapy.

VbBS Issue Summaries 11/13/14

Updated evidence review (late 2012-current)

Uveitis

1) **Kempen 2011**, MUST trial
    a. Included in 2013 P&T review
    b. Included patients with posterior, intermediate, and panuveitis
    c. Implants and systemic steroids found to have the same impact on visual outcomes; however, implants had much higher rates of cataract and glaucoma development
    d. Objective visual outcomes for intermediate, posterior, and panuveitis improved over 24 months in both the implant and systemic treatment groups. No breakdown in outcomes was given for these three groups
    e. Authors also note: "Nearly all phakic eyes receiving implant therapy can be expected to require cataract surgery, and approximately 25% of implant-treated eyes will require glaucoma surgery over 24 months."
2) **Comyn 2013**, review of intraocular implants for various eye conditions
    a. 3 studies reviewed for intraocular steroid implants for uveitis. All studies mixed intermediate, posterior and panuveitis
        i. 2 studies of fluocinolone
            1. 1 study found lower rate of recurrence with implant vs systemic steroids, while 1 study (MUST above) found no difference between implant and systemic therapy
            2. Very high rates of cataract surgery and interventions for increased intraocular pressure
        ii. 2 studies of dexamethasone
            1. 1 study showed short term benefit in reducing inflammation (2 months).
            2. 1 retrospective study in children found improvement in vision and ability to spare children systemic steroid therapy

VBRS Issue Summaries 11/13/14

Diabetic macular edema

1) **NICE 2013**, evidence review for fluocinolone implant for diabetic macular edema
    a. Fluocinolone acetonide intravitreal implant is recommended as an option for treating chronic diabetic macular oedema that is insufficiently responsive to available therapies only if the implant is to be used in an eye with an intraocular (pseudophakic) lens
    b. Decision based on 2 manufacturer sponsored trials (N=956 patients)
        i. Fluocinolone implant improved best corrected visual acuity significant over sham implant
        ii. Significantly more cataracts and increased intraocular pressure in the steroid group vs sham
    c. Economic study determined ICER of £22,655 to £26,526 per QALY gained for fluocinolone acetonide intravitreal implant compared with optimised standard of care.
    d. Previous NICE review had found no evidence of benefit of fluocinolone for all diabetic macular edema
    e. Subgroup of patients with previous cataract surgery/intraocular lens in place were separated for analysis as this group removed one of the outstanding complications/increased cost from the steroid treatment (cataract development and increased cost from cataract surgery)

2) **Comyn 2013**, review of intraocular implants for various eye conditions
    a. 2 trials of flucoinolone implant for diabetic macular edema reviewed
        i. Both showed short term gains in visual acuity vs sham, but differing results for long term improvement at 3 yrs
        ii. Very high rate of complications in implant group
            1. 90-91% of patients with implant required cataract surgery!
            2. 8-33% required surgical intervention for increased intraocular pressure
    b. 1 trial of dexamethasone implant for DME reviewed
3) **Qi 2012**, meta-analysis of triamcinolone implant vs subtenon triamcinolone for diabetic macular edema
    a. N=5 studies (172 eyes)
    b. No benefit seen from either method at 6 months on visual acuity
        i. Short term improvement seen over sham, but long term data not yet available

Central/branch retinal vein occlusion

4) **Comyn 2013**, review of intraocular implants for various eye conditions
    a. 4 studies reviewed for CRVO
        i. 1 study of triamcinolone injection showed it significantly improved visual acuity at 12 months vs grid laser
        ii. 2 trials of dexamethasone implant showed initial improvement, but no sustained improvement at 12 months vs sham
        iii. 1 study of flucoinolone implant showed no benefit and 100% of phakic eyes required cataract surgery and 30% of eyes required surgical intervention for increased intraocular pressure
    b. 1 study for BRVO
        i. 1 trial of dexamethasone implant showed no long term improvement vs sham, and high rates of cataract surgery in the implant arm
            1. Implants would need to be reinserted every 3-4 months based on trial results and therefore would increase adverse events
5) **Pielen 2013**, systematic review of various intravitreal therapies for CRVO/BRVO
    a. N=11 studies (4 CRVO, 5 BRVO, 2 both)
        a. 2 studies with triamcinolone
        b. 1 study with dexamethasone
    b. CRVO: Triamcinolone stabilized visual acuity for CRVO. Dexamethasone implant had no difference compared to sham
    c. BRVO: No significant effect was found for triamcinolone at 12 months. BRVO patients treated with dexamethasone implant deteriorated to approximately +6 letters after temporary visual improvement at month 12
    d. Significantly greater cataract progression with intraocular steroids
    e. All anti-VEGF agents show a better gain of BCVA than steroids at month 12 (CRVO, BRVO).
    f. In BRVO best improvement of BCVA was found for ranibizumab at month 12
6) **Gawaily 2010**, Cochrane review of intravitreal steroids for CRVO with macular edema vs observation
    a. Included steroid implants as a possible therapeutic modality
    b. No RCTS identified that met inclusion criteria (mainly due to lack of observation arm)

VbEG Issue Summaries 11/13/14

c. Conclusions: There is inadequate evidence for the use of intravitreal steroids for CRVO-ME due to a paucity of RCTs and well-designed observational studies on the topic; therefore, it is still an experimental procedure.

7) **NICE 2011**, technology appraisal of dexamethasone implant for treatment of macular edema resulting from central retinal vein occlusion
   a. Dexamethasone intravitreal implant is recommended as an option for the treatment of macular oedema following central retinal vein occlusion.
   b. Dexamethasone intravitreal implant is recommended as an option for the treatment of macular oedema following branch retinal vein occlusion when: treatment with laser photocoagulation has not been beneficial, or treatment with laser photocoagulation is not considered suitable because of the extent of macular haemorrhage.
   c. Data analysis
      i. Dexamethasone for BRVO showed no difference in visual acuity compared to sham at 180 days, although there was significant improvement at earlier time points
      ii. Dexamethasone for BRVO was significantly better than sham only for those patients with previous treatment with laser coagulation
         1. In the subgroup with BRVO and previous laser therapy 22.2% had an improvement in BCVA from baseline of at least 15 letters at day 30 compared with 2.8% in the sham group ($p = 0.028$). Differences between the dexamethasone and sham groups were also statistically significant at days 60 ($p < 0.001$), 90 ($p = 0.011$) and 180 ($p = 0.022$).

VbBS Issue Summaries 11/15/14

Summary

1) *Uveitis*: some benefit seen with steroid implants; however, systemic steroid therapy appears to be equally effective. High rates of complications seen, including cataracts and increased intraocular pressure. Studies did not differentiate between posterior, intermediate, and panuveitis. The treatment appears to have an equal level of effectiveness and side effects for these 3 conditions.

2) *Macular edema*: Short-term benefit seen for intraocular steroid implants, but at the cost of an exceedingly high rate of complications (near 100% rate of cataract surgery required, high rates of surgical intervention for increased intraocular pressure). NICE concluded therapy was only cost-effective in eyes which already had undergone cataract surgery to reduce this complication risk/cost.

3) *Retinal vein occlusion*: For central retinal vein occlusion, some benefit seen with intraocular steroid implants, but anti-VEGF therapy has better outcomes with fewer complications. For branch retinal vein occlusion, studies have found no long term benefit while significant complications were seen. NICE completed a subgroup analysis and found that patients with BRVO who had previously undergone laser grid therapy had a significant improvement in visual acuity with steroid implants compared to sham.

Pars Planitis

Issue: Pars planitis (ICD-9 363.21/ICD-10 H30.2x) is currently on line 387 CENTRAL SEROUS CHORIORETINOPATHY. However, this diagnosis is a type of uveitis which is more appropriate for another line with other uveitis diagnosis codes and treatments.

The placement of pars planitis was reviewed in October, 2009. At that time, pars planitis was on line 672, SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY. Several community ophthalmologists asked the HSC to move this diagnosis from its very low, uncovered line, to a higher, covered line. This request was denied as a review found little need for treatment.

In June, 2010, as part of the biennial review at that time, several ophthalmologists again requested that the placement of pars planitis, among several other diagnoses, be reviewed. The ophthalmologists provided evidence that there were effective treatments for pars planitis, and that treatment was necessary in many cases. During this review, a new line was created, entitled Central Serous Retinopathy. This line was originally supposed to contain a variety of unrelated ophthalmologic diagnoses which only required treatment in some cases. Central serous retinopathy, pars planitis, and hypotony were placed on this line with a guideline regarding when certain of these conditions, including pars planitis, should be treated. Initially, this line was scored to an unfunded position, but it was later moved into the funded region.

On review, pars planitis is also known as intermediate uveitis or posterior cyclitis. Its treatments are much the same as posterior uveitis and panuveitis. HERC staff recommends moving from the central serous retinopathy line to the very similar priority chorioretinal inflammation line.

Current guideline note:
GUIDELINE NOTE 10, CENTRAL SEROUS CHORIORETINOPATHY AND POSTERIOR CYCLITIS
Line 387
Central serous chorioretinopathy (H35.71x) is included on this line 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.

VbBG Issue Summaries 11/13/14

HERC staff recommendations:

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
    a. Panuveitis and sympathetic uveitis were added to this line when it was created during the ICD-10 ophthalmology review but were not moved form line 269 in apparent mistake
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 below
    a. Add new line number for pars planitis
4) Modify GN 116 as shown below
    a. Add steroid implants as treatment for intermediate uveitis and panuveitis
        i. Add diagnostic code for panuveitis and pars planitis to the guideline
        ii. Remove wording restricting coverage to posterior disease
    b. Evidence is similar for posterior, intermediate and panuveitis
        i. Evidence of effectiveness is poor for all conditions and treatment should be a third line therapy
    c. Note: FDA approval is only for posterior uveitis
5) Modify GN 177 as shown below
    a. Change current guideline regarding coverage of intraocular steroids for central retinal vein occlusion
        i. Evidence supporting efficacy is for treatment of the resulting macular edema
    b. Add coverage for intraocular steroids for branch retinal vein occlusion only for patients who have failed laser photocoagulation
        i. Follows NICE guidance and evidence
6) Add intraocular steroid implants as a treatment for diabetic macular edema in patients with artificial lens or with planned cataract removal surgery
    a. Add CPT 67027 and 67028 to line 100 DIABETIC AND OTHER RETINOPATHY
    b. Add the new guideline shown below to line 100
    c. Alternative: continue with current non-coverage due to exceedingly high rate of complications

VbDS Issue Summaries 11/13/14

GUIDELINE NOTE 10, CENTRAL SEROUS CHORIORETINOPATHY AND POSTERIOR CYCLITIS

Line 363, 387

Central serous chorioretinopathy (H35.71x) is included on ~~this~~ line 387 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 ~~100~~363

Intraocular steroid implants (CPT 67027, 67028) are only included on Line ~~100~~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.

GUIDELINE NOTE XXX INTRAOCULAR STEROID IMPLANTS FOR DIABETIC MACULAR EDEMA

Line 100

Intraocular steroid implants (CPT 67027, 67028) is included on this line for treating chronic diabetic macular edema (ICD-9 362.07/ ICD-10 E11.311) only when

1) there has been insufficient response to available therapies, and
2) the implant is to be used in an eye with an intraocular (pseudophakic) lens or in a phakic eye scheduled for cataract surgery.

VbBS Issue Summaries 11/13/14

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. This CG needs final approval by HERC at the 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.

VBBS Issue Summaries 11/13/14

This coverage guidance and HERC staff recommended changes to the Prioritized list were discussed at the August VBBS meeting. HERC staff recommended adding cervical epidural steroid injections to 4 spinal lines and facet joint injections to 3 spinal lines, both with new guidelines. After discussion, the VBBS decision was to continue to exclude these procedures. The major concerns of the VBBS were increase in costs if these procedures were covered, and the weak level of evidence supporting the HTAS recommendation to include these procedures.

HTAS relied on expert testimony and desire to provide options to surgery in recommending coverage. The epidural steroid injections are currently ancillary, whereas the facet joint injections are excluded. The VBBS requested clarification about the level of evidence needed to move a procedure from the ancillary list to the prioritized list. Based on the presumption that procedures on the ancillary list should only not be covered if evidence of harm or ineffectiveness was found, the VBBS decided to cover epidural steroid injections. However, due to the low level of evidence, the VBBS decided to not cover facet joint injections. Later in the meeting, however, the decision was regarding epidural steroid injections was reopened and the general decision was that HERC staff needed to obtain clarification on the level of evidence required to add something to the Prioritized List when it is on the Ancillary List. The decisions on both procedures were tabled until the November VBBS meeting.

At the August HERC meeting, HERC members clarified the level of evidence required to add a previously ancillary procedure to the prioritized list. The HERC felt that ancillary list procedures were unlikely to have been reviewed in the past and should be subject to the same level of evidence requirements to be added to the prioritized list. In other words, Ancillary procedures needed to have good evidence of effectiveness to be added to the prioritized list.

The HTAS summary of evidence is shown in the table below. The procedures in question had very low to low level of evidence of effectiveness.

VBBS Issue Summaries 11/13/14

Expert input: Dr. David Sibell, OHSU Comprehensive Pain Clinic

> I've always found it interesting to see what different authorities view as evidence based medicine, when it comes to low back pain. My understanding is that, for acute radiculopathy, there is good evidence that transforaminal epidural steroid injection reduces pain for 6-8 weeks (though it does not reliably affect rate of surgery, which has many other determinants); and that physical therapy and waiting are also effective.
>
> For chronic low back pain, there are repeated studies that demonstrate prolonged improvement in pain and function in patients diagnosed with painful facet arthropathy. The problem is that there are also some very poor quality studies in this literature, and reviewers often group those studies together, even though they use non-standard techniques. It turns out that, if you do the procedure wrong, it doesn't work well…go figure. How likely is it that this treatment would be considered? It makes the highest degree of difference for patients with chronic low back pain (combined with physical therapy, in almost all cases) of anything we do.
>
> PT & CBT also have a considerable evidence base, for both acute and chronic LBP.
>
> I'm glad that medications are getting another look. The evidence is poor for the most commonly used therapies, so there is a chance to do something better for patients.

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.
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	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.

VoBS Issue Summaries 11/13/14

Indication	Population characteristics	Comparator	Strength of Evidence	Conclusions
	stable/ controlled			
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 pain	Non-specific neck pain > 6 months 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	Placebo injection (local anaesthetic ± Sarapin)	Very low	No benefit in terms of pain or function at both three and twelve months or on opioid use or employment at twelve months based on one RCT.
Facet Neurotomy				

VBS Issue Summaries 11/13/14

Indication	Population characteristics	Comparator	Strength of Evidence	Conclusions
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

VbBS Issue Summaries 11/13/14

HERC staff recommendations:

Option 1 (following previous VBBS discussion)

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 Excluded 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 Excluded List
3) Add an entry to the new "excluded list" for CPT 63210, 64633-64634, 64479-64480, 64490-64495

Option 2 (following HTAS recommendations with August 2014 VBBS guideline edits)

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 lines 374 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT, 412 SPINAL DEFORMITY, CLINICALLY SIGNIFICANT, 545 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT, 588 SPINAL DEFORMITY, NOT CLINICALLY SIGNIFICANT
    a. Add a new guideline note regarding cervical epidural steroid injections as shown below
    b. Advise DMAP to remove 63210 from the Ancillary List
2) Add an entry to the new "excluded list" for CPT 64479-64480, 0213T– 0218T
3) Add 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) to lines 412, 545, 588
    a. Advise DMAP to remove 64490-64492, 64633 and 64634 from the Excluded List
    a. Adopt a new guideline note regarding facet joint radiofrequency neurotomy as shown below

VBBS Issue Summaries 11/13/14

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 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 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.

VbBS Issue Summaries 11/13/14

VbBS Issue Summaries 11/13/14

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 *OR* **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

VBBS Issue Summaries 1/15/14

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 additonal	**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

WBS Issue Summaries 11/13/14

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.

VBS Issue Summaries 11/13/14

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.

Electromyelography (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	• History of cancer with new onset of LBP	MRI	ESR
	• 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	
	• Multiple risk factors for cancer present	Plain radiography or MRI	
Spinal column infection	• Fever • Intravenous drug use • Recent infection	MRI	ESR and/or CRP
Cauda equina syndrome	• Urinary retention • Motor deficits at multiple levels • Fecal incontinence • Saddle anesthesia	MRI	None
Vertebral compression fracture	• History of osteoporosis • Use of corticosteroids • Older age	Lumbosacral plain radiography	None

Possible cause	Key features on history or physical examination	Imaging*	Additional studies*
Ankylosing spondylitis	• 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)	• 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
	• Radiculopathic signs** present >1 month • Severe/progressive neurologic deficits (such as foot drop), progressive motor weakness	MRI***	Consider EMG/NCV
Spinal stenosis	• Radiating leg pain • Older age • Pain usually relieved with sitting (Pseudoclaudication a weak predictor)	None	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.

WBS Issue Summaries 11/13/14

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

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:

8) documented neuroforaminal stenosis (without infection or neoplasia)
9) radicular pain in a corresponding dermatomal distribution,
10) pain is intractable and conservative therapy has failed,
11) fluoroscopic guidance or CT guidance is utilized,
12) interlaminar approach is utilized,
13) no more than two injections without clinically meaningful improvement in pain and function, AND
14) 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.

VBBS Issue Summaries 11/13/14

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.

COVERAGE GUIDANCE: ABLATION FOR ATRIAL FIBRILLATION

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*).

VCBS Issue Summaries 11/13/14

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. *(weak recommendation)*	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 *(strong recommendation)*	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

VbBS Issue Summaries 11/13/14

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 *(weak recommendation)*	
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 *(weak recommendation)*	PVI may help maintain sinus rhythm without significant additional risks

VbBS Issue Summaries 11/13/14

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**

VbB5 Issue Summaries 11/13/14

93613	Intracardiac electrophysicologic 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**

VoBS Issue Summaries 11/13/14

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.

VbBS Issue Summaries 11/13/14

COVERAGE GUIDANCE: NUCLEAR CARDIAC IMAGING

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.

VbBS Issue Summaries 11/13/14

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.

VbBS Issue Summaries 11/13/14

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	*SPECT vs. ETT* Not recommended for coverage (weak recommendation) *SPECT vs. ECHO* Not recommended for coverage (strong recommendation)	*SPECT vs. ETT* Sufficient evidence of small net benefit over ETT, may outweigh potential harms due to radiation, upgrading algorithmic derived recommendation against from “strong” to “weak”. *SPECT vs. ECHO*** 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)	*SPECT vs. ETT* Insufficient evidence, but has potential risks of radiation exposure, unlike alternatives, and is higher cost.

VbBS Issue Summaries 11/13/14

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variation in values and preferences	Coverage recommendation	Rationale
						*SPECT vs. ECHO*** 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

VbBS Issue Summaries 11/13/14

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

VbBS Issue Summaries 11/13/14

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	Congential 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

VBS Issue Summaries 1/1/13/14

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

VoBS Issue Summaries 11/13/14

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

VbBS Issue Summaries 11/13/14

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).

VbBS Issue Summaries 11/19/14

Treatment of obstructive sleep apnea in children with craniofacial anomalies

Question: Treatment of OSA (sleep apnea) in children with craniofacial anomalies

Question source: HERC Staff

Issue: In May 2014 VbBS and HERC approved a modified guideline on the treatment of sleep apnea based on a review in adults. As such, surgical codes for the treatment of sleep apnea in adults were removed from the higher sleep apnea line 210 as there is insufficient evidence of effectiveness. Tonsillectomy and adenoidectomy codes were left on Line 210 for children alone.

However, children with craniofacial anomalies may need these surgical procedures and the removal of these codes may cause significant challenge when trying to get procedures covered.

From Anna Kuang, Craniofacial plastic surgeon at OHSU

> We have a significant subset of craniofacial patients who need jaw surgery (distraction or formal jaw surgery) as means to obviate need for tracheostomy and or improve airway. Mandibular osteotomies the only surgical option besides tracheostomy (T&As helpful for managing them post op).
>
> Commonly affected kids:
> Any kid with a craniofacial syndrome may have associated micrognathia and glossoptosis WITH or WITHOUT cleft palate. And they can have midface hypoplasia that need midface advancement or distraction also WITH or WITHOUT cleft palate.
> Kids with skeletal dysplasia have assoiciated micrognathia and glossoptosis
> Pierre Robin Sequence diagnosis is micrognathia, glossoptosis, WITH or WITHOUT cleft palate
> Cleft Lip/Palate and Craniofacial syndromic kids have congenital nasal obstruction, deviated septum, and or hypoplastic noses and need opens septorhinoplasty and other nasal surgeries.
>
> Diagnosis of OSA in pediatric population in difficult (multiple sleep studies, airway evals, CT/MRI's, repeat visits, multiple disciplines) and time consuming. Once the diagnosis is made, we often have to proceed quickly with surgical intervention. Only a small percentage of kids have CPAP as an option due to age and age/diagnosis compliance issues. Delay in approval or surgical intervention procedures is associated with increased morbidity.

VbBS Issue Summaries 11/13/14

GUIDELINE NOTE 27, TREATMENT OF SLEEP APNEA IN ADULTS

Line 210

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;
- 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 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.

VbBS Issue Summaries 11/13/14

GUIDELINE NOTE 118, OBSTRUCTIVE SLEEP APNEA DIAGNOSIS AND TREATMENT FOR CHILDREN *(being reviewed this meeting)*

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

Summaries 11/13/14

Code placement completed May 2014 VbBS/HERC meeting

Code	Description	Recommendation
21193	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft	**Remove from 210**. (Remains only on line 646)
21194	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; with bone graft (includes obtaining graft)	**Remove from 210.** (Remains only on line 646)
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation	**Remove from 210.** (Remains only on line 646)
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation	**Remove from 210**. (Remains only on line 646)
21198	Osteotomy, mandible, segmental;	**Remove from 210.** (Remains only on line 646)
21199	Osteotomy, mandible, segmental; with genioglossus advancement	**Remove from 210.** (Remains only on line 646)
21206	Osteotomy, maxilla, segmental (eg, Wassmund or Schuchard)	**Remove from 210**. (Remains only on line 646)
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)	**Remove from 210.** (Remains only on line 646)

Code	Description	Recommendation
21209	Osteoplasty, facial bones; reduction	**Remove from 210.** (Remains only on line 646)
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)	**Remove from 210.** (Remains on lines 242,612,673).
21215	Graft, bone; mandible (includes obtaining graft)	**Remove from 210.** (Remains on lines 242,612,673).
21230	Graft; rib cartilage, autogenous, to face, chin, nose or ear (includes obtaining graft)	**Remove from 210**. (Remains on line 673).
21235	Graft; ear cartilage, autogenous, to nose or ear (includes obtaining graft)	**Remove from 210**. (Remains on 405,673).
30117	Excision or destruction (eg, laser), intranasal lesion; internal approach	**Remove from 210**. (Remains on multiple other lines)
30140	Submucous resection inferior turbinate, partial or complete, any method	**Remove from 210.** (Remains on multiple other lines)
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft	**Remove from 210.** (Remains on multiple other lines)
42140	Uvulectomy, excision of uvula	**Remove from 210.** **Place on DMAP Excluded File**.
42145	Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty)	**Remove from 210.** Will remain on 71 and 325
42160	Destruction of lesion, palate or uvula (thermal, cryo or chemical)	**Remove from 210.** (Remains on 656).

WORKS Issue S

HERC Staff Recommendations:

1) Add surgical codes in above table back to Line 210 (in addition to the preexisting tonsillectomy and adenoidectomy codes)

2) Delete the coding specification from Line 210 as it is no longer necessary given the revised guideline that states surgery for sleep apnea in adults is not covered
   ~~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 Guideline Note 27 as follows

GUIDELINE NOTE 27, TREATMENT OF SLEEP APNEA IN ADULTS

Line 210

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;
- 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.

WBS Issue Summaries 11/13/14

4) Modify Guideline Note 118 as follows:

GUIDELINE NOTE 118, OBSTRUCTIVE SLEEP APNEA DIAGNOSIS AND TREATMENT FOR CHILDREN ***(being reviewed this meeting)***

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 those 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

VbBS Issue Summaries 11/10/14

Adenoidectomy

Question: When is adenoidectomy alone indicated and/or effective?

Question source: Tracy Muday, MD, OHP Medical Director

Issue:
From Dr. Muday:

> We have lots of requests for adenoidectomy alone for young kids, usually under 4, sometimes under 2. My understanding of why they are doing the adenoidectomy alone is related to the risk of adenotonsillectomy in the younger group, and they feel that the adenoidectomy alone is likely to improve the kid's symptoms.
> Truthfully, my 3 ENTs have a gestalt of kids that they feel need tubes or adenoidectomy. The diagnosis that they use for this adjusts itself depending on what is covered. When OME was above the line, all the tubes were done with a dx of OME. When OME went below the line, they started paying attention to who had recurrent AOM, and that became the diagnosis. When we put limits on adenoidectomy with tubes for OME, they started coding for OSA and sinusitis

Adenoidectomy for chronic otitis media
Adenoidectomy for treatment of chronic otitis media was extensively reviewed in 2012 and guideline revisions made to clarify when this procedure is appropriate. Adenoidectomy was reaffirmed as a treatment for possible children with chronic otitis media receiving their second set of tubes in the Chronic Otitis Media guideline.

Adenoidectomy for chronic sinusitis
Adenoidectomy for chronic sinusitis was last reviewed in 2008. Some evidence was found that younger children (younger than age 12) may benefit for adenoidectomy for chronic sinusitis, but overall the body of evidence was scanty. Adenoidectomy was added to the chronic sinusitis line based mainly on expert opinion. It was noted that "If surgery is indicated, evidence shows that adenoidectomy should be performed before endoscopic sinus surgery (which is currently covered)." Adenoidectomy was added to the chronic sinusitis line for children younger than age 12 (42830, 42835).

Adenoidectomy for OSA
The obstructive sleep apnea guideline (GN 118) was extensively reviewed in 2013, but adenoidectomy as a single procedure was not reviewed. Evidence presented during this review focused on adenotonsillectomy.

VHBS Issue Summaries 11/13/14

Adenoidectomy

Current List placement:

CPT	Code Description	Current Lines
42820	Tonsillectomy and adenoidectomy; younger than age 12	47 CONGENITAL AIRWAY OBSTRUCTION WITH OR WITHOUT CLEFT PALATE 51 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS; INTESTINAL PERFORATION 68 CONGENITAL ANOMALIES OF UPPER ALIMENTARY TRACT, EXCLUDING TONGUE 206 SLEEP APNEA AND NARCOLEPSY 370 STREPTOCOCCAL SORE THROAT AND SCARLET FEVER; VINCENT'S DISEASE; ULCER OF TONSIL; UNILATERAL HYPERTROPHY OF TONSIL 556 CHRONIC DISEASE OF TONSILS AND ADENOIDS
42821	Tonsillectomy and adenoidectomy; age 12 or over	47,68,51,206,370,556
42830	Adenoidectomy, primary; younger than age 12	47,51,206, 470 CHRONIC SINUSITIS 481 CHRONIC OTITIS MEDIA 556
42831	Adenoidectomy, primary; age 12 or over	47,51,206,481,556
42835	Adenoidectomy, secondary; younger than age 12	47,51,206,470,481,556
42836	Adenoidectomy, secondary; age 12 or over	47,51,206,481,556

VhBS Issue Summaries 11/13/14

GUIDELINE NOTE 35, SINUS SURGERY

Lines 366,470

Sinus surgery 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

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

Lines 47,51,370,556

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.

GUIDELINE NOTE 51, CHRONIC OTITIS MEDIA WITH EFFUSION

Lines 317,481

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).

Patients with specific higher risk conditions (including craniofacial anomalies, Down's syndrome, and cleft palate, or documented speech and language delay) along with hearing loss and chronic otitis media with effusion are intended to be included on Line 317. Otherwise hearing loss associated with chronic otitis media with effusion (without those specific higher risk conditions) is only included on Line 481.

For coverage to be considered on either Line 317 or Line 481, there should be a 3 to 6 month watchful waiting period after diagnosis of otitis media with effusion, and if documented hearing loss is greater than or equal to 25dB in the better hearing ear, tympanostomy surgery may be indicated, given short- but not long- term improvement in hearing. Formal audiometry is indicated for children with chronic OME present for 3 months or longer. Children with language delay, learning problems, or significant hearing loss should have hearing testing upon diagnosis. Children with chronic OME who are not at risk for language delay (such as those with hearing loss <25dB in the better hearing ear) or developmental delay (should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

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

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

VOBS Issue Summaries 11/13/14

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.

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

VABS Issue Summaries 11/13/14

Adenoidectomy

Evidence—Adenoidectomy for chronic sinusitis

No NICE or SIGN guidances found

AAP and IDSA guidelines on chronic sinusitis in children addressed only diagnostic criteria and antibiotic treatment. Neither addressed surgery

1) **van den Aardweg 2010**, Cochrane review of adenoidectomy for chronic nasal symptoms in children
   a) N=1 study with 76 subjects who underwent adenoidectomy for improvement in episodes of common colds
   b) The risk differences were non-significant, being 2% (95% CI -18% to 22%) and -11% (95% CI -28% to 7%) after 12 and 24 months, respectively.
   c) Authors' conclusions: Current evidence regarding the effect of adenoidectomy on recurrent or chronic nasal symptoms or nasal obstruction alone is sparse, inconclusive and has a significant risk of bias.
2) **Brietzke 2008,** meta-analysis of adenoidectomy for treatment of pediatric rhinosinusitis
   a) N=9 studies (10-121 subjects)
      i) 6 cohort, 4 case-control
   b) All studies showed that sinusitis symptoms or outcomes improved in half or more patients after adenoidectomy.
   c) The summary estimate of the proportion of patients who significantly improved after adenoidectomy was 69.3% (95% CI = 56.8—81.7%, $p < 0.001$).
   d) Conclusion: Adenoidectomy reduces caregiver reported symptoms of chronic rhinosinusitis in a majority of pediatric patients. Given its simplicity, low risk profile, and apparent effectiveness, adenoidectomy should be considered first line therapy for medically refractory, uncomplicated pediatric rhinosinusitis.

VbBS Issue Summaries 11/13/14

Evidence: adenoidectomy for OSA

1) Shintani 1998, cohort study
   a. N=13 children who underwent adenoidectomy alone (part of a larger cohort study of 134 children with OSA who underwent various surgical interventions)
      i. Adenoidectomy was only indicated for children without tonsillar hypertrophy.
   b. Significant improvements of AHI and the lowest SaO2 were noted 2 months after the treatments in 84.5% (11:13) of children undergoing adenotonsillectomy only and in 75.4% (86:114) of children undergoing adenotonsillectomy
   c. 2 out of the 13 adenoidectomy alone children required repeat surgery within 4-9 months for recurrent OSA compared to 0 of the adenotonsillectomy group

2) **Hensley 2011**, review of adenoidectomy for OSA
   a. N=6 studies included with adenoidectomy for OSA, including Shintani 1998
      i. 1 cohort study of 206 children who underwent adenoidectomy for OSA. Follow up 3-5 years. Questionnaire results showed 74–87% improvement in symptoms. No PSG data.
      ii. 1 prospective cohort with 21 children with adenoidectomy, part of larger study with various surgical interventions. Analysis performed for whole group – reduction in mean AHI 11.04–>2.14.
      iii. 3 retrospective cohort studies, looked at rate of re-operation after adenoidectomy. 0.55-29% had subsequent tonsillectomy/ revision adenoidectomy. (N=100-13,005)

Other guidelines

1) **AAP practice guideline 2012** for treatment of OSA in children
    a. Adenotonsillectomy is very effective in treating OSAS. Adenoidectomy or tonsillectomy alone may not be sufficient, because residual lymphoid tissue may contribute to persistent obstruction.

Expert Input—Adenoidectomy for OSA

Derek Lam, MD, OHSU ENT

I'll have to take some time to do a more thorough literature review so I can provide some evidence, but off the top of my head I can tell you that there are definitely patients, especially younger ones, say 12-24 months for whom adenoidectomy alone may absolutely be an appropriate procedure for OSA. Often this may be the primary source of obstruction when the tonsils are small, and there is far less morbidity related to an adenoidectomy than a T&A (less pain, less potential for bleeding, faster recovery). As such, I think it would be a mistake to removal OSA as an indication for adenoidectomy alone. Because that would effectively put ENTs like myself in the uncomfortable position of recommending a T&A in order to get surgery authorized when an adenoidectomy alone would potentially suffice in situations where patients are clearly obstructing and need to have surgery. Admittedly this is a relatively uncommon clinical scenario, but certainly not so uncommon as to warrant removing this as an indicated procedure for OSA.

Dr. Ericka King, MD, OHSU ENT

I agree with Derek that there is certainly a cohort for whom adenoidectomy alone is a reasonable surgical intervention. There is fairly limited data, but I was able to find one study that directly assessed the question: Shintani et al. Int J Pediatr Otorhinolaryngol 1998; 44:51. In this study, they selected children with an AHI of >10. Those with minimal tonsillar hypertrophy underwent adenoidectomy alone, with n=13. In this group, 84.5% demonstrated improvement on postop sleep study (defined as reduction of AHI by at least 1/2, with SpO2 nadir >85%). In the same study, kids that underwent T&A interestingly only had a 75.4% rate of improvement. This is obviously a small study and limited, but one of the few out there. The risks and recovery associated with adenoidectomy alone are much lower than a tonsillectomy, and I feel it is a very reasonable and valuable intervention in selected young children (<3 yrs) with isolated adenoid hypertrophy and history/PSG suggestive of OSA.

VBES Issue Summaries 11/15/14

Expert Input—adenoidectomy for chronic sinusitis

Dr. Ericka King, MD, OHSU ENT

I disagree that the evidence supporting adenoidectomy is poor; actually it's fairly robust. The role in CRS is likely to be due to biofilm formation/ functioning of the adenoid pad as a bacterial reservoir; there is excellent evidence for this that I don't have time to summarize right now. Clinically, adenoidectomy alone has been shown to result in significant improvement in many studies, which are variably powered. Here are a few:
- Takahashi et al. Acta Otorhinolaryngol Belg 1997; 51:85. This study looked at 78 kids aged 5-7 with sinusitis and COME; 45 underwent adenoidectomy alone, the other 33 were controls. They found an improvement in symptoms win 56% after adeniodectomy vs 24% of the control group.
- Vanderberg et al. Arch Otolaryngol Head Neck Surg 1997; 123:675. This group looked at 48 kids with CRS, and found complete or near complete symptom resolution in 58%,

some improvement in 21%, and minimal/no improvement in 21% after adenoidectomy alone.
- Ramadan et al. Laryngoscope 2004; 114:2103. The authors studied 202 children with chronic or recurrent acute sinusitis by clinical and CT criteria that failed extensive medical management. They were randomized to endoscopic sinus surgery (ESS) + adeonidectomy, ESS alone, or adenoidectomy alone. These groups showed 87.%, 75%, and 52% improvement rates respectively, with children 6 years and under less likely to improve than older children (60% vs 84% overall).

Maximal medical management generally consists of prolonged antibiotics (3-6 weeks depending on the paper), nasal steroids and saline irrigations. This is a very difficult regimen for many young children, particularly the topical therapies. Additionally, for very good reasons we are trying to avoid CT scanning, particularly in young children. Thus, especially for young kids, I feel it is very reasonable to start with an adenoidectomy instead of a trial of medical therapy.

VbBS Issue Summaries 11/13/14

Summary: Evidence supports use of adenoidectomy for medically refractory chronic sinusitis in children. Based on limited evidence, adenoidectomy alone appears to be effective for treatment of OSA in children without tonsillar hypertrophy.

Adenoidectomy

HERC staff recommendations:

1) Continue coverage of adenoidectomy for chronic sinusitis in children
    a. Clarify GN 35 to indicate when adenoidectomy is indicated as shown below
        i. Consider whether inhaled or oral steroids are appropriate in young children
2) Clarify coverage for adenoidectomy for OSA in children in GN 118 as shown below

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.

VbBS Issue Summaries 11/13/14

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

VbBS Issue Summaries 11/15/14

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*

Summaries 11/13/14

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/TYMPANOPLASTY, 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.

VBS Issue Summaries 1/1/13/14

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

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).

Vbbs Issue Summaries 11/15/14

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 11/13/14

Breastfeeding supplies and support

Question: Should the guideline on coverage of breastfeeding support and supplies be clarified?

Question Source: Breastfeeding Coalition of Oregon
Christine Seals, CCO Medical Director
Helen Bellanca, Maternal Child Family Program Director, Health Share

Issue summary: There are concerns about inadequate or inconsistent coverage of both breastpumps and lactation support among OHP recipients. The January 1, 2015 Prioritized List refers to the HRSA guidelines to be covered on Line 3. HRSA specifically requires costs for renting breastfeeding equipment and comprehensive lactation support to be covered. The federal ACA requires coverage of breast pumps for lactating mothers and lactation counseling support for commercial plans.

Both WIC and OHP currently provide breastpumps. Sometimes OHP CCOs are providing pumps as first line, and sometimes mothers are being referred to WIC if they need pumps. There are also concerns that inadequate WIC penetration may mean that

There is currently no OHP coverage of lactation visits outside of the immediate postpartum hospital stay where it is bundled within the delivery hospital stay.

There are implementation concerns about paying for lactation consultants separately based on the fact that these are often nonlicensed providers.

VBBS Issue Summaries 11/13/14

From WIC, Bonnie Ranno

> Staff in WIC are excited about the inclusion of lactation services on HERC's prioritized list. There is such good evidence that the provision of lactation support, counseling, and equipment can increase breastfeeding exclusivity and duration, which then translates to significant health care savings and improved health for mothers and children.
>
> Our WIC breastfeeding team has gathered some information to help guide your writing of the HERC Guideline on Lactation Services. Please see the following attached documents:
>
> - Recommendations and evidence base for the provision of lactation services in Oregon, with references
> - Examples of what other states are providing in regards to Medicaid coverage of lactation services
>
> You had also asked about whether WIC would be able to change their policies regarding the provision of breast pumps for women returning to work or school. While WIC's funding for breast pumps is uncertain from year to year, we have been able to provide pumps for a number of WIC participants, and expect that we will be able to continue to do so, especially with some shifting from hospital pumps to personal pumps. It appears unlikely, however, that WIC's guidelines for electric pump distribution will broaden to include women who are not exclusively breastfeeding or those who are only away from their babies for a few hours. Those mothers would still qualify for a manual pump, though. I will also attach a FAQs document re Oregon WIC's breast pump program, which provides additional information.

In closing, we just want to reiterate that the HERC guideline will help to correct a real problem. CCOs have experienced a lot of confusion about lactation coverage, and clear guidance is needed. Putting lactation services on the prioritized list will help Oregon to

- Correct the equity issues that exist across the state in regard to lactation services
- Save money by preventing current and future health problems of mothers and babies
- Implement evidence-based and best practices pertaining to breastfeeding
- Fulfill Oregon Medicaid's requirement of complying with the Affordable Care Act

Prioritized List status (as of January 1, 2015)

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/uspstf/uspsabrecs.htm
2. American Academy of Pediatrics (AAP) Bright Futures Guidelines (published 2008):
   http://brightfutures.aap.org/pdfs/aap%20bright%20futures%20periodicity%20sched%20101107.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

HRSA Guideline (referred to in #3 above)

Type of Preventive Service	HHS Guideline for Health Insurance Coverage	Frequency
Breastfeeding support, supplies, and counseling.	Comprehensive lactation support and counseling, by a trained provider during pregnancy and/or in the postpartum period, and costs for renting breastfeeding equipment.	In conjunction with each birth.

USPSTF, 2008

Recommendation: The USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding (Grade B recommendation).

HERC Issue Summaries 11/13/14

Breastfeeding supplies and support

From the Healthcare.gov website describing benefits:
https://www.healthcare.gov/what-are-my-breastfeeding-benefits/

The health care law requires most health insurance plans to provide breastfeeding equipment and counseling for pregnant and nursing women.

Health insurance plans must provide breastfeeding support, counseling, and equipment for the duration of breastfeeding. These services may be provided before and after you have your baby.

These rules apply to Health Insurance Marketplace plans and all other health insurance plans, except for grandfathered plans.

Coverage of breast pumps
Your health insurance plan must cover the cost of a breast pump – and may offer to cover either a rental or a new one for you to keep.

Your plan may provide guidance on whether the covered pump is manual or electric, how long the coverage of a rented pump lasts, and when they'll provide the pump (before or after you have the baby).

es 11/13/14

Code	Code Description	Line placement
99401	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 15 minutes	650 lines.
99402	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 15 minutes	650 lines.
99403	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 45 minutes	650 lines
99404	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 60 minutes	650 lines
99411	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to individuals in a group setting (separate procedure); approximately 30 minutes	650 lines
99412	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to individuals in a group setting (separate procedure); approximately 60 minutes	650 lines
99078	Physician or other qualified health care professional qualified by education, training, licensure/regulation (when applicable) educational services rendered to patients in a group setting (eg, prenatal, obesity, or diabetic instructions)	650 lines
S9443	Lactation classes, non-physician provider, per session	DMAP Ancillary Codes File
V24.1	Postpartum care and examination of lactating mother	1 PREGNANCY

Breastfeeding supplies and support

Code	Code Description	Line placement
Z39.1	Encounter for care and examination of lactating mother	1 PREGNANCY
Z39.2	Encounter for routine postpartum follow-up	1,6

WIC criteria

Does the mother or the baby have a **medical need** for a pump**?**
Possible examples include:
□ Infant is unable to nurse due to prematurity or another health problem, or
□ Mother needs to increase milk production (multiple birth, previous breast surgery)
If yes, Loan Multi-User Double Electric Breast Pump

Is the mother going to work or school more than 20 hrs/wk **and**,
□ Is the infant at least 4 weeks old, **and**
□ Is the infant exclusively breastfeeding, **and**
□ Are mother and baby not having any problems with breastfeeding, **and**
□ Is mother planning to breastfeed exclusively for at least four to six months and not expecting any formula from WIC?

If yes, personal double electric pump offered. If no, hand pump recommended.

DMAP rules
410-122-0250 Breast Pumps

(1) Indications and limitations of coverage and medical appropriateness:

(a) The Division of Medical Assistance Programs (Division) may cover electric breast pumps for any of the following conditions:

(A) Medical appropriateness for infant:
(i) Pre-term;
(ii) Term and hospitalized beyond five days;
(iii) Separated from mother for an undetermined length of time;
(iv) Cleft palate or cleft lip;
(v) Cranial-facial abnormalities;
(vi) Inability to suck adequately;
(vii) Re-hospitalized for longer than two days;
(viii) Failure to thrive;

(B) Medical appropriateness for mother:
(i) Breast abscess;
(ii) Mastitis;
(iii) Hospitalized due to illness or surgery (for short-term use to maintain lactation);
(iv) Short-term treatment with medications that may be transmitted to the infant;
(v) A hand pump or manual expression has been tried for one week without success in mothers with established milk supply;

(b) Documentation that transition to breast feeding started as soon as the infant was stable enough to begin breast feeding;
(c) Use E1399 for an electric breast pump starter kit for single or double pumping;

HBS Issue Summaries 11/13/14

(d) An electric breast pump starter kit will be reimbursed separately from the breast pump rental; Durable Medical Equipment, Prosthetics, Orthotics and Supplies

VbBS Issue Summaries 11/13/14

(e) Electric breast pump rental cannot exceed 60 days,

(f) An electric breast pump may only be purchased when cost effective for one of the following conditions:

(i) Cleft palate or cleft lip;
(ii) Cranial-facial abnormalities;
(iii) Inability to suck adequately;
(iv) Infant is separated from mother for an undetermined length of time;

(g) Electric breast pump rental charges apply to the purchase price;

(h) The following services are not covered:

(i) Accessories;
(ii) An electric breast pump for the comfort and convenience of the mother;
(iii) Supplemental Nutrition System (SNS);
(iv) Heavy duty, hospital grade breast pumps;
(v) Replacement parts.

(2) Documentation requirements:

(a) For services that require prior authorization (PA): Submit documentation for review which supports conditions of coverage as specified in this rule are met;

(b) For services that do not require PA: Medical records which support conditions of coverage as specified in this rule are met must be on file with the durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) provider and made available to the Division on request.

(3) Procedure Codes:

(a) E0602 – Breast pump, manual, any type – the Division will purchase;
(b) E0603 – Breast pump, electric (AC and/or DC), any type:

(A) The Division will purchase or rent on a monthly basis;
(B) PA required

VbBS Issue Summaries 11/15/14

(c) E1399 – Electric breast pump starter kit;
(A) The Division will purchase;
(B) PA required.

Evidence

USPSTF, 2008

1) **The USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding.**
   Grade: B Recommendation.
2) **Strategies that include prenatal and postnatal components are most effective and strategies should include:**
   a. **formal breastfeeding education for mothers**
   b. **direct support of mothers during breastfeeding**
   c. **training of primary care staff about breastfeeding and techniques for breastfeeding support**
   d. **peer support**
3) system level interventions encouraged

AHRQ, 2007

1. Health Technology Assessment
2. Assessment of impacts of breastfeeding on maternal and infant health in developed countries
3. 29 systematic reviews or metaanalysis included, 43 unique primary studies as well
4. In infants:
   a. Found that breastfeeding significantly reduces the risk of:
      i. Acute otitis media
      ii. Severe (i.e. requiring hospitalization) lower respiratory tract diseases
      iii. Non-specific gastroenteritis
      iv. Necrotizing enterocolitis
      v. Atopic dermatitis,
      vi. Asthma (young children)
      vii. Obesity
      viii. Type 1 and 2 diabetes
      ix. Childhood leukemia
      x. Sudden infant death syndrome (SIDS)
   b. Found no clear association with
      i. Cognitive performance
      ii. Mortality (in developed countries)
      iii. Cardiovascular outcomes
5. In women,
   a. A history of lactation is associated with:
      b. Reduced risk of type 2 diabetes
      c. Reduced risk of breast cancer
      d. Reduced risk of ovarian cancer.
      e. Protective effect against postpartum depression
   f. No clear relationship was found between a history of lactation and
      i. Osteoporosis
      ii. Return to pre-pregnancy weight (negligible) and postpartum weight loss

VbBS Issue Summaries 11/13/14

WHO 2013

1) Systematic review, update of 2007 systematic review
2) Most studies are observational, and potentially subject to selection bias and confounding. Most studies were conducted in high income countries.
3) 2 RCTs exist, one to formula versus breastfeeding and the other to breastfeeding counseling. Both demonstrated a higher IQ in breastfed infants but no significant impacts on other health outcomes. Maternal IQ was accounted for.
4) Concluding differences (pp 67-68):

TABLE 10.1
Pooled effects for each outcome, from all studies and from those deemed to be of higher scientific quality

Outcome	Pooled effect (95% confidence interval)	
	All studies	High-quality studies[a]
Mean total blood cholesterol (mmol/L)	-0.01 (-0.05; 0.02)	0.00 (-0.02; 0.02)
Mean systolic blood pressure (mmHg)	-1.02 (-1.45; -0.59)	-0.71 (-1.24; -0.19)
Mean diastolic blood pressure (mmHg)	-0.37 (-0.71; -0.04)	-0.27 (-0.64; 0.09)
Odds ratio of type-2 diabetes	0.66 (0.49-0.89)	Not estimated
Odds ratio of overweight/obesity	0.76 (0.71; 0.81)	0.88 (0.83; 0.93)
Mean performance in intelligence test (points)	3.45 (1.92-4.98)	2.19 (0.89-3.50)

[a] High-quality studies include those with larger sample sizes and adjustment for confounding variables relevant to each outcome (see individual chapters for further details).

WBS Issue Summ

Johns, 2013

1. Systematic review of breast milk expression, prevalence and outcomes
2. 7 papers between 1999 and 2012 identified
3. Breastmilk feeding only at the breast for the duration of breastfeeding is rare in developed countries
4. Many reasons for breastpumping:
    a. Difficulty establishing breastfeeding
    b. Mothers with premature or low birth weight infants
    c. Mothers who are unwell
    a. Elevated BMI – expression may increase duration of breastfeeding among obese mothers
    b. Mastitis, breast engorgement, nipple pain
    c. Concerns about over or under supply
    d. Return to paid work
    e. Cultural factors and also embarrassment about feeding in public
    f. Ability to have others perform the “task” of feeding the infant
5. Impact on breastfeeding outcomes
    a. Contradictory results
    b. Impact on maternal mental health contested

Cochrane 2012

1. Systematic review of duration of breastfeeding, comparing at least 6 months exclusive to 3-4 months mixed breastfeeding

2. Found less gastrointestinal infection, and possibly respiratory infection among those exclusively versus partially breastfed. Lactational amenorrhea and weight loss may be maternal benefits
3. Supported recommendation of WHO for exclusive breastfeeding x 6 months

Guidance from CMS
http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Quality-of-Care/Downloads/Lactation_Services_IssueBrief_01102012.pdf

State Medicaid survey in 2008 found:

- 25 of the responding States covered breastfeeding education services
- 15 of the responding States covered individual lactation consultations
- 31 of the responding States covered equipment rentals.

"Due to the multiple health benefits associated with breastfeeding, CMS encourages States to go beyond the requirement of solely coordinating and referring enrollees to the Special Supplemental Food Program for Women, Infants, and Children (WIC) (established in 42 C.F.R. § 431.635) and include lactation services as separately reimbursed pregnancy-related services.
States may use the following Medicaid coverage categories to reimburse lactation services:

- Inpatient hospital services (other than services in an institution for mental disease), per Social Security Act (SSA)§ 1905(a)(1);
- Outpatient hospital services, per SSA § 1905(a)(2)(A) and 42 C.F.R. § 440.10;
- Early and periodic screening, diagnostic and treatment services for individuals who are eligible under the plan and are under the age of 21, per SSA § 1905(a)(4)(B);
- Physicians' services furnished by a physician under the physician's supervision, whether furnished in the office, the patient's home, a hospital, or a nursing facility, or elsewhere, per SSA § 1905(a)(5)(A);
- Services furnished by a nurse-midwife, which the nurse-midwife is legally authorized to perform under State law, per SSA § 1905(a)(17);
- Freestanding birth center services, per SSA § 1905(a)(28); and
- Services furnished by nurse practitioner "

They recommend to:

- Eliminate variation of coverage among Medicaid managed care plans and encourage managed care contractors to provide breastfeeding education, either by means of referrals to Special Supplemental Food Program for Women, Infants, and Children (WIC) or direct provision of the services through its provider network. WIC provides breastfeeding women with lactation support by means of counseling, the provision of breastfeeding educational materials, the option to receive an enhanced food package, follow-up support through peer counselors, and the provision of breast pumps or other equipment to help reinforce a healthy and successful breastfeeding routine.

WIC

1. Policy paper (see WIC - HERC Guideline Information, with References)
2. Recommend strongly covering lactation support services
3. Draw attention to the IBCLC certification as well as doulas and traditional health workers as potential sources of lactation assessment and support and peer supports
4. Provide examples of other states successfully implementing payment (see WIC - State Examples of Lactation Support payments)

WBS Issue Summaries 11/15/14

Breastfeeding supplies and support

Cost savings analysis, North Carolina Medicaid

North Carolina Medicaid performed a cost analysis

1. If North Carolina increased breastfeeding rates up to Healthy People 2020 goals then:
    a. 14-18 infant deaths would be prevented
    b. With 75% getting some lactation support, estimate $4.77 million in costs, $7 million saved
    c. Cost savings

Condition	NC Medicaid Cases Averted	Estimated Cost Savings
Lower Respiratory Tract Infections	500	$2.5 Million
Gastroenteritis	6,000	$2.5 Million
Necrotizing Enterocolitis	10	$2.1 Million
Total Cost		$7.1 Million

Professional associations

United states breastfeeding committee makes the following "model payer recommendations"

Breastfeeding Support & Counseling Services Benefit Guidelines

	Coverage	Permitted Providers	Coverage Criteria	Member Costs, Exclusions, Maximums
Education & Support				
Prenatal/postpartum breastfeeding classes	Covered benefit for one class series in the prenatal period and one class series up to 12 months postpartum	Approved lactation care providers,[8] licensed providers (such as MD, APRN, DO, PA), contracted network providers, RN certified childbirth/breastfeeding educators, and Registered Dietitians (RD, RDN, LDN)[9]	No referral or prior authorization required	No cost to member Prenatal and postpartum series up to a total of 18 class weeks
Breastfeeding support groups	Covered benefit for one monthly meeting up to a maximum of 12 meetings	Approved lactation care providers, licensed providers (such as MD, APRN, DO, PA), contracted network providers, RN certified childbirth/breastfeeding educators, and Registered Dietitians (RD, RDN, LDN)	No referral or prior authorization required	No cost to member One monthly meeting up to a total of 12 meetings
Lactation Counseling				
In-patient hospital	Covered benefit included as part of inpatient stay for facility employed providers; separately payable service (with place of service code) for non-employee in-network providers	Network hospitals, employed approved lactation care and/or licensed providers; in-network non-employee providers	No referral or prior authorization required	No cost to member
Outpatient hospital, home, provider office/clinic	Covered benefit for 6 outpatient lactation consultation visits per birth up to 2 hours per visit	Approved lactation care providers, licensed providers (such as MD, APRN, DO, PA); non-licensed providers, RN, and RD, RDN, LDN may bill as 'incident-to' physician services[10]	No referral or prior authorization required; prior authorization required beyond 6 visits	No cost to member Up to 6 visits per birth, up to 2 hours per visit

HERC Staff Asssessment

1) Breastfeeding is associated with a large number of improved maternal and infant health outcomes. The HRSA, ACA, USPSTF, and many others recommend comprehensive support to encourage and sustain breastfeeding.
2) Pumping - There are situations in which pumping would allow for short term uptake (e.g. medical necessity) and long-term provision of exclusive breastfeeding (e.g. inability of mother to provide breastfeeding directly because of work or school). The Prioritized List indicates breast pumps should be covered by its reference to HRSA Guidelines. Major federal and national organizations universally recommend coverage.

   a. There is inconsistency across CCOs and DMAP about expectations for coverage of breast pumps by OHP versus WIC. Currently, WIC is interested in continuing to provide breastpumps for women returning to work or to school.
3) Lactation support – there is not coverage for lactation support aside from what is bundled into the hospital delivery stay
4) DMAP is actively revising their rules for breast pump coverage

HERC Staff Recommendation:

1. Add codes S9443, V24.1, and Z39.1 to Line 3

S9443	Lactation classes, non-physician provider, per session
V24.1	Postpartum care and examination of lactating mother
Z39.1	Encounter for care and examination of lactating mother

2. Add a new guideline

   Guideline Note XXX Breastfeeding support and supplies
   Line 3

   Breastpumps and supplies are covered for postpartum women who are exclusively breastfeeding infants or intending to, and there is maternal or infant medical necessity.

   For cases in which there is a medical indication for breast pumps, the pumps should be supplied within 24-48 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 at least up to 3-6 months)*.

VbBS Issue Summaries 11/13/14

Section 3.0

Coverage Guidances-HTAS

HTAS Coverage Guidance Summary

Oregon Health Evidence Review Commission

November 13, 2014

Oregon Health Authority

Oregon Health & Science University

Center For Evidence-based Policy

Coverage Guidance

For HERC review and approval:

- Indications for Hyperbaric Oxygen Therapy

Indications for Hyperbaric Oxygen Therapy

- 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
- Multiple other indications with varying levels of evidence

Indications for Hyperbaric Oxygen Therapy

Primary evidence source:

Washington State Health Care Authority Health Technology Assessment Program (WA HTA). (2013). Hyperbaric oxygen therapy (HBOT) for tissue damage, including wound care and treatment of central nervous system (CNS) conditions. Olympia: WA HTA. 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

- 1 guideline - Underwater and Hyperbaric Medical Society (UHMS),
- 1 additional review

Indications for Hyperbaric Oxygen Therapy Draft 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.

Indications for Hyperbaric Oxygen Therapy Draft HERC Coverage Guidance

- 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*).

Indications for Hyperbaric Oxygen Therapy Draft HERC Coverage Guidance

- 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.

Indications for Hyperbaric Oxygen Therapy

Slides detailing evidence review follow

Indications for Hyperbaric Oxygen Therapy Evidence Review - Effectiveness

Diabetic non-healing wounds, including foot ulcers

- HBOT effective in improved wound healing and limb salvage (moderate 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)
  - CEA ~ £ 25,000

Indications for Hyperbaric Oxygen Therapy Evidence Review - Effectiveness

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

Indications for Hyperbaric Oxygen Therapy Evidence Review - Effectiveness

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

Indications for Hyperbaric Oxygen Therapy Evidence Review - Effectiveness

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

Indications for Hyperbaric Oxygen Therapy Evidence Review - Effectiveness

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

Indications for Hyperbaric Oxygen Therapy Evidence Review - Effectiveness

Sensorineural hearing loss

- Acute: Mixed results - possible benefit if present 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

Indications for Hyperbaric Oxygen Therapy Evidence Review - Effectiveness

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

Indications for Hyperbaric Oxygen Therapy Evidence Review – 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

Indications for Hyperbaric Oxygen Therapy Evidence Review - 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

Indications for Hyperbaric Oxygen Therapy
Evidence Review – 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)

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: INDICATIONS FOR HYPERBARIC OXYGEN THERAPY

DRAFT for HERC meeting materials 11/13/2014

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.

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

DRAFT

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 Heath 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

Bennett, M.H., Lehm, J.P., &Jepson, N. (2011).Hyperbaric oxygen therapy for acute coronary syndrome. *Cochrane Database of Systematic Reviews, Issue 8*. Art. No.: CD004818. DOI: 10.1002/14651858.CD004818.pub3. Retrieved from http://summaries.cochrane.org/CD004818/hyperbaric-oxygen-may-reduce-the-risk-of-dying-the-time-to-pain-relief-and-the-chance-of-adverse-heart-events-in-people-with-heart-attack-and-unstable-angina

Bennett, M.H., Stanford, R.E., &Turner, R. (2012a). Hyperbaric oxygen therapy for promoting fracture healing and treating fracture non-union. *Cochrane Database of Systematic Reviews, Issue 11*. Art. No.: CD004712. DOI: 10.1002/14651858.CD004712.pub4. Retrieved from http://summaries.cochrane.org/CD004712/using-oxygen-at-high-pressure-in-a-compression-chamber-for-the-treatment-of-broken-bones

Bennett, M.H., Trytko, B., & Jonker, B. (2012b). Hyperbaric oxygen therapy for the adjunctive treatment of traumatic brain injury. *Cochrane Database of Systematic Reviews, Issue 12*. Art. No.: CD004609. DOI: 10.1002/14651858.CD004609.pub3. Retrieved from http://summaries.cochrane.org/CD004609/does-hyperbaric-oxygen-therapy-improve-the-survival-and-quality-of-life-in-patients-with-traumatic-brain-injury

DRAFT

Buckley, N.A., Juurlink, D.N., Isbister, G., Bennett, M.H. & Lavonas, E.J. (2011).Hyperbaric oxygen for carbon monoxide poisoning. *Cochrane Database of Systematic Reviews, Issue 4*. Art. No.: CD002041. DOI: 10.1002/14651858.CD002041.pub3. Retrieved from http://summaries.cochrane.org/CD002041/there-is-insufficient-evidence-to-support-the-use-of-hyperbaric-oxygen-for-treatment-of-patients-with-carbon-monoxide-poisoning

Holland, N.J., Bernstein, J.M., &Hamilton, J.W. (2012).Hyperbaric oxygen therapy for Bell's palsy. *Cochrane Database of Systematic Reviews, Issue 2*. Art. No.: CD007288. DOI: 10.1002/14651858.CD007288.pub2. Retrieved from http://summaries.cochrane.org/CD007288/high-pressure-hyperbaric-oxygen-therapy-for-bells-palsy

Leof, A., Kriz, H., & King, V. (2012).*Hyperbaric oxygen therapy for treatment of gas gangrene.* Portland, OR: Center for Evidence-based Policy, Oregon Health and Science University.

National Institute for Health and Clinical Excellence (NICE). (2012). *Diabetic foot problems: Inpatient management of diabetic foot problems. NICE clinical guideline 119*. London: NICE. Retrieved from www.nice.org.uk/guidance/CG119

Phillips, J.S., & Jones, S.E.M. (2013).Hyperbaric oxygen as an adjuvant treatment for malignant otitis externa. *Cochrane Database of Systematic Reviews, Issue 5*. Art. No.: CD004617. DOI: 10.1002/14651858.CD004617.pub3. Retrieved from http://summaries.cochrane.org/CD004617/hyperbaric-oxygen-as-an-additional-treatment-for-malignant-otitis-externa

Washington State Health Care Authority Health Technology Assessment Program (WA HTA). (2013). *Hyperbaric oxygen therapy (HBOT) for tissue damage, including wound care and treatment of central nervous system (CNS) conditions.* Olympia: WA HTA. Retrieved from http://www.hca.wa.gov/hta/documents/021513_hbot_final_report.pdf

Xiao, Y., Wang, J., Jiang, S., & Luo, H. (2012). Hyperbaric oxygen therapy for vascular dementia. *Cochrane Database of Systematic Reviews, Issue 7*. Art. No.: CD009425. DOI: 10.1002/14651858.CD009425.pub2. Retrieved from http://summaries.cochrane.org/CD009425/hyperbaric-oxygen-therapy-for-vascular-dementia

Additional Sources Provided by Expert

Murad, M.H., Altayar, O., Bennett, M., Wei, J.C., Claus, P.L., Asi, N., et al. (2013). Using GRADE for evaluating the quality of evidence in hyperbaric oxygen therapy clarifies evidence limitations. *Journal of Clinical Epidemiology, 67*(1), 65-72. doi: 10.1016/j.jclinepi.2013.08.004. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/24189086

Undersea and Hyperbaric Medical Society (UHMS). (2014). *Hyperbaric oxygen therapy indications* (13th ed.). L.K. Weaver (Ed.). Durham, NC: UHMS. Retrieved from http://membership.uhms.org/

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

SUMMARY OF EVIDENCE

Clinical Background

The following clinical background summary is extracted from the WA HTA report (2013, p. 2-3).

> Hyperbaric oxygen therapy (HBOT) involves the systemic administration of 100% oxygen while the patient is inside a treatment chamber under pressures > 1 atmosphere absolute (ATA). Hyperbaric oxygen was introduced as a medical treatment more than 200 years ago and has been advocated as a treatment for a wide variety of conditions over the years. Despite a large body of published literature, it remains unclear as to the indications for which HBOT is most effective and safe. Among the indications for which questions still remain are diabetic non-healing wounds, including foot ulcers; other non-healing wounds, including skin and tissue grafts, thermal burns, and surgical wounds; refractory osteomyelitis; late radiation tissue injury (LRTI); brain injury; cerebral palsy; headache and migraine; multiple sclerosis; and sensorineural hearing loss.
>
> Foot wounds are one of the most common complications of diabetes and are responsible for substantial morbidity. At any given time, lower extremity ulcers affect approximately 1 million diabetics. HBOT is used along with traditional systemic and topical therapies to promote diabetic wound healing. It is purported to reverse anaerobic infection, improve blood supply, and reduce ischemic nerve damage.
>
> Chronic wounds other than those related to diabetes include venous and pressure sores, with causes that are related to venous insufficiency, pressure, trauma, vascular disease, and immobilization. Although the causes of chronic

DRAFT

wounds vary, in all cases, at least one of the phases of wound healing is compromised.

Surgical wounds present a medical problem if they are large in size, especially if bones and tendons are exposed and therefore are not amenable to primary closure. By increasing the oxygen tension in hypoxic wounds, HBOT is thought to restore the level of oxygenation required for compromised tissue to function efficiently. HBOT is also proposed as a means of preparing a base for skin grafts and flaps or preserving compromised grafts and flaps.

Thermal burns are the third largest cause of accidental death, with 300,000 serious burns and 6000 fatalities occurring annually in the United States. HBOT for thermal burns is directed at enhancing host defenses, preserving marginally viable tissue, protecting the microvasculature, augmenting neovascularization, and promoting wound closure.

Chronic osteomyelitis can develop when bacterial or fungal infection within bone deprives the bone of its blood supply, and the resulting ischemia causes bone tissue necrosis. It has been hypothesized that the additional oxygen delivered during HBOT may promote collagen synthesis and angiogenesis in patients with hypoxic osteomyelitic wounds.

More than 1.4 million Americans are diagnosed with cancer each year, and approximately half of these patients receive radiation therapy as part of their management. Radiation side effects can be categorized as either acute or delayed (chronic) complications; the latter may develop months or years after radiation treatment and collectively are known as late radiation tissue injury (LRTI) or late radiation side effects. Although any tissue may be affected, late radiation tissue injury occurs most commonly in the head and neck, chest wall, breast, and pelvis, reflecting the anatomical areas most commonly irradiated. Chronic radiation damage is called *osteoradionecrosis (ORN)* when bone is damaged and *soft tissue radionecrosis* when muscle, skin, or internal organs have been damaged. Evidence continues to emerge as to the effectiveness of HBOT for the treatment of LRTI, including ORN.

The use of HBOT for brain injuries is based on a theory that oxygen availability to these cells stimulates the cells to function normally, reactivating them metabolically or electrically. Traumatic brain injury (TBI), accounts for more than 1.3 million emergency room visits, approximately 275,000 hospitalizations, and 52,000 deaths annually.

Cerebral palsy is a neuromuscular disorder that arises in children due to damage of the developing brain. This disorder occurs in 0.1% to 0.5% of live births and is

DRAFT

characterized by impairments of muscle control, the senses, and perception. There is no known cure for cerebral palsy; the usefulness of HBOT for the treatment of cerebral palsy relates to the possibility of restoring function in portions of the brain that have suffered damage due to lack of oxygenation or other trauma.

More than 45 million individuals in the United States suffer from chronic, recurring headaches. Approximately 90% of headaches are primary headaches, which do not arise from an underlying medical condition. Cluster headaches are quite rare and occur in only 0.1% of the population. Migraine headache affects more than 28 million individuals in the United States and more than 300 million individuals worldwide. The theory is that HBOT might favorably influence vascular headache resistant to conventional drug therapy.

Multiple sclerosis (MS) is a demyelinating disease of the central nervous system (CNS) that afflicts an estimated 400,000 individuals in the United States and more than 2.5 million worldwide. The use of HBOT as a treatment for MS was originally based on the demonstrated ability of HBOT to produce vasoconstriction with increased oxygen delivery and some anecdotal evidence of efficacy. For several years, there was a flurry of investigation into its effectiveness for the treatment of MS, which produced a number of randomized studies in the UK, U.S., and Europe.

Sudden sensorineural hearing loss (SSHL), or sudden deafness, is a rapid loss of hearing with onset over a period of less than 72 hours. The estimated incidence of SSHL ranges from 5 to 20 per 100,000 persons per year but may be as high as 300 per 100,000 persons per year. HBOT has been proposed for the treatment of SSHL, the rationale being that the hearing loss appears to be caused by a hypoxic event in the cochlear apparatus; therefore, HBOT may potentially reverse the oxygen deficit, increase oxygen pressures in the cochlea, and improve microcirculation. Proving the effectiveness of HBOT for SSHL is complicated given the fact that up to two thirds of SSHL cases resolve spontaneously.

Bell's palsy is an acute unilateral facial weakness without an identifiable cause. It is often associated with ear discomfort, noise sensitivity and decreased tear production. It is estimated that it affects one person in 60 during their lifetime. Corticosteroids improve rates of recovery, while antiviral agents do not. It is hypothesized that in Bell's palsy, hypoxic degeneration of the facial nerve can be reduced and functional recovery can be improved with use of HBOT.

DRAFT

Fractures of bone are common and typically heal within three to six months (Bennett, 2012a). However, the fracture healing process may be impaired leading to delayed or non-union of the fractured bone. Non-union is considered present when there has been no evidence of healing after six months. Rates vary widely, but range from 5% to 10% of fractures. In cases where there is a strong possibility of a delayed or non-union, extra interventions to promote healing are often appropriate. HBOT has been proposed as one of those interventions.

Malignant otitis externa is a potentially fatal infection of the external ear canal and surrounding soft tissue and bone (Phillips, 2013). It may be complicated by involvement of cranial nerves, principally the facial nerves and the contents of the jugular foramen. It is an uncommon condition mainly found in the elderly or in diabetics. Traditionally the mainstay of treatment has been prolonged antibiotic therapy, repeated debridement of necrotic tissue and sometimes aggressive surgical management. Hyperbaric oxygen has been proposed as a beneficial adjunctive therapy.

Carbon monoxide is a gas generated from incomplete combustion, and poisoning with CO is an important cause of injury worldwide (Buckley, 2011). In the United States alone, there are an estimated 50,000 annual incidences of CO poisoning. There are two syndromes that can occur after acute CO poisoning, persistent and delayed neurologic sequelae. Standard treatment for CO poisoning includes removal from the site of exposure, administration of supplemental oxygen, and general supportive care. The elimination of carboxyhemoglobin is shortened significantly by the administration of 100% oxygen at atmospheric pressure. The administration of HBOT further hastens this process.

Dementia is a condition characterized by loss of memory, confusion, problems with speech and comprehension, and changes in personality (Xiao, 2012). The number of dementia cases is projected to reach 81 million by the year 2040. Vascular dementia, the second most common form of dementia, is not a single disease but a group of syndromes based on a variety of vascular conditions. There are no current effective treatments, and possible benefits of HBOT have been proposed.

Cardiovascular disease (CVD) is the leading cause of death in the world (Bennett, 2011). Acute coronary syndrome (ACS) is defined as unstable or persistent angina with or without myocardial infarction (MI). A significant number of patients with acute MI will suffer major morbidity or mortality, despite interventions such as thrombolysis or angioplasty. Hyperbaric oxygen therapy has been proposed to improve outcomes following ACS.

Gas gangrene is a bacterial infection usually caused by Clostridium perfringens bacteria (Leof, 2012). Infection of this type is a medical emergency and can cause myonecrosis,

gas production and sepsis and, without immediate treatment, may progress to toxemia, shock and death. Treatment usually consists of wound debridement and excision and can frequently require amputation. HBOT therapy has also been frequently used.

Technology Description

The technology description is extracted from the WA HTA report (2013, p. 3-4).

> HBOT involves the therapeutic administration of 100% oxygen at environmental pressures > 1 ATA, the atmospheric pressure at sea level. Administering oxygen at pressures greater than 1 ATA requires compression. This is achieved by placing the patient in an airtight chamber. The pressure is increased inside the chamber, and 100% oxygen is given for respiration, which delivers a greatly increased pressure of oxygen to the lungs, blood, and tissues.
>
> There are 2 types of chambers used for administering HBOT: a monoplace chamber for a single patient; or a multiplace chamber used for multiple patients and medical personnel. No standard protocol has been identified for administering HBOT.

Costs for HBOT were reported in the WA HTA report for three different populations, public employees, Medicaid and labor and industry. Costs, average treatment days and the range of days of treatment are presented in the table below:

Population	Public Employee	Medicaid	Labor and Industry
Average allowed amount per patient	$27,710	$46,774	$9,526
Average days of treatment	29	23	20
Range of days of treatment	1-101	1-93	1-120

Evidence Review

Effectiveness of HBOT

The majority of the evidence presented in this document that pertains to HBOT comes from the trusted sources listed at the beginning of this document. However, for several conditions, evidence was determined by HTAS to be insufficient for the committee to recommend policy, therefore they requested that additional evidence provided by the assigned expert be incorporated into this document. Two such evidence sources were utilized. One was the book, Hyperbaric Oxygen Therapy Indications, published by the Undersea and Hyperbaric Medical Society (UHMS) in 2014. The other, Murad 2013, is a systematic review of the literature on HBOT for all outcomes. The authors included 17

systematic reviews that included 44 RCTs and 131 observational studies, plus an additional 5 RCTs published after the dates of the SRs. The authors (three of whom are members of the GRADE working group) then rated the quality of the evidence using GRADE for all indications for which there was sufficient information, and compared that rating to an assessment using the American Heart Association (AHA) criteria that relies primarily on study type. This AHA evidence quality grading system is used by the UHMS, and in this framework, level A evidence is derived from multiple RCTs or meta-analyses, level B is derived from a single RCT or non-randomized studies, and level C is derived from expert opinion or case studies. When the evidence is from one of these two sources, it will be identified as such by *italics.*

Diabetic Nonhealing Wounds, Including Foot Ulcers

Moderate-quality evidence from three systematic reviews (1437 participants), including 16 peer-reviewed studies reporting on the effectiveness of HBOT for the treatment of diabetic foot ulcers, suggests that the addition of HBOT to standard wound care promotes wound healing and limb salvage in the short term (WA HTA, 2013). The results are clinically meaningful, with pooled data from three studies suggesting that eight patients would need to be treated with HBOT as an adjunct to standard wound care for an additional one person to have complete wound healing. In addition, the findings from two studies (one good quality, one fair quality) provide moderate quality evidence that the effectiveness of HBOT to heal remains significant at one-year follow-up. Incidence of healing and wound size reduction are clinically synonymous but are often measured as separate research outcomes. There was insufficient evidence to determine the effectiveness of HBOT to reduce wound size but given that the evidence supports HBOT for improved incidence of healing, it is reasonable to assume that further study into the effectiveness of HBOT to reduce wound size would find similar benefits. There is low-quality evidence suggesting no benefit from HBOT on quality of life (QOL) measures.

A NICE guideline on inpatient management of diabetic foot problems recommends that HBOT not be offered as a treatment unless part of a clinical trial (NICE, 2012). However, the evidence review that supports the guideline included six RCTs, and allowed authors to conclude that there was moderate evidence that HBOT resulted in fewer surgical interventions and low evidence that it resulted in fewer major amputations. On the other hand, there was moderate evidence that HBOT did not reduce the number of minor amputations, or improve complete wound healing at 4 to 6 weeks, and low evidence that it does not reduce ulcer surface area. A cost-effectiveness evaluation found that an incremental cost-effectiveness ratio of around £25,000.

DRAFT

Other Nonhealing Wounds, Including Skin and Tissue Grafts, Thermal Burns and Surgical Wounds

Overall, there is limited low-quality evidence from 12 peer-reviewed studies, suggesting that HBOT may improve healing when employed as an adjunct treatment for venous ulcers, flaps and grafts, and surgical reconstruction (without grafts or flaps) (WA HTA, 2013). There is low confidence in the reported estimate of effects for these conditions and the reported benefits should be interpreted with caution.

Venous Ulcers

The evidence for venous wounds includes two small RCTs (total N=46) and one case series (n=35). One of the RCTs found a significant reduction in wound area after 6 weeks but no difference at 18 weeks, while the other found a 59% reduction in wound area in the HBOT group compared to a 26% increase in the control group after 30 days.

UHMS 2014 notes the existence of one RCT evaluating HBOT for treatment of leg ulcers of undefined etiology, but go on to state:

> *"HBOT treatment is not indicated in the primary management of venous stasis ulcers of the lower extremities."*

Murad 2013 states that for venous ulcers, the quality of evidence is listed as class B using the AHA grading system. The authors report that for the outcome of the proportion of ulcers healed, the relative effect size is 5.00 (95% CI 0.28 to 90.18), and using GRADE, has low quality evidence; evidence from one RCT was downgraded for increased risk of bias and imprecision, and upgraded for a large treatment effect.

Surgical Reconstruction without Flaps and Grafts

For patients who have undergone surgical reconstruction without flaps or grafts, the evidence is limited to two poor quality prospective cohort studies (N=84). One found improved healing in more HBOT patients (89% vs. 83%), while the other found significantly more patients suffered infection and breakdown in the control group (78% vs. 17%). *This indication is not addressed in the UHMS 2014 book or by Murad 2013.*

Compromised Flaps and Grafts

For graft and flap survival, the evidence includes three RCTs (2 poor quality, 1 unknown quality), four case series and one additional study of unknown design. Total N=425. One of the RCTs found significantly better graft survival at 7 days in the HBOT group, while another found no significant benefit when compared to heparin and dexamethasone. The third RCT found improved healing of compromised skin grafts, while the study of unknown design reported significantly greater delay in wound healing in the control group (55% vs. 11%).

UHMS 2014 reported on a large number of animal studies. With regard to studies in humans, the authors report that there are no fewer than 16 studies supporting the effectiveness of HBOT for threatened grafts, which include a range of study types from RCTs to animal research. The only RCT discussed in detail (Perrins 1967) was included in the WA HTA report and was rated poor quality; it found that grafts survived in 64% of the HBOT arm compared to 17% of control (p<0.01). The authors also reference one retrospective cohort study and 8 case series to support their assessment. They state:

> *"the use of HBOT for the salvage of compromised grafts and flaps should be considered as a class 1b intervention according to the American Heart Association Evidence-based Guidelines as it is both useful and effective based on evidence from a single randomized trial and non-randomized studies with the potential benefit far outweighing the risks."*

Murad 2013 states that for split skin grafting, the quality of evidence is listed as class B using the AHA grading system. The authors report that for the outcome of complete graft survival at day 7, the relative effect size is 3.5 (95% CI 1.35 to 9.11), and using GRADE, has low quality evidence; evidence from one RCT was downgraded for increased risk of bias, imprecision and indirectness, and upgraded for a large treatment effect.

For flap grafting for limb skin defects, the quality of evidence is listed as class B using the AHA grading system. Murad et al. report that for the outcome of flap survival at day 7, the relative effect size is 1.18 (95% CI 1.02 to 1.35), and using GRADE, has low quality evidence; evidence from one RCT was downgraded for increased risk of bias and imprecision.

In addition, there is insufficient evidence from one study to determine the effectiveness of HBOT for crush injuries, insufficient evidence (primarily due to mixed results) from two studies to determine if HBOT is effective for the treatment of thermal burns, and insufficient evidence from one study to determine the effectiveness of HBOT for the treatment of acute traumatic peripheral ischemia.

Crush Injuries

For crush injuries, the evidence is limited to one fair quality RCT of 36 patients, which found significantly more complete healing in the HBOT group, but no difference in time to healing, number of amputations or length of hospital stay.

UHMS 2014 reports approximately 600 clinical cases of using HBOT for crush injuries, and of those, approximately 80% reported positive outcomes. Only one RCT is specifically discussed (Bouachour 1996), which was included as the only RCT in the WA HTA review and rated fair quality. UHMS states that complete wound healing

occurred in 94% of the HBOT group compared to 33% of controls (p<0.01), and that there was a need for additional surgeries in 6% of the HBOT group compared to 33% of controls (p<0.05). The description of this study in the WA HTA report adds additional information:

> *"…significantly more complete healing among the HBOT group (94% complete healing) compared with controls (56% complete healing) (RR, 1.7; 95% CI, 1.11-2.61; NNT, 3), no significant difference with regard to mean time to healing among the HBOT group (50.2 days) versus controls (55.8 days) (MD, 5.6 days; 95% CI, –19 to 7.8), no significant difference with regard to the number of amputations among the HBOT group (0) versus controls (2) (RR, 0.2; 95% CI, 0.01-3.89), and no significant difference in mean length of hospital stay among the HBOT group (22.4 days) versus controls (22.9 days) (MD, –5.0; 95% CI, –9.96 to 8.96)."*

Murad 2013 states that for crush injuries, the quality of evidence is listed as class B using the AHA grading system. The authors report that for the outcome of complete wound healing without necrosis requiring excision, the relative effect size is 1.70 (95% CI 1.11 to 2.61), and using GRADE, has low quality evidence; evidence from one RCT was downgraded for increased risk of bias and imprecision.

Thermal Burns

For patients with thermal burns, the evidence includes two fair quality RCTs (N=141). One found no significant difference in hospital length of stay, additional surgeries or mortality, while the other found better time to healing in the HBOT group (20 days vs. 44 days).

Acute Traumatic Peripheral Ischemia

For acute traumatic peripheral ischemia, the evidence is limited to one case series (n=23) that did not provide detailed data.

Refractory Osteomyelitis

Low-quality evidence from 23 primary data studies (one fair quality nonrandomized controlled trial, one poor quality nonrandomized controlled trial, 21 case series) suggests that HBOT may be effective as an adjunct treatment for refractory osteomyelitis but there is low confidence in the reported estimate of effects (WA HTA, 2013). There is some evidence from the one small, fair-quality, nonrandomized trial that HBOT may reduce the rates of relapse infection (0% vs. 33%), but this is contradicted by the other nonrandomized trial, which found no significant difference in relapse rate (14% for HBOT, 7% for control). The latter trial (n=28) also found no benefit from HBOT as an adjunct to surgery and antibiotics with regard to cure (79% cure for HBOT vs.

93% cure for control). Further good-quality studies are necessary to determine the effectiveness of HBOT for the treatment of refractory osteomyelitis.

UHMS 2014 reports that the evidence pertaining to the use of HBOT for refractory osteomyelitis consists of 26 reports, three of which utilized some kind of comparison group, although none were RCTs. The authors recommend the use of HBOT either before or after surgical debridement, depending on location of the infection, rationalizing that:

> *"The overwhelming majority of available studies supported the use of HBOT as a beneficial adjunct in the management of refractory osteomyelitis …. Treatment success rates generally exceeded that found in the literature for "standard of care" therapy using antibiotics and debridement alone…."*

Murad 2013 states that for refractory osteomyelitis, the quality of evidence is listed as class B using the AHA grading system. The authors report that for the outcome of infection cure, the relative effect size is 0.85 (95% CI 0.62 to 1.15), and using GRADE, has very low quality evidence; evidence from one prospective cohort study was downgraded for imprecision.

Late Radiation Tissue Injury

There is moderate-quality evidence from 35 primary data studies suggesting that HBOT improves outcomes of late radiation tissue injury affecting bone and soft tissues (WA HTA, 2013). There is no overall estimate of effect because of the heterogeneity between studies, but the evidence suggests that radiation-induced tissue and bone damage to the head and neck, anus, and rectum show consistent clinical improvement with HBOT. There is also moderate-quality evidence that HBOT reduces the risk of developing ORN following tooth extraction in a previously irradiated area.

Brain Injury

For TBI, moderate quality evidence consisted of seven studies that included 571 people (Bennett, 2012b). The results of two studies indicate use of HBOT results in a statistically significant decrease in the proportion of people with an unfavorable outcome one month after treatment using the Glasgow Outcome Scale (GOS) (RR for unfavorable outcome with HBOT 0.74,95% CI 0.61 to 0.88, P = 0.001). This five-point scale rates the outcome from one (dead) to five (good recovery); an 'unfavorable' outcome was considered as a score of one, two or three. Pooled data from final follow-up showed a significant reduction in the risk of dying when HBOT was used (RR 0.69, 95% CI 0.54 to 0.88, P = 0.003) and suggests we would have to treat seven patients to avoid one extra death (number needed to treat [NNT] 7, 95% CI 4 to 22, moderate quality evidence). The Glasgow Coma Scale (GCS) has a total of15 points, and two small trials reported a significant improvement in GCS for patients treated with HBOT

(mean difference [MD] 2.68 points, 95%CI1.84 to 3.52, P < 0.0001), although these two trials showed considerable heterogeneity (I^2 = 83%).The improvement of 2.68 points in GCS is difficult to interpret. This scale runs from three (deeply comatose and unresponsive) to 15 (fully conscious), and the clinical importance of an improvement of approximately three points will vary dramatically with the starting value (for example an improvement from 12 to 15 would represent an important clinical benefit, but an improvement from three to six would leave the patient with severe and highly dependent impairment). In general, the studies were small and carried a significant risk of bias. None described adequate randomization procedures or allocation concealment, and none of the patients or treating staff were blinded to treatment.

Evidence from six poor or very-poor-quality primary data studies are insufficient to determine if HBOT is effective in improving health outcomes among patients with brain injuries other than TBI (WA HTA, 2013).

Cerebral Palsy

There is insufficient evidence from six studies (two RCTS and four observational studies) to determine the effectiveness of HBOT for the treatment of cerebral palsy (WA HTA, 2013). Inconsistencies in the direction of the results, a paucity of studies, small sample sizes, differences in baseline characteristics, and the number of treatment sessions provided, all contributed to the low-quality grade assigned to motor function, which was considered the major outcome of interest. Fair- to poor-quality observational data suggests an improvement in motor function and other disease-specific subjective outcome measures among children receiving HBOT, but a fair-quality RCT found no additional benefit from HBOT among children receiving HBOT versus those receiving pressurized air.

Multiple Sclerosis

Moderate-quality evidence from nine trials suggests little effect of HBOT on outcomes related to MS (WA HTA, 2013). Two small, good-quality trials found modest benefits, while seven fair-quality trials found no benefit. Furthermore, the statistical benefits observed in the two positive trials are unlikely to translate into clinically significant benefits for the patient. Of note, there were no RCTs found on this topic post 1990, and there appears to be little interest in further investigation into the use of HBOT for MS.

Migraines and Cluster Headaches

Low-quality evidence from three fair-quality RCTs suggest that 40 to 45 minutes of HBOT is effective in significantly relieving an acute migraine attack (WA HTA, 2013). Just two patients need to be treated to obtain significant relief for one additional patient. There is no evidence that HBOT can prevent migraines, reduce the nausea and vomiting associated with migraines, or reduce the need for rescue medication, based on

two fair quality trials. There is insufficient evidence from two studies to determine the effectiveness of HBOT for preventing, relieving, or terminating cluster headaches.

Sensorineural Hearing Loss

Low-quality evidence (due to mixed results) from eight RCTs is inconclusive as to whether there is a benefit of HBOT for the treatment of sensorineural hearing loss in the acute phase (WA HTA, 2013). A large systematic review suggests that HBOT is beneficial among patients who present within two weeks of onset of the disease; however, there is no evidence that the statistical benefit observed translates into a functional benefit, and the results from a recent RCT do not suggest benefit from HBOT. Moderate-quality evidence suggests that HBOT provides no added benefit to patients presenting with chronic sensorineural hearing loss.

Murad 2013 reports that for chronic idiopathic sudden sensorineural hearing loss (> 2 weeks after presentation), the quality of evidence is listed as class A using the AHA grading system. The authors report that for the outcome of any improvement in hearing, the relative effect size is 0.64 (95% CI 0.30 to 1.33), and using GRADE, has very low quality evidence; evidence from one RCT was downgraded for increased risk of bias, imprecision and indirectness.

Delayed or Non-healing Fractures

No studies met the inclusion criteria of the review that addressed this indication (Bennett, 2012a). Authors identified three ongoing RCTs. Three excluded RCTs either did not report fracture healing outcomes or had been abandoned.

Bell's Palsy

No RCTs met the inclusion criteria of the review that addressed this indication (Holland, 2012). One small RCT (n=79) that did not meet criteria because the outcome assessor was not blinded reported that patients treated with HBOT had facial function recovery more often than those treated with prednisone (RR 1.26, 95% CI 1.04 to 1.53).

Malignant Otitis Externa

No RCTs met the inclusion criteria of the review that addressed this indication (Phillips, 2013).

Carbon Monoxide Poisoning

Seven RCTs of varying quality were identified; one was excluded because it did not evaluate clinical outcomes (Buckley, 2011). Of the six remaining trials involving 1361 participants, two found a beneficial effect of HBOT for the reduction of neurologic sequelae at one month, while four others did not. One of these is an incomplete publication (an abstract of an interim analysis). Although pooled random effects meta-analysis does not suggest a significant benefit from HBOT (OR for neurological deficits 0.78, 95%CI 0.54 to 1.12), significant methodologic and statistical heterogeneity was

apparent among the trials, and this result should be interpreted cautiously. Moreover, design or analysis flaws were evident in all trials. Importantly, the conclusions of one positive trial may have been influenced by failure to adjust for multiple hypothesis testing, while interpretation of the other positive trial is hampered by a high risk of bias introduced during the analysis including an apparent change in the primary outcome. Both were also stopped early 'for benefit', which is likely to have inflated the observed effect. In contrast three negative trials had low power to detect a benefit of HBOT due to exclusion of severely poisoned patients in two and very poor follow-up in the other. One trial that was said to be finished around eight years ago has not reported the final analysis in any forum. (Strength of evidence: very low)

Murad 2013 reports that for carbon monoxide poisoning, the quality of evidence is listed as class A using the AHA grading system. The authors report that for the outcome of resolution of signs and symptoms at 4-6 weeks, the relative effect size is 0.78 (95% CI 0.54 to 1.12), and using GRADE, has very low quality evidence. Evidence from multiple RCTs was downgraded for increased risk of bias, inconsistency and imprecision.

Vascular Dementia

One study involving 64 patients was included in the review (Xiao, 2012). It compared HBOT as an adjuvant to donepezil with donepezil alone. This one study was judged to be of poor methodological quality. Patients receiving HBOT plus donepezil had significantly better cognitive function than the donepezil only group after 12 weeks of treatment, measured by the Mini-Mental State Examination (MMSE) (WMD 3.50; 95% CI 0.91 to 6.09) or by Hasegawa's Dementia Rating Scale (HDS) (WMD 3.10; 95% CI 1.16 to 5.04). There were no deaths or withdrawals, and the study did not mention safety assessment at all. Global function, behavioral disturbance and activities of daily living were not investigated in the study. (Strength of evidence: very low)

Acute Coronary Syndrome

Six trials with 665 participants contributed to this review (Bennett, 2011). There was a significant decrease in the risk of death with HBOT (RR 0.58, 95% CI 0.36 to 0.92, P = 0.02). The extent of heart muscle damage was lower following HBOT, as shown by a lesser rise in muscle enzyme in the blood (mean difference (MD) 493 IU, P = 0.005) and a better LV ejection fraction (MD 5.5%, P = 0.001). There was evidence from individual trials of reductions in the risk of major adverse coronary events (MACE) (RR 0.12, P = 0.03); re-infarction (RR 0.28, P = 0.04) and dysrhythmias following HBOT (RR 0.59, P = 0.01), and the time to relief of pain was reduced with HBOT (MD 353 minutes shorter, P < 0.00001). One trial suggested a significant incidence of claustrophobia in single occupancy chambers of 15% (RR of claustrophobia with HBOT 31.6, P = 0.02). The authors conclude:

For people with ACS, there is some evidence from small trials to suggest that HBOT is associated with a reduction in the risk of death, the volume of damaged muscle, the risk of MACE and time to relief from ischemic pain. In view of the modest number of patients, methodological shortcomings and poor reporting, this result should be interpreted cautiously. The routine application of HBOT to these patients cannot be justified from this review. (p. 4)
(Strength of evidence for risk of death: low)

Gas Gangrene

Evidence pertaining to the use of HBOT for this indication is limited to four retrospective comparison studies and 13 case series (Leof, 2012). All four of the retrospective comparison studies compared mortality rates between patients treated with HBOT and those receiving standard wound care. All four studies found that HBOT improved survival rates. One of the cohort studies included reported that amputation rates among survivors were lower for HBOT patients (18%) than for controls (75%). The significance of these findings was not reported. (Strength of evidence: low)

Optimal Dose, Frequency and Duration of HBOT

The available data from 13 studies provides insufficient evidence to determine the optimal treatment frequency, duration or dose for HBOT (WA HTA, 2013). No studies reported on the optimal duration of treatment sessions; there were mixed results from subgroup analysis involving 8 studies looking at frequency; and significant heterogeneity means that there is low confidence in the available results from five studies that looked at dose.

Harms of HBOT

There is moderate evidence suggesting that harms associated with HBOT are generally mild and self-limiting (WA HTA, 2013). The majority of reported harms include barotrauma, temporary visual disturbances, and, more rarely, oxygen toxicity. Occasional reports of seizures represent the most serious side effects. The Medical Services Advisory Committee (MSAC) of Australia reported an overall harms incidence rate of 6.3%; 17% incidence of general pain or discomfort during decompression; 4.8% incidence of ear pain; 1.5% incidence of tympanostomy tube placements; 0.9% incidence of persistent ocular changes; 0.6% incidence of ear barotrauma; 0.34% incidence of abdominal pain; and 0.1% incidence of claustrophobia.

Notable indication-specific harms found in the literature include the following:

- Among patients with late radiation tissue injury, there were reports of ear pain (16% in a trial of 150 patients), transient myopia (3% in one study 8% in another), and confinement anxiety (1.7%).

- Pooled data from two trials reported severe pulmonary complications (defined as either, rising oxygen requirements and infiltrates in chest x-ray or cyanosis and hyperpnoea so severe as to imply “impending hyperoxic pneumonia”) among 13% of TBI patients receiving HBOT compared with none in the control groups (RR, 15.57; 95% CI, 2.11-114.72).
- One study reported ear problems among 47% of children with cerebral palsy receiving HBOT versus 22% among controls (P significant but value not reported). Another study reported a 12% seizure rate and found that 35% of patients reported ear problems. Another reported that 8% of 50 children stopped treatment due to adverse events, including seizures, and one other study reported 1 seizure in an observational study of 230 patients.
- Among patients with MS, a 2011 Cochrane Collaboration review reported 77 patients (55%), across 4 trials, suffered temporary deterioration in visual acuity in the HBOT group versus 3 patients (2.3%) in the sham group (OR, 24.87; 95% CI, 1.44-428.5; NNT, 1; 95% CI, 1-2).
- Six of the case series evaluating HBOT for gas gangrene reported on harms (total N= 337). Two deaths were attributed to HBOT treatment, and seizures occurred in 7% of patients.
- Among patients with TBI, two studies reported an incidence of 13% for significant pulmonary impairment in the HBOT group versus 0% in the non-HBOT group (P = 0.007).

Differential Efficacy or Safety

The evidence is insufficient to determine the differential effectiveness and safety of HBOT according to sex, race, ethnicity, disability, wound duration, or treatment setting (WA HTA, 2013). There is evidence of very low quality suggesting that younger TBI patients may recover faster with HBOT than older patients. There is low quality evidence suggesting that radiation dose influences the effectiveness of HBOT to prevent ORN among head and neck cancer survivors. There is low quality evidence that transcutaneous oxygen measurement (TCOM) is a good predictor of response to HBOT when measured under hyperbaric conditions, and there is mixed evidence as the whether TCOM can predict response to HBOT by first measuring the response of a wound to normal air or to 100% oxygen breathed at sea level. There is insufficient evidence from poor-quality studies to determine the differential safety of HBOT across populations.

DRAFT

Costs of HBOT

HBOT may be cost-effective under very specific assumptions of effectiveness and costs (WA HTA, 2013). All included cost analyses found HBOT to be cost-effective or cost saving. However, the available economic evaluations were severely limited by sparse cost data and unreliable efficacy and cost estimates used to make model assumptions. Only one model was found to be robust during sensitivity analysis, making most estimates very unreliable. Overall, there is low-quality evidence to suggest that HBOT may be a cost-effective treatment under certain conditions, for certain populations and indications.

Evidence Summary

Moderate-quality evidence supports the addition of HBOT to standard wound care to promote short term wound healing and limb salvage among patients with diabetic foot ulcers with continued improvement at one year follow-up. There is insufficient evidence to determine the effect of HBOT on QOL or other health outcomes. There is also moderate-quality evidence suggesting that HBOT improves outcomes of late radiation tissue injury affecting bone and soft tissues. Moderate-quality evidence also suggests that HBOT reduces the risk of dying following TBI and may improve functional outcomes.

There is limited low-quality evidence suggesting that HBOT may improve healing when employed as an adjunct treatment for venous ulcers, flaps and grafts, crush injuries, and surgical reconstruction (without grafts or flaps) but more study is needed to support the current evidence. Low-quality evidence (due to mixed results) is inconclusive as to whether or not there is a benefit of HBOT for the treatment of sensorineural hearing loss in the acute phase of the disease. HBOT may reduce the rates of relapse infection among patients with refractory osteomyelitis but further good-quality studies are necessary to confirm this finding (very low quality evidence). Low-quality evidence suggests that 40- to 45-minutes of HBOT is effective in significantly relieving an acute migraine attack, but there is no evidence that HBOT can prevent migraines, reduce the nausea and vomiting associated with migraines, or reduce the need for rescue medication.

Low quality evidence suggests that HBOT may decrease the risk of death and other major adverse coronary events in patients with ACS, and may decrease the risk of death and amputation in patients with gas gangrene.

Moderate-quality evidence suggests little benefit of HBOT for the treatment of MS. Low-quality evidence suggests no benefit of HBOT for preventing, relieving, or terminating cluster headaches. There is also no evidence that HBOT is beneficial among patients presenting with chronic sensorineural hearing loss. There is insufficient evidence,

DRAFT

primarily due to mixed results or an overall paucity of studies, to determine if HBOT is effective for the treatment of thermal burns, cerebral palsy, brain injuries other than TBI, delayed or non-union of fractures, bell's palsy, carbon monoxide poisoning, vascular dementia or malignant otitis externa.

Overall, there is a low quality of evidence to suggest that HBOT may be a cost-effective treatment under certain conditions and for certain populations and indications, but current data are insufficient to determine the most cost-effective uses of the technology.

There is moderate-quality evidence from across studies that harms associated with HBOT are usually mild, self-limiting, and with most resolving after the termination of treatment. The most common harms include myopia, barotrauma, claustrophobia, and oxygen toxicity. Life-threatening adverse events are rare but do occur on occasion and can include seizures and death.

DRAFT

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
Diabetic nonhealing wounds	Improved wound healing and limb salvage	Moderate	Moderate to high cost, offset by reduced hospitalization and other treatment costs	Moderate, favoring treatment	Recommended for coverage (*strong recommendation*), when criteria are met	Consistent evidence of effectiveness for improved wound healing for up to one year, based on 16 studies. Coverage criteria based on expert input supporting Medicare coverage criteria.
Venous ulcers	Possible improved healing	Low	Moderate	High	Not recommended for coverage (*weak recommendation*)	Two small trials find reduction in wound area, but no evidence for complete wound healing and no evidence of superior results after 30 days. Expert opinion does not recommend HBOT for this condition.
Compromised flaps and	Possible improved graft survival	Low	Moderate	Moderate	Recommended for coverage (*weak*	Four studies (3 RCTs) had mixed

DRAFT

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
grafts					*recommendation*)	results, with most evidence suggesting improved healing.
Surgical reconstruction without flaps and grafts	Unknown	Very Low	Moderate	High	Not recommended for coverage (weak)	The evidence is insufficient (no RCTs) to suggest that benefit exceeds harm.
Crush injuries	More complete wound healing	Low	Moderate	Moderate	Recommended for coverage (weak)	Evidence limited to one fair quality RCT showing more complete wound healing
Thermal burns	Unknown due to conflicting evidence	Very Low	Moderate	Moderate to high variability	Not recommended for coverage (*weak*)	Conflicting evidence from 2 RCTs prevents conclusions regarding efficacy.
Refractory osteomyelitis	Possible reduced rate of relapse	Very Low	Moderate	Moderate to high variability	Not recommended for coverage (weak)	Conflicting evidence from 2 trials prevents conclusions regarding efficacy .
Late radiation tissue injury	Improved outcomes	Moderate	Moderate	Low to moderate variability (preference towards treatment)	Recommended for coverage (*strong*)	Consistent evidence from 35 studies shows clinical improvement with HBOT
Brain injury – Acute TBI	Possible reduced risk of dying, unclear improvement in functional outcomes	Moderate	Moderate	Moderate variability	Not recommended for coverage (*weak*)	Evidence (7 studies) limited by high risk of bias and unclear clinical significance. Expert opinion does not recommend HBOT for this condition.
Brain injury other than TBI	Unknown	Very Low	Moderate	High variability	Not recommended for coverage (*weak*)	The evidence is insufficient (very poor quality) to suggest

DRAFT

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
						that benefit exceeds harm.
Cerebral palsy	Unknown	Very Low	Moderate to high (chronic condition)	Moderate variability (some would prefer treatment in spite of insufficient evidence)	Not recommended for coverage (*strong*)	Conflicting evidence (2 RCTs) prevents conclusions regarding efficacy.
Migraine HA	Aborts HA after 40-45 minutes, but no effect on prevention or reduction in N/V or rescue meds	Low	Moderate to high (Chronic condition)	High variability	Not recommended for coverage (*weak*)	Lack of clinically important benefit based on 3 RCTs suggests that benefits do not exceed harms, particularly given logistic considerations
Cluster HA	No benefit	Very low	Moderate to high	High variability	Not recommended for coverage (*weak*)	The evidence is insufficient (2 studies) to suggest that benefit exceeds harm.
Multiple sclerosis	No benefit	Moderate	Moderate to high	Moderate variability	Not recommended for coverage (*strong*)	Nine studies had mixed results, with most (7) finding no benefit
Sensorineural hearing loss – acute	Unknown	Low	Moderate	Moderate variability	Not recommended for coverage (*weak*)	Conflicting evidence (8 RCTs) prevents conclusions regarding efficacy. Potential small benefit is likely not clinically significant.
Sensorineural hearing loss – chronic	No benefit	Low	Moderate	Low variability (preference against HBOT)	Not recommended for coverage (*strong*)	Evidence suggests no benefit from HBOT.
Delayed or non-healing fractures	Unknown	Very Low	Moderate	Low variability (preference against HBOT)	Not recommended for coverage (*weak*)	Lack of evidence (0 RCTs) prevents conclusions regarding

DRAFT

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
						efficacy.
Bell's palsy	Unknown	Very Low	Moderate	Moderate variability	Not recommended for coverage (*weak*)	Lack of evidence (0 RCTs) prevents conclusions regarding efficacy.
Malignant otitis externa	Unknown	Very Low	Moderate	Low variability (preference against HBOT)	Not recommended for coverage (*weak*)	Lack of evidence (0 RCTs) prevents conclusions regarding efficacy.
Vascular dementia	Unknown	Very Low	Moderate to high (chronic condition)	Moderate variability	Not recommended for coverage (*weak*)	Lack of evidence (1 small poor RCT) prevents conclusions regarding efficacy.
Acute coronary syndrome	Decreased risk of death and MACE	Low	Moderate	High variability	Not recommended for coverage (*weak*)	Evidence from 6 RCTs limited by high risk of bias; concerns regarding logistic considerations. Expert opinion does not recommend HBOT for this condition.
Gas gangrene	Decreased risk of death and amputation	Low	Moderate	Low to moderate variability (preference towards treatment)	Recommended for coverage (*strong*)	Consistent evidence (4 cohort studies) suggest decreased mortality; RCT may not be reasonable.

*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

DRAFT

POLICY LANDSCAPE

Quality Measures

No quality measures were identified when searching the National Quality Measures Clearinghouse.

Payer Coverage Policies

Coverage policies for selected payers are included here.

Medicare

A national coverage determination for hyperbaric oxygen therapy was identified in the Medicare Coverage Database. Indications and limitations of coverage are detailed in Appendix D.

Washington HTA Limitations of Coverage

Hyperbaric Oxygen Therapy is a covered benefit with conditions consistent with the criteria identified in the reimbursement determination.

Limitations of Coverage

1. Crush injuries and suturing of severed limbs; as an adjunct when loss of function, limb, or life is threatened.
2. Compromised skin grafts and flaps (not for primary management of wounds).
3. Chronic refractory osteomyelitis unresponsive to conventional medical and surgical management.
4. Osteoradionecrosis; as an adjunct to conventional treatment.
5. For prevention of osteoradionecrosis associated with tooth extraction in a radiated field.
6. Soft tissue radionecrosis; as an adjunct to conventional treatment.
7. Diabetic wounds in patients who meet the following three criteria:
    a. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
    b. Patient has a wound classified as Wagner grade III or higher; and
    c. Patient has failed an adequate course of standard wound therapy.

Non-Covered Indicators

1. Brain injury including traumatic (TBI) and chronic brain injury
2. Cerebral Palsy
3. Multiple Sclerosis
4. Migraine or cluster headaches
5. Acute and chronic sensorineural hearing loss
6. Thermal burns
7. Non-healing venous, arterial and pressure ulcers

DRAFT

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/outcome[1]

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

***Moderate*:** The subcommittee is moderately confident in the 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

DRAFT

Appendix B. Applicable Codes

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
870-897	Open wound, various locations
250.8	Diabetes with other specified manifestations
990	Effects of radiation, unspecified
854	Intracranial injury of other and unspecified nature
389.1	Sensorineural hearing loss
730.0-2	Osteomyelitis
346.9	Migraine headache
399.0	Cluster headache
340	Multiple sclerosis
343	Cerebral palsy
940-949	Burns
800-829	Fractures
351.0	Bell's palsy
380.14	Malignant otitis externa
986	Toxic effects of carbon monoxide
E868	Accidental poisoning by CO
E952	Suicide by gases
E962.2	Assault by gases
E982.1	Poisoning by CO, undetermined
290.40	Vascular dementia
410	Acute myocardial infarction
411.81	Acute coronary occlusion without infarction
040.0	Gas gangrene
ICD-9 Volume 3 (Procedure Codes)	
93.95	Hyperbaric oxygenation
CPT Codes	
99183	Physician attendance/supervision of hyperbaric oxygen therapy, per session
HCPCS Level II Codes	
C1300	Hyperbaric oxygen, full body chamber, per 30 minutes

Note: Inclusion on this list does not guarantee coverage

DRAFT

Appendix C. HERC Guidance Development Framework

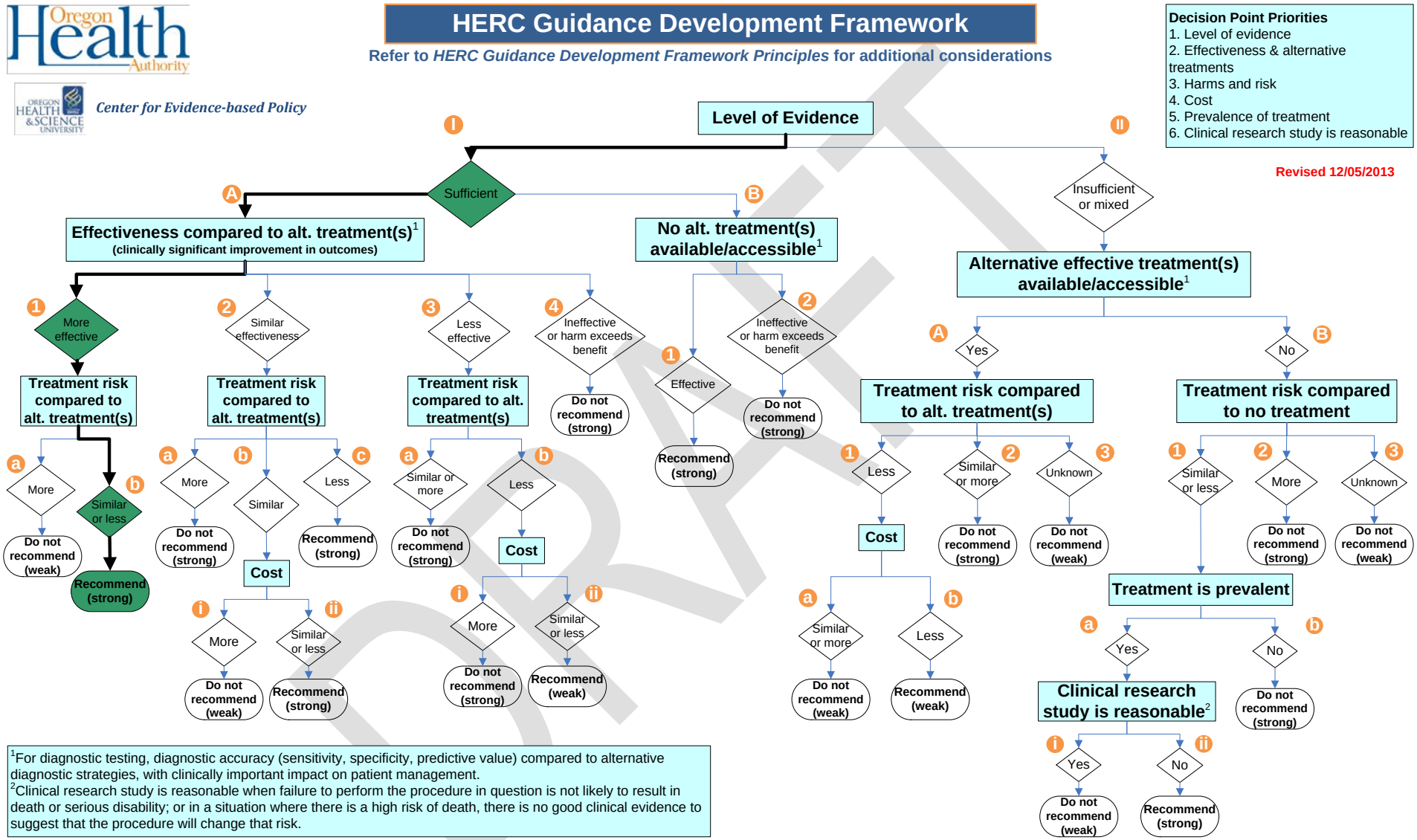
HERC Guidance Development Framework Principles

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.

DRAFT

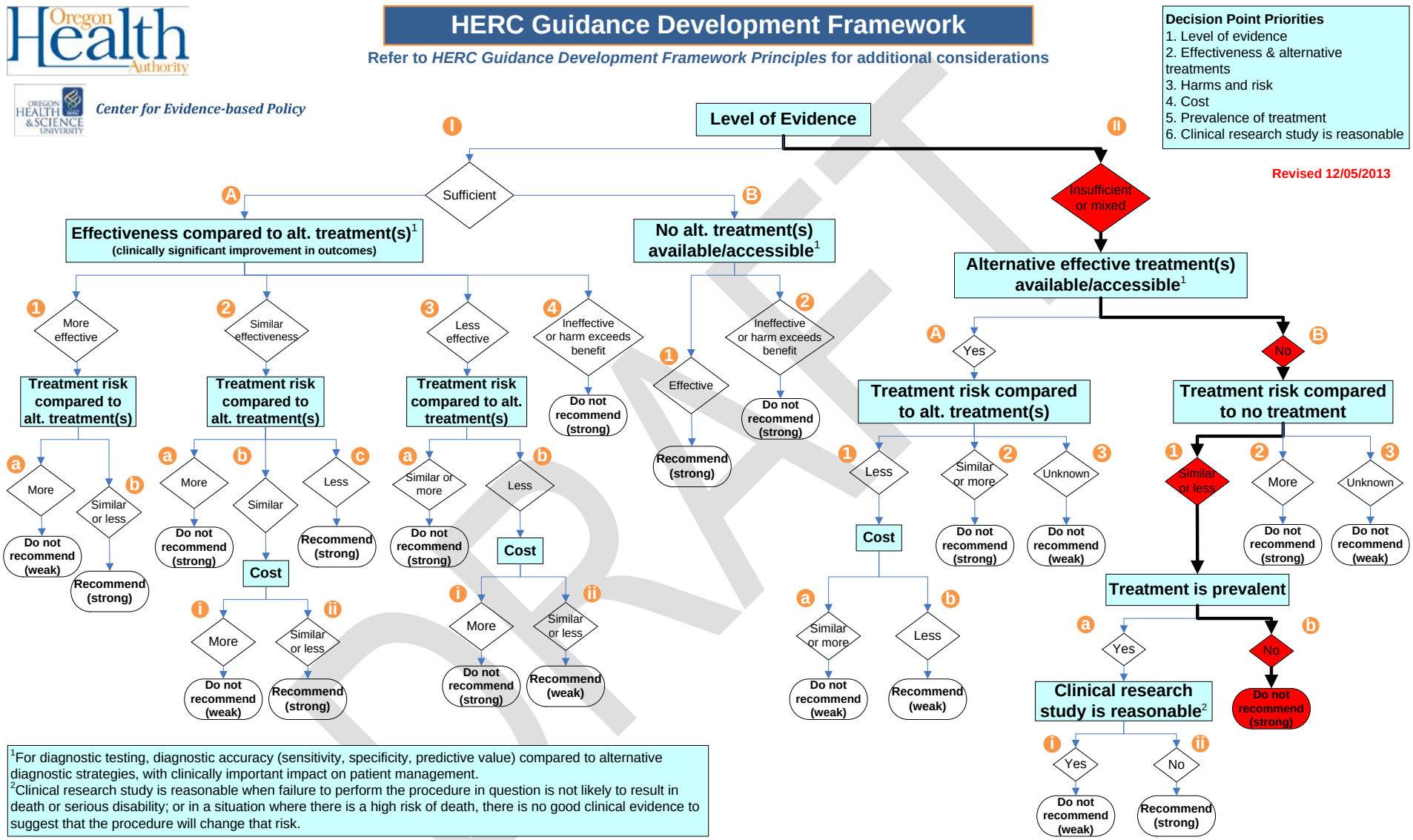
Diabetic nonhealing wounds; Venous ulcers; Compromised flaps and grafts; Crush injuries; Late radiation tissue injury; Gas gangrene



[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.

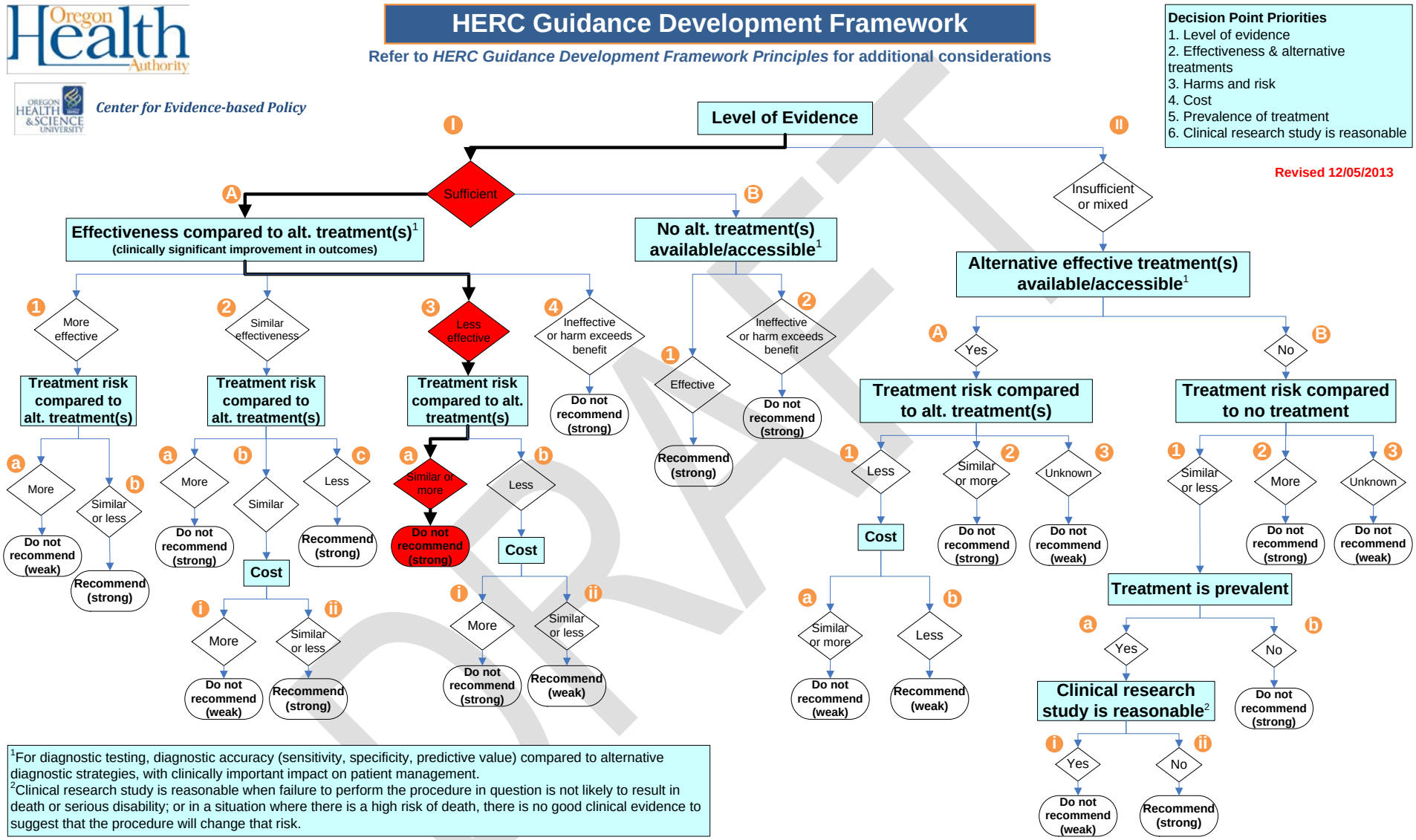
DRAFT

Cerebral Palsy



[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.

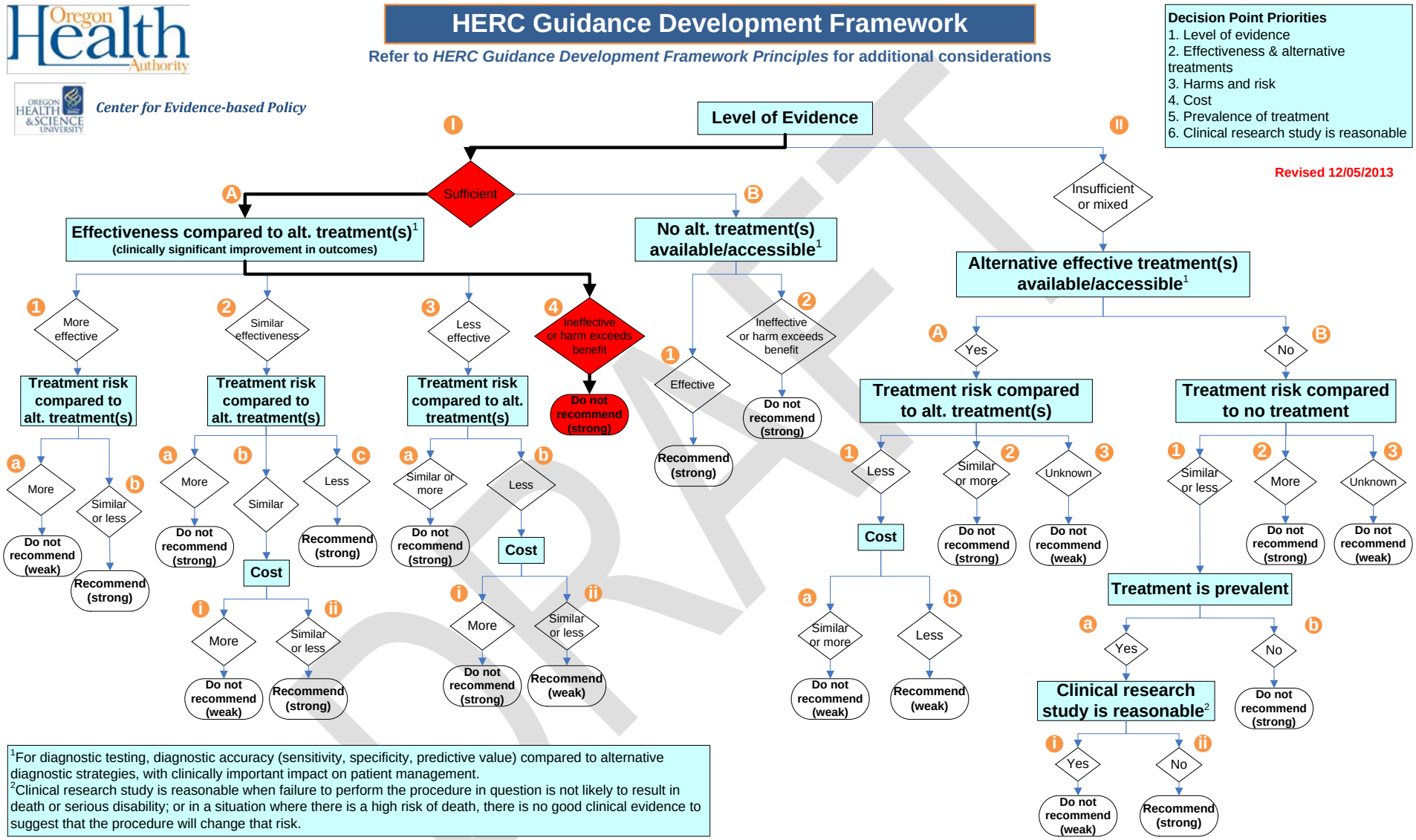
DRAFT



[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.

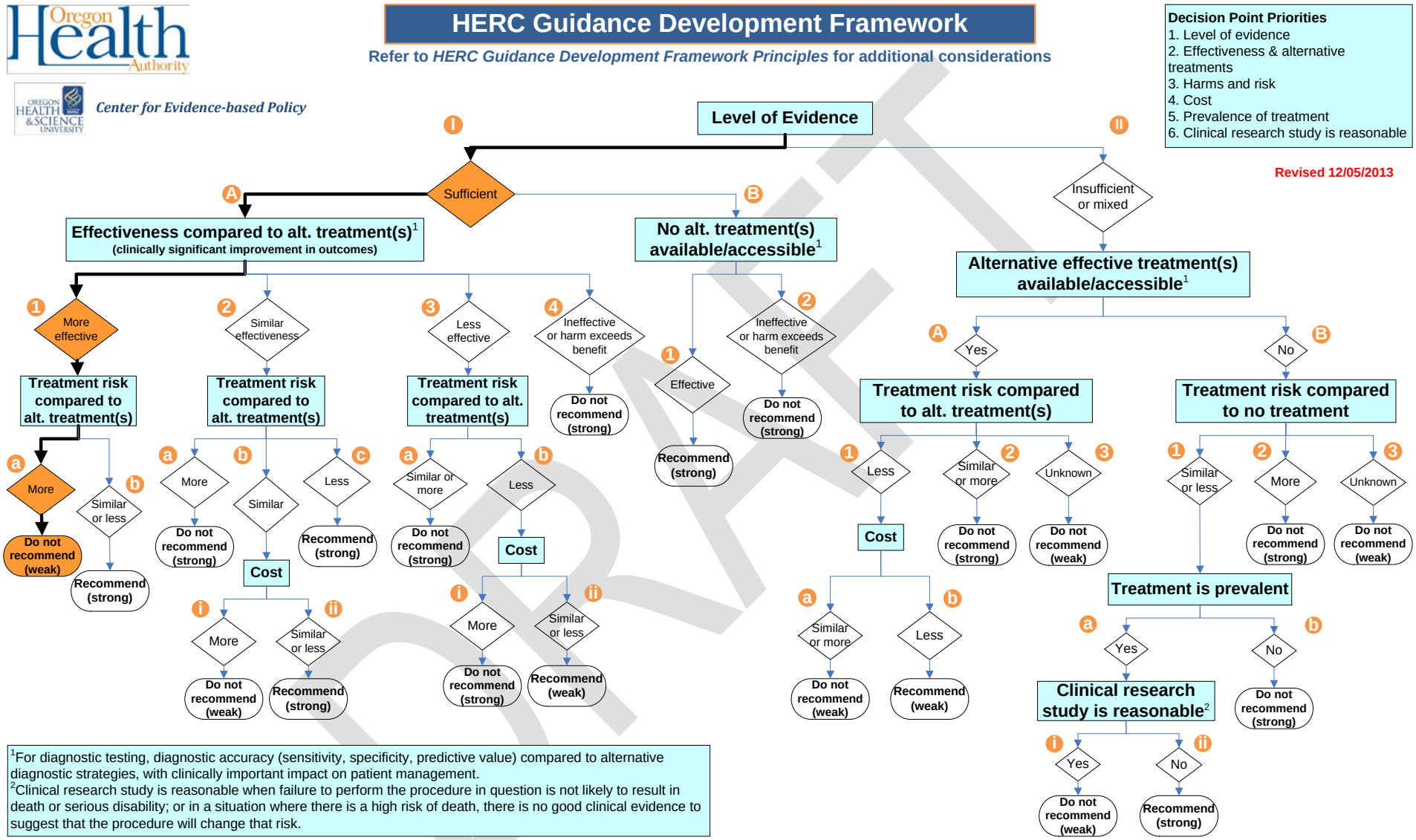
DRAFT

Multiple sclerosis



[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.

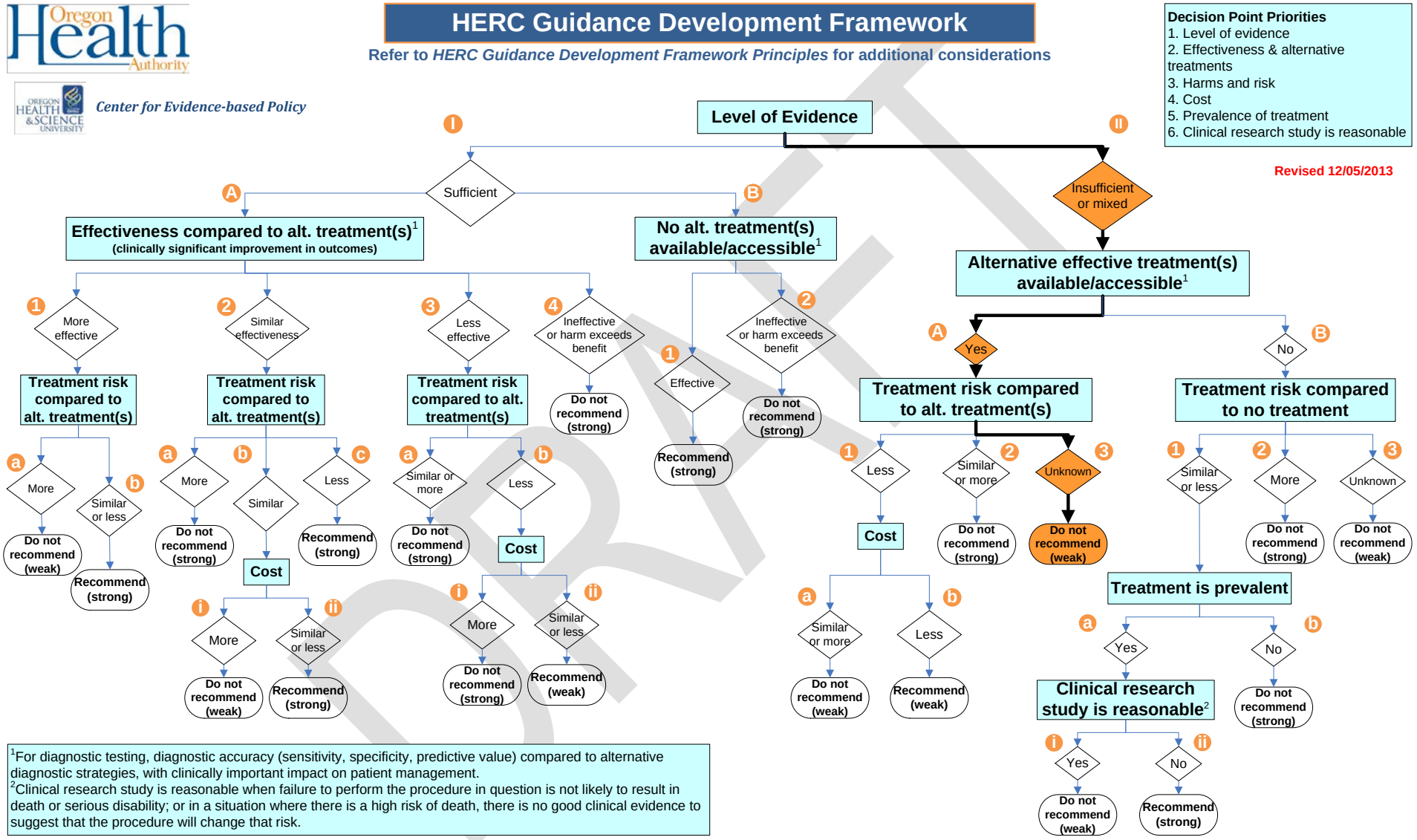
Acute coronary syndrome



[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.

DRAFT

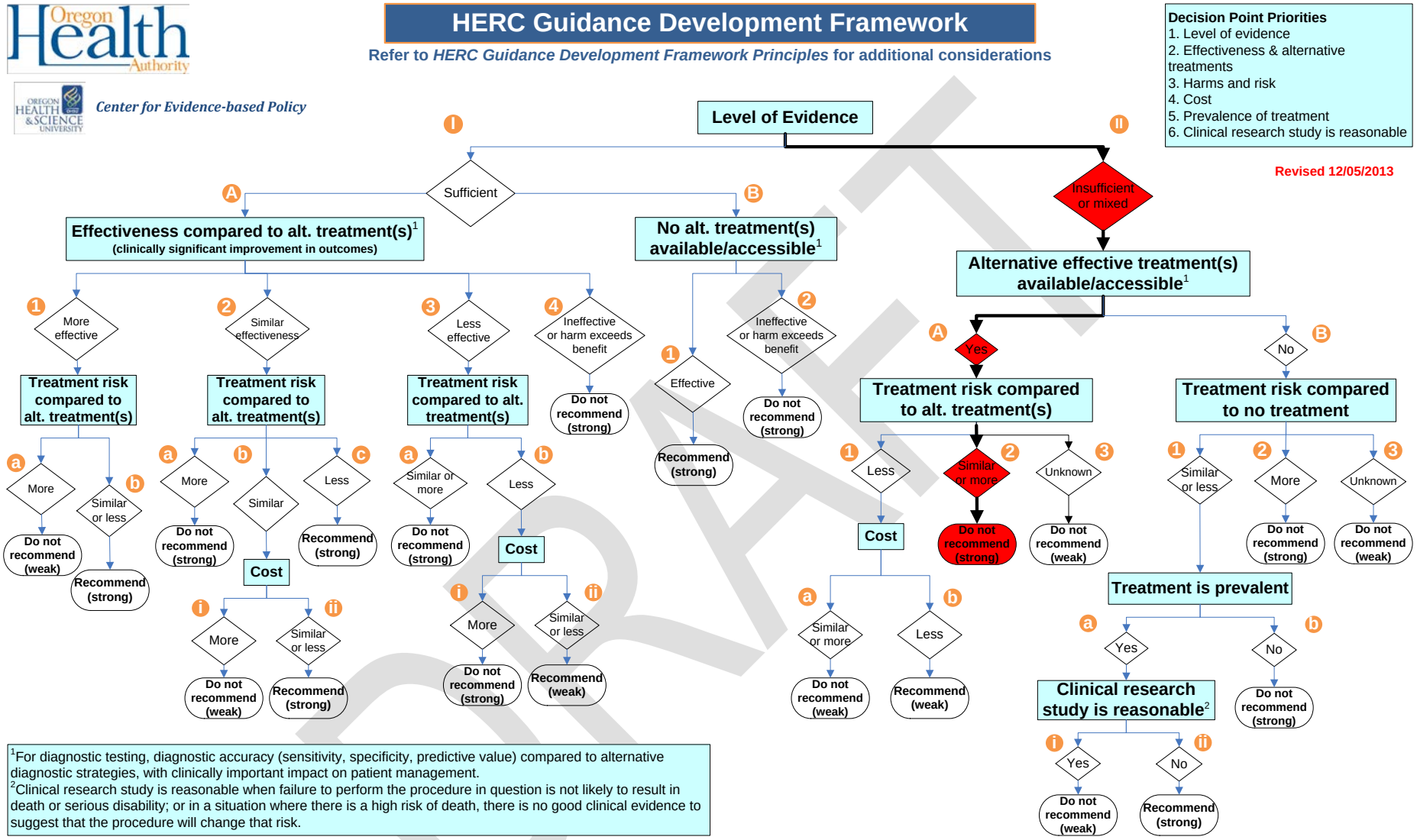
Brain injury other than TBI; Migraines; Cluster headache; Acute sensorineural hearing loss; Delayed or non-healing fractures; Bell's palsy; Malignant otitis externa; Vascular dementia; Thermal burns



[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.

DRAFT

Surgical reconstruction without flaps and grafts; Refractory osteomyelitis



[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.

DRAFT

Appendix D. CMS National Coverage Determination

National Coverage Determination: Hyperbaric Oxygen Therapy

Publication Number: 100-3
Manual Section Number: 20.29
Effective Date: 6/19/2006

Indications and Limitations of Coverage

A. Covered Conditions

Program reimbursement for HBO therapy will be limited to that which is administered in a chamber (including the one man unit) and is limited to the following conditions:

1. Acute carbon monoxide intoxication,
2. Decompression illness,
3. Gas embolism,
4. Gas gangrene,
5. Acute traumatic peripheral ischemia. HBO therapy is a valuable adjunctive treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened.
6. Crush injuries and suturing of severed limbs. As in the previous conditions, HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened.
7. Progressive necrotizing infections (necrotizing fasciitis),
8. Acute peripheral arterial insufficiency,
9. Preparation and preservation of compromised skin grafts (not for primary management of wounds),
10. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management,
11. Osteoradionecrosis as an adjunct to conventional treatment,
12. Soft tissue radionecrosis as an adjunct to conventional treatment,
13. Cyanide poisoning,
14. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment,
15. Diabetic wounds of the lower extremities in patients who meet the following three criteria:
    a. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
    b. Patient has a wound classified as Wagner grade III or higher; and
    c. Patient has failed an adequate course of standard wound therapy.

DRAFT

The use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30-days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in patients with diabetic wounds includes: assessment of a patient's vascular status and correction of any vascular problems in the affected limb if possible, optimization of nutritional status, optimization of glucose control, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate off-loading, and necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

B. Noncovered Conditions

All other indications not specified under §270.4(A) are not covered under the Medicare program. No program payment may be made for any conditions other than those listed in §270.4(A).

No program payment may be made for HBO in the treatment of the following conditions:

1. Cutaneous, decubitus, and stasis ulcers.
2. Chronic peripheral vascular insufficiency.
3. Anaerobic septicemia and infection other than clostridial.
4. Skin burns (thermal).
5. Senility.
6. Myocardial infarction.
7. Cardiogenic shock.
8. Sickle cell anemia.
9. Acute thermal and chemical pulmonary damage, i.e., smoke inhalation with pulmonary insufficiency.
10. Acute or chronic cerebral vascular insufficiency.
11. Hepatic necrosis.
12. Aerobic septicemia.
13. Nonvascular causes of chronic brain syndrome (Pick's disease, Alzheimer's disease, Korsakoff's disease).
14. Tetanus.
15. Systemic aerobic infection.
16. Organ transplantation.
17. Organ storage.
18. Pulmonary emphysema.
19. Exceptional blood loss anemia.

DRAFT

20. Multiple Sclerosis.
21. Arthritic Diseases.
22. Acute cerebral edema.

DRAFT

Draft Coverage Guidance Implementation: Oregon Health Plan Indications for Hyperbaric Oxygen Treatment

Recommendations of the Value-based Benefits Subcommittee on 08/14/2014:
For HERC review 11/13/2014

Recommended changes to the Prioritized List based on Coverage Guidance on Indications for Hyperbaric Oxygen Treatment.

1) For the October 1, 2014 and January 1, 2015 Prioritized Lists, add/delete diagnoses on line 358/336 as shown below

For the October 1, 2014 PL and January 1, 2015 PL:

Line: 358/336

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,E11.628I70.361-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.
   a. Diagnoses included on new line as shown below
   b. CPT and HCPCS codes included from both lines
   c. 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

DRAFT

3) Modify GN 107 as shown below

For all Lists:

GUIDELINE NOTE 107, HYPERBARIC OXYGEN

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

Hyperbaric oxygen is a covered service 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
- 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

Note detailed coding changes appear in the table below.

ICD-9 code	Code description	Current Placement	Staff recommendation
040.0	Gas gangrene	239,336	No change
250.7	Diabetes with peripheral circulatory disorders	8,30,169,239	Add to line 336 with guideline Includes gangrene
250.8	Diabetes with other specified manifestations	30,75,297,349,381	Add to line 336 with guideline Includes diabetic ulcers
290.40	Vascular dementia	75,205,297,349,381	Do not add
340	Multiple sclerosis	75,255,297,349,381	Do not add
343	Cerebral palsy	75,297,349,381,(498)	Do not add
346.9	Migraine headache	414	Do not add
351.0	Bell's palsy	491	Do not add
380.14	Malignant otitis externa	209	Do not add
389.1	Sensorineural hearing loss	317,450	Do not add
339.0	Cluster headache	414	Do not add
410	Acute myocardial infarction	73	Do not add
411.81	Acute coronary occlusion without infarction	73	Do not add
526.4	Inflammatory conditions of jaw	188,270,336	Osteomyelitis of the jaw Remove from 336
526.89	Other specified diseases of the jaws	336, 533	Guideline restricting to

			osteoradionecrosis of the jaw No change
639.0	Genital tract and pelvic infection following abortion or ectopic and molar pregnancies	39,336	Guideline restricting to necrotizing soft-tissue infection No change
639.6	Embolism following abortion or ectopic and molar pregnancies	39,336	No change
670.02	Major puerperal infection, delivered, with mention of postpartum complication	1,336	Guideline restricting to necrotizing soft-tissue infection No change
670.04	Major puerperal infection, postpartum condition or complication	1,336	Guideline restricting to necrotizing soft-tissue infection No change
673.0x	Obstetrical air embolism	1,336	No change
686.00	Pyoderma, unspecified	209,336(D)	Scheduled for removal from line 336
686.01/ L88,	Pyoderma gangrenosum	336	Scheduled for removal from line 336 with ICD-10
686.09/ L08.89,	Other pyoderma	336	Scheduled for removal from line 336 with ICD-10
709.3	Degenerative skin disorders	336,633	Unclear what diagnosis this is related to. Remove from 336
728.0	Infective myositis	135,239,336	Form of gangrene. No change
730.0	Acute osteomyelitis	188	Do not add
730.1	Chronic osteomyelitis	258	Do not add
730.2	Unspecified osteomyelitis	Excluded	Do not add
730.9	Unspecified infection of bone	258,336	Remove from line 336
785.4	Gangrene	239,336	No change
800-829	Fractures	Variable based on location	Do not add
854	Intracranial injury of other and unspecified nature	75,297,349,381	Do not add
870-897	Open wound, various locations	Variable based on location	Do not add—diabetic wounds and wounds with gangrene can be covered with other included codes
927-929	Crush injury	135	Add to 336 Note: some ICD-10 codes already added to line
940-949	Burns	61,76,200,613	Do not add

DRAFT

958.0	Air embolism	75,297,336,349,381	No change
986	Toxic effects of carbon monoxide	107,373	No change
987.x	Toxic effects of other gas	107,373	No change
990	Effects of radiation, unspecified	336,427	Current guideline limits to osteoradionecrosis—add soft tissue injury as an indication
993.3	Caisson disease	373	No change
996.52	Mechanical complication due to graft of other tissue, not elsewhere classified	336,427	No change in coding Add to guideline
996.7x	Other complications due to inserted device or prothesis	290,336	No change
999.1	Air embolism as a complication of medical care, not elsewhere classified	290,336	No change
E868	Accidental poisoning by CO	Ancillary	No change
E952	Suicide by gases	Ancillary	No change
E962.2	Assault by gases	Ancillary	No change
E982.1	Poisoning by CO, undetermined	Ancillary	No change

DRAFT

HERC Coverage Guidance – Indications For Hyperbaric Oxygen Therapy
Disposition of Public Comments

Table of Contents

Commenters 1
Public Comments Grouped by Commenter 2
References Provided by Commenters 8

Commenters

Identification	Stakeholder
A	Emeritus Physician and Clinical Professor of Medicine, Seattle, WA *[Submitted April 21, 2014]*
B	Medical Director, Springfield, OR *[Submitted June 1, 2014]*
C	Medical Director, Wound Healing and Hyperbaric Medicine, Adventist Medical Center, Portland, OR (appointed expert) *[Submitted June 30, 2014]*

DRAFT

Public Comment Grouped by Commenter

Ident.	#	Comment	Disposition
A	1	According to one website (biomedexperts.com), I am the #1 expert in the world on carbon monoxide (CO) poisoning, based upon the fact that I have more published more papers in the medical literature on the topic (46) than anyone ever has. I understand that you are considering elimination of reimbursement for hyperbaric oxygen treatment of CO poisoning. I am writing to tell you that I believe that would be a mistake.	Thank you for taking the time to comment.
	2	Last year, I served as the Clinical Expert for the State of Washington Health Technology Assessment of hyperbaric oxygen therapy. You may find it interesting that we did not even consider three commonly treated diagnoses where hyperbaric oxygen is considered proven, primary treatment -- decompression sickness, arterial gas embolism, and CO poisoning.	Thank you for providing this information, along with the transcript of the WA HTA meeting.
	3	I understand that your group is going back and re-evaluating yet another time clinical studies that are now over a decade old. You will not find the answer in meta-analyses such as that done by the Cochrane Group or the American Society of Emergency Medicine. All clinical trials in the area have had some flaws, some more than others. They have all used different endpoints (some clinically irrelevant) and have had varying degrees of follow-up (some even using questionnaires self-administered by the patient at home when they would not return for re-evaluation). All have also used different protocols for treatment of hyperbaric and control patients (one hospitalizing control patients not receiving hyperbaric treatment for three to six days of oxygen by mask, something that is not even done at their own institution or any other hospital in the world). There is no surprise that averaging six totally different studies yields no firm conclusions and the usual recommendation that "more good quality studies are needed." Well, it has been over a decade since Weaver published his clinical trial as lead article in the *New England Journal of Medicine*. No trials randomizing hyperbaric oxygen with normobaric oxygen are underway at this time, to my knowledge. I would probably be aware of it if there were any.	HTAS is aware of this controversy, and has elected not to make a recommendation regarding coverage or non-coverage of HBOT for CO poisoning.
	4	In the meantime, what is a managing physician to do? When you get severe CO poisoning tonight because of malfunction of your furnace and are taken to the emergency department, the physician there may call a regional or national expert in hyperbaric medicine for advice. Do you want the expert to say, "I don't know what to do because I am waiting for more high quality clinical trials to be performed and published"? Of course not. You would want the expert's opinion based upon his or her synthesis of the data available. And that opinion might be to give hyperbaric oxygen in selected cases.	See comment #3

DRAFT

Ident.	#	Comment	Disposition
	5	The most common hyperbaric treatment performed for CO poisoning in the US is one treatment, followed by up to two additional treatments if the patient remains symptomatic. The treatment is typically done as an outpatient and the goal is prevention of chronic brain injury. The alternative is oxygen by mask in the emergency department until the patient's blood carbon monoxide level is normal and the patient is asymptomatic (usually 6-12 hours).	Thank you for this information.
	6	The most similar experimental approach to this common practice was the study by Weaver and that is why most experts in the field use it for guidance instead of meta-analyses that give no management recommendations and simply call for additional research. Weaver demonstrated that a practical hyperbaric protocol reduced the incidence of chronic brain sequellae by 50% at one year, as compared to oxygen at sea level pressure.	There were methodologic problems with the Weaver study, as noted in the coverage guidance. Because of this controversy, HTAS has removed any reference to this condition in the coverage recommendations.
	7	I am sure that the cost of treating patients with CO poisoning with hyperbaric oxygen does not even show up on your state budget radar screen. Of an estimated 50,000 emergency department visits for CO poisoning in the US annually, only about 1,500 (3%) are treated with hyperbaric oxygen. The rest are treated in emergency departments (which may actually be more expensive in some situations, depending on the hospital's emergency department hourly charge for occupancy of a room). My speculation is that you are talking about less than $20,000 annually for hyperbaric oxygen treatment of selected carbon monoxide-poisoned patients in Oregon. Is your group willing to deny that and accept the responsibility that you are instead allowing you citizens to develop chronic brain injury because "more well designed clinically studies are needed"? I hope not.	Thank you for this information See comment #3; HTAS is not recommending against coverage for CO poisoning.
B	1	Thank you for the opportunity to provide public comment regarding hyperbaric oxygen therapy (HBOT). This is a subject of considerable concern to the citizens of Oregon.	Thank you for taking the time to comment.
	2	Attached is a review published in the prestigious *British Medical Journal* regarding evidence based medicine and the effectiveness of the parachute. Although it was written as satire, it points out a crucial concept relevant to your current endeavor defining indications for HBOT.	HTAS is aware of the parachute example, and in fact, it has been referenced by public commenters for a variety of previous topics that HTAS has considered.
	3	Higher levels of evidence are based on large scale human Randomized Controlled Trials (RCT), which we believe reflects medical reality. But, as the *BMJ* article symbolizes, not everything in reality can be reduced to such large scale RCT's for many reasons, not the least of which is the ability to collect large control populations, with very similar characteristics, willing or ethically appropriate to forgo a recognized treatment in the name of science. That is to say, there are simply not sufficient numbers of people willing, nor should be selected, to jump out of an airplane without a parachute in order to prove the value of the parachute for those who do. That does not negate the effectiveness of the parachute.	HTAS is aware of this and agrees that RCTs are not always feasible. When they are not can be considered feasible is a matter of common sense to some, but a matter of opinion to others. Indeed, whether or not a clinical trial is reasonable is explicitly considered in the guidance development framework attached to every coverage guidance (see pages 30-36). In the parachutes example, clearly no one would disagree with the feasibility of performing a RCT.

DRAFT

Ident.	#	Comment	Disposition
	4	We have the same difficulty with HBOT. There is a paucity of level 1A evidence for HBOT, not for lack of interest or motivation, but due to the practical and ethical impediments to producing a good RCT. In the case of the diabetic foot ulcer, for example, how can we possibly find a large cohort stratified for consistency in diabetes control, medications required for that control, medical comorbidities, obesity, smoking history, arterial disease, degree of neuropathy, quality of footwear, access to medical care and socioeconomic factors, all of which directly impact the outcome of the wound as confounding variables. Rather than negate the value of lower levels of evidence, especially experimental studies which are at the bottom of the "evidence pyramid", this is an inherent, hidden detraction of higher levels of evidence, including an RCT. It is erroneous to equate a well-designed RCT in an animal model with "poor" evidence.	HTAS is not entirely clear on the point that the commenter is making. We agree that stratifying a cohort based on a number of factors known to influence the outcome of procedure is challenging, but can usually be accomplished statistically in the analysis. A well designed RCT in the animal model is not "poor evidence", but has limited applicability in humans.
		The second point I will try to make is the problem of consolidating the entire spectrum of skin grafts and flaps into a single diagnostic category. There is a vast difference between a split thickness skin graft, a large, complex myocutaneous surgical flap, and a traumatic compromised tissue flap. It is erroneous to compare these as the same condition in assessing the effectiveness of HBOT for "grafts and flaps". It is here where the parachute problem becomes especially pertinent. In my experience treating patients with HBOT, one of the most urgent needs for this therapy is in a woman with breast reconstruction in which the nipple/areolar complex becomes compromised postoperatively. Hyperbaric oxygen is the treatment of choice as the nipple/areola becomes dusky, purple, dying and, I might add, physically and psychologically irreplaceable tissue. This is an emergency situation, but does not threaten life or limb. You will never see any RCT supporting the effectiveness of HBOT in this situation. The evidence will always be, at best, deductive and based on experimental models, low level "poor" evidence. But I can assure you that if this situation arises with you or a loved one, you ARE going to want HBOT and you are going to want it NOW. It would be erroneous for the State of Oregon to disallow, or even delay in any way, insurance coverage of this crucial treatment of a potentially devastating disfigurement on the basis of lack of evidence that will never exist. Although considerably more rare, the same may be said of sudden blindness in acute central retinal artery occlusion, or deafness in acute sensorineural hearing loss. Carbon Monoxide poisoning is yet another example where human RCT studies will never exist.	The coverage guidance document currently recommends coverage of HBOT for compromised flaps and grafts. Is the commenter suggesting that coverage NOT be recommended for some subset of flaps and grafts? If so, which subset is not defined. Central retinal artery occlusion is not addressed in this coverage guidance. See comments A3-7 regarding CO poisoning. Regarding acute sensorineural hearing loss, the appointed expert provided additional information, referencing a 2012 Cochrane review and the AAO practice guideline. This information was reviewed by HTAS at their April meeting, and is repeated in comment #C4.
	5	I appreciate the due diligence being done by the Oregon Health Evidence Review Commission. I know you will read this with due consideration. I hope you will all enjoy the parachute	Thank you for your comment.

DRAFT

Ident.	#	Comment	Disposition
		"study", but understand the seriousness of its underlying message.	
C	1	Thank you for the opportunity to provide additional comments regarding the OHA technology assessment on hyperbaric oxygen therapy. In large part, I have no disagreement with the recommendations of the technology assessment. I appreciate all of the work that has gone into the review by the OHA, and I will make this as brief as possible.	Thank you for your comment.
	2	There are three indications for which the HERC assessment does not recommend hyperbaric medicine that are all indications that have been reviewed and approved by the UHMS (thermal burns, refractory osteomyelitis, acute idiopathic sudden sensorineural hearing loss). The current UHMS indications book uses AHA criteria and not GRADE methodology, so it is difficult to use GRADE to argue for the use of HBOT. Dr. Murad's paper comparing the AHA criteria with GRADE is very informative, but has limitations in that it asks one single question and one single outcome for each hyperbaric indication. This limits the ability of a heterogenous body of literature to provide high quality, consistent answers for a single patient population.	HTAS does not disagree regarding the use of GRADE in this instance. HTAS has incorporated the Murad review into this coverage guidance.
	3	I am currently chair of the UHMS Clinical Practice Guideline Oversight Committee, and Dr. Murad is a member of the oversight committee as well. We are currently undertaking a more detailed review of all of the indications for HBOT using GRADE methodology, so we will shortly have a better ability to provide a more direct answer for these indications. My request would be for the HERC take these new publications under consideration (after they are published) in order to update their guidance documents.	HTAS will be sure to review this additional information when this coverage guidance is updated.
	4	Until then, please consider the comments regarding ISSHL that I have already been submitted to the committee. In brief, the Cochrane review on ISSHL did find that there was a significant improvement in the decibel level of hearing gain, but questioned the clinical significance of that improvement. I have provided the WHO definitions for hearing loss, showing that there was a significant improvement from moderate and severe hearing loss to minimal hearing loss, which does not require the use of hearing aids. Additionally, the American Academy of Otolaryngology and Head and Neck Surgery recommends HBOT for ISSHL (CPG attached), as there are no other treatment options that have had a similar improvement in hearing, which can be life-altering.	The reference provided is a process document outlining the methods used by the AAO to develop their practice guidelines. The AAO practice guideline on ISSHL was previously submitted by the commenter, and response was provided in another document (HBOT Supplemental Review: Additional Review of Evidence Provided by Public Commenter) and already reviewed by the committee. Commenter's previous statements regarding amount of hearing improvement demonstrated in the Cochrane review, and WHO hearing loss definitions, are correct, and are repeated below for ease of consideration: "for patients with severe hearing loss (61-80 dB loss) as defined by the World Health Organization (WHO), the improvement was 37.7 dB. For patients with moderate hearing loss (41-60 dB), the

Ident.	#	Comment	Disposition
			improvement in hearing was 19.3 dB. Using the WHO grades for hearing impairment, this represents a significant improvement from both of these categories to the slight hearing loss (26-40 dB) category (see attached slides courtesy of Heather Murphy-Lavoie, MD), which does not usually require a hearing aid. Considering that the costs of hearing aids are between $1500-3000 per pair, need to be replaced every few years, and do not provide fully functional hearing, a limited course of HBOT ($2000-5000 for a series of 10 sessions) may be a more cost effective and superior clinical result." The previous response to this comment is repeated below: The American Academy of Otolaryngology Clinical Practice Guideline (Stachler 2012) states the following with regard to use of HBOT for sudden hearing loss: "Value judgments: Although hyperbaric oxygen therapy (HBOT) is not widely available in the United States and is not recognized by many US clinicians as an intervention for ISSNHL, the panel felt that the level of evidence for hearing improvement, albeit modest and imprecise, was sufficient to promote greater awareness of HBOT as an intervention for ISSNHL." The authors of the guideline reference the SR included in the WA HTA report (Bennett 2007), and in summarizing this review, state the following: "Although the chance of a 50% improvement was not significantly increased following HBOT, the chance of a 25% increase was. Data indicated that a physician would need to treat 5 patients with HBOT therapy to improve 1 person's hearing by 25%. Whether this is truly clinically significant is debatable." A literature search performed by the guideline authors identified one additional RCT published after the date of the SR which found no significant difference between HBOT and the control arm in the percentage of patients who regained hearing either

DRAFT

Ident.	#	Comment	Disposition
			moderately or completely. The authors conclude with the following: "Given the small number of patients in the trials reviewed, methodological shortcomings, and poor reporting, the reported findings of benefit should be interpreted cautiously. The substantial cost, the potential adverse effects (including barotrauma), a question of the clinical significance of reported benefits, and the confounding effect of cointerventions (steroids, antivirals, rheologic agents) make it difficult to weigh benefits and harms."

DRAFT

References Provided by Commenters

Commenter	References
A	(1) Weaver, L. K., Hopkins, R. O., Chan, K. J., Churchill, S., Elliott, C. G., Clemmer, T. P., et al. (2002). Hyperbaric oxygen for acute carbon monoxidepoisoning. *New England Journal of Medicine, 347*(14), 1057-1067.
B	(1) Smith, G., & Pell, J. P. (2003). Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials. *Bmj*, *327*(7429), 1459-1461.
C	(1) Rosenfeld, R. M., Shiffman, R. N., Robertson, P. (2013). Clinical Practice Guideline Development Manual, Third Edition: A Quality-Driven Approach for Translating Evidence into Action. *Otolaryngology -- Head and Neck Surgery 148*: S1-S55.

DRAFT

Section 4.0

Coverage Guidances

Action Summary for Rescanning of Coverage Guidance Topics Approved in 2012

EbGS Recommended Actions to HERC:

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

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 Recommended Actions to HERC:

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)

Topic: MRI FOR BREAST CANCER SCREENING

Coverage Recommendation (Box Language):

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

Source report:

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

Scanning results:

One AHRQ review was identified on the use of breast MRI for evaluation of abnormalities identified during routine screening (mammography). Two reviews and one guideline were identified in the core sources that specifically addressed the use of MRI for breast cancer screening and were published after the date of the WA HTA report (an update is in progress and due for publication in December 2014). In addition, the USPSTF report on Screening for Breast Cancer is currently being updated; the final research plan was posted in July 2014. Summary results and/or conclusions of the two completed reviews and the one guideline are presented below:

Hayes. (2014). Magnetic Resonance Imaging (MRI) for Surveillance for Breast Cancer Recurrence Following Mastectomy and Breast Reconstruction
https://www.hayesinc.com/subscribers/subscriberArticlePDF.pdf?articleId=16955

- While the risk of locoregional recurrence is low after mastectomy, recurrences in residual breast tissue or the chest wall may be difficult to detect in a timely manner. Breast MRI is more sensitive than mammography for diagnosis of breast cancer; however, the rates of false-positive findings on postoperative MRI images of the breast limit the clinical utility of this test in women who have undergone reconstruction.
- Because there are numerous surgical techniques for reconstruction after breast cancer, and various histological types of breast cancer, designing a clinical trial with adequate power to examine the usefulness of breast MRI for surveillance for recurrence in patient subgroups could be challenging.
- The use of breast MRI increases facility utilization and costs due to the need for contrast media and the possibility that the test findings will prompt additional testing including

biopsy. Centers that provide breast MRI for surveillance should be equipped to perform MRI-guided breast biopsy.

Hayes Rating: D2

BCBS. (2014). Screening Asymptomatic women with dense breasts and normal mammograms for breast cancer. Accessed on September 9, 2014 from http://www.bcbs.com/blueresources/tec/vols/28/28_15.pdf

Author's Conclusions and Comment

As with mammography in general, the decision on which imaging modality(s) to use hinges in part on the tradeoff between detecting cancers and performing a much higher number of unnecessary biopsies to detect those cancers. This topic is clearly subject to continued controversy, as the response to recommendations to potentially reduce the number of screening mammograms for asymptomatic women in their 40s has shown. A related, but probably less difficult, issue is how many screening tests women undergo.

There are several areas where technologies are changing and where future studies may clarify the choices to be made. For example, ABUS performs faster and is less operator-dependent than handheld ultrasound. How the differences between ABUS and handheld US will translate into differences in health outcomes for women with dense breasts remain to be seen. Additional research on tomosynthesis may also be helpful. Given the variety of potential choices, careful studies of multiple modalities on the same women are useful. Because different types of imaging may be more or less accurate in detecting different types of breast cancer (e.g., invasive tumors versus ductal carcinoma in situ or larger [e.g., greater than 1 cm] or smaller tumors) or detecting it in women with different characteristics besides breast density (e.g., large versus small breasts), comparing the results of various types of breast imaging in different populations cannot be addressed simply by adjusting for women's age, tumor stage, etc. There is also a trade-off between enhancing the number of expected cancers by, for example, selecting women with additional risk factors, versus testing these technologies in a true screening population likely to be encountered in clinical practice. Finally, the assumption that finding more cancers using additional techniques besides mammography produces better health outcomes on a population level will need to be verified.

Women with dense breasts on mammography are at higher risk of breast cancer and of having any cancer missed by mammography. One possibility is to use additional imaging for women with dense breasts and normal mammograms. Both MRI and US have been

suggested by different groups. Existing evidence on US suggests that adding it to mammography will increase the cancer yield while also increasing the number of recalls and unnecessary biopsies. One study showed that adding MRI to mammography and US increases the sensitivity while decreasing the specificity. Digital mammography is more sensitive than film mammography for women with dense breasts. Insufficient evidence is available on other modalities, such as tomosynthesis and automated breast ultrasound.

NICE. (2013). Familial breast cancer: Classification and care of people at risk of familial breast cancer and management of breast cancer and related risks in people with a family history of breast cancer. Accessed on September 9, 2014, from http://www.nice.org.uk/guidance/cg164/resources/guidance-familial-breast-cancer-pdf

Surveillance for women with no personal history of breast cancer
MRI surveillance
1.6.7 Offer annual MRI surveillance to women:

- aged 30–49 years who have not had genetic testing but have a greater than 30%
- probability of being a BRCA carrier[1]
- aged 30–49 years with a known BRCA1 or BRCA2 mutation
- aged 20–49 years who have not had genetic testing but have a greater than 30% probability of being a TP53 carrier
- aged 20–49 years with a known TP53 mutation. [new 2013]

1.6.8 Consider annual MRI surveillance for women aged 50–69 years with a known TP53 mutation. [new 2013]

1.6.9 Do not offer MRI to women:

- of any age at moderate[2] risk of breast cancer
- of any age at high[3] risk of breast cancer but with a 30% or lower probability of being a BRCA or TP53 carrier

[1] Guidance recommends use of carrier probability calculation method such as BOADICEA (http://ccge.medschl.cam.ac.uk/boadicea)
[2] Lifetime risk of developing breast cancer is at least 17% but less than 30%.
[3] Lifetime risk of developing breast cancer is at least 30%. High risk group includes rare conditions that carry an increased risk of breast cancer, such as Peutz-Jegher syndrome, (STK11), Cowden (PTEN), familial diffuse gastric cancer (E-Cadherin).

- aged 20–29 years who have not had genetic testing but have a greater than 30% probability of being a BRCA carrier
- aged 20–29 years with a known BRCA1 or BRCA2 mutation
- aged 50–69 years who have not had genetic testing but have a greater than 30% probability of being a BRCA or a TP53 carrier, unless mammography has shown a dense breast pattern[4]
- aged 50–69 years with a known BRCA1 or BRCA2 mutation, unless mammography has shown a dense breast pattern.[5] [new 2013]

Surveillance for women with a personal and family history of breast cancer

MRI surveillance

1.6.13 Offer annual MRI surveillance to all women aged 30–49 years with a personal history of breast cancer who remain at high risk of breast cancer, including those who have a BRCA1 or BRCA2 mutation. [new 2013]

1.6.14 Do not offer MRI surveillance to any women aged 50 years and over without a TP53 mutation unless mammography has shown a dense breast pattern. [new 2013]

1.6.15 Consider annual MRI surveillance for women aged 20–69 years with a known TP53 mutation or who have not had a genetic test but have a greater than 30% probability of being a TP53 carrier. [new 2013]

Surveillance for women who remain at moderate risk of breast cancer

1.6.16 Ensure that surveillance for people with a personal history of breast cancer who remain at moderate risk of breast cancer is in line with Early and locally advanced breast cancer (NICE clinical guideline 80). [new 2013]

[4] Surveillance recommendations for this group reflect the fact that women who at first assessment had a 30% or greater BRCA carrier probability and reach 60 years of age without developing breast or ovarian cancer will now have a lower than 30% carrier probability and should no longer be offered MRI surveillance.
[5] Surveillance recommendations for this group reflect the fact that women who at first assessment had a 30% or greater TP53 carrier probability and reach 50 years of age without developing breast cancer or any other TP53-related malignancy will now have a lower than 30% carrier probability and should no longer be offered MRI surveillance.

Summary:

The recently published evidence addresses three different clinical scenarios, which are distinct from the current coverage guidance. One addresses women with a personal history of breast cancer, another women with dense breasts and the third, women with a history of familial breast cancer. Because there are two sources that are currently being updated and likely apply to a broader population, it may be desirable to delay update of this guidance until those reports are available.

Topic: VISCOSUPPLEMENATION FOR OSTEOARTHRITIS OF THE KNEE

Coverage Recommendation (Box Language):

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

Source report:

Hayes, Inc. (2010). *Hyaluronic Acid/Viscosupplementation.* Produced for the Medicaid Evidence-based Decisions Project and the Washington Health Technology Assessment Program. Portland, OR: Center for Evidence-based Policy, Oregon Health and Science University. Retrieved September 10, 2012, from http://www.hta.hca.wa.gov/documents/ha_final_report_042610.pdf Coverage Guidance: Viscosupplementation for Osteoarthritis of the Knee 10/11/2012 2

Hayes, Inc. (2010). *Viscosupplementation for osteoarthritis of the knee.* Produced for the Medicaid Evidence-based Decisions Project. Portland, OR: Center for Evidence-based Policy, Oregon Health and Science University. Retrieved September 10, 2012, from http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/index.cfm

Samson, D. J., Grant, M. D., Ratko, T. A., Bonnell, C. J., Ziegler, K. M., & Aronson, N. (2007). *Treatment of primary and secondary osteoarthritis of the knee.* AHRQ Evidence Report/Technology Assessment No. 157. AHRQ Publication No. 107-E012. Evidence Report/Technology Assessment, (157), 1-157. Retrieved September 10, 2012, from http://www.ncbi.nlm.nih.gov/books/NBK38385/

Scanning results:

Two reviews and one guideline pertaining to OA of the knee were identified in the core sources that were published after the date of the MED report. In addition, an AHRQ report is in progress, and a Hayes report addressed post-operative viscosupplementation for a variety of knee conditions. Summary results and/or conclusions of the two completed reviews and the guideline are presented below:

CADTH.(2014). Viscosupplementation for the Treatment of Osteoarthritis of the Knee: Clinical Effectiveness and Guidelines
http://www.cadth.ca/media/pdf/htis/mar-2014/RB0647%20Viscosupplementation%20for%20Knee%20OA%20Final.pdf

Of the nine systematic reviews (SR) identified, five SRs indicated some benefit regarding the use of intra-articular hyaluronic acid (IAHA) for the treatment of knee osteoarthritis (OA), whereas the other four SRs did not identify any benefit. In the SRs identifying benefits, IAHA was noted to be most efficacious around eight weeks. Prolonged effects of IAHA were observed in studies that compared it to other active treatments, particularly intra-articular corticosteroid injections. In the SRs that observed no benefits of IAHA for knee OA, one highlighted a particularly large placebo effect which appeared to skew the IAHA effectiveness, while another noted that probable industry bias swayed results in favour of IAHA. The other two SRs observed no clinical benefit; however, it was proposed that IAHA could be an alternative to non-steroidal anti-inflammatory drugs in older populations at risk for adverse events, due to its comparable favourable safety profile.

Three of the identified guidelines do not recommend IAHA for the treatment of knee OA10- and another does not include any conclusive recommendations. Of the four guidelines that recommend IAHA use for knee OA, one conditionally recommends IAHA for patients with inadequate response to initial therapy, another recommends IAHA use for moderate to severe knee OA (noting this was based on consensus only), and the other two guidelines provide algorithms for IAHA use.

Rutjes, A. W., Jüni, P., da Costa, B. R., Trelle, S., Nüesch, E., & Reichenbach, S. (2012). Viscosupplementation for Osteoarthritis of the KneeA Systematic Review and Meta-analysis. Annals of internal medicine, 157(3), 180-191. http://eds.b.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=4&sid=daad4ec3-c5c4-41d9-b425-6257dfbd50ff%40sessionmgr114&hid=106

Data Synthesis: Eighty-nine trials involving 12 667 adults met inclusion criteria. Sixty-eight had a sham control, 40 had a follow-up duration greater than 3 months, and 22 used cross-linked forms of hyaluronic add. Overall, 71 trials (9617 patients) showed that viscosupplementation moderately reduced pain (effect size, -0.37 [95% CI, -0.46 to -0.28]). There was important between-trial heterogeneity and an asymmetrical funnel plot: Trial size, blinded outcome assessment, and publication status were associated with effect size. Five unpublished trials (1149 patients) showed an effect size of -0.03 (CI, -0.14 to 0.09). Eighteen large trials with blinded outcome assessment (5094 patients) showed a clinically irrelevant effect size of -0.11 (CI, -0.18 to -0.04). Six trials (811 patients) showed that viscosupplementation increased, although not statistically

significantly, the risk for flare-ups (relative risk, 1.51 [CI, 0.84 to 2.72]). Fourteen trials (3667 patients) showed that viscosupplementation increased the risk for serious adverse events (relative risk, 1.41 [CI, 1.02 to 1.97]).

Limitations: Trial quality was generally low. Safety data were often not reported.

Conclusion: In patients with knee osteoarthritis, viscosupplementation is associated with a small and clinically irrelevant benefit and an increased risk for serious adverse events.

VADOD.(2014). Clinical practice guideline for the non-surgical management of hip & knee osteoarthritis.
http://www.healthquality.va.gov/guidelines/CD/OA/VADoDOACPGFINAL090214.pdf

Recommendations

22.For patients with symptomatic osteoarthritis of the knee, clinicians may consider intra-articular corticosteroid injection. [C]

23.There is insufficient evidence to recommend for or against the use of intra-articular hyaluronate/hylan injection in patients with OA of the knee; however it may be considered for patients who have not responded adequately to nonpharmacologic measures and who have an inadequate response, intolerable adverse events, or contraindications to other pharmacologic therapies. [I]

Summary:

Although the evidence is somewhat mixed, it does not appear to be substantially different from when the current coverage guidance recommendations were made. In addition, another review is currently in progress, it may be reasonable to consider updating this guidance once it has been completed.

Topic: LUMBAR DISCOGRAPHY

Coverage Recommendation (Box Language):

Lumbar discography should not be a covered service for patients with low back pain and uncomplicated lumbar degenerative disc disease.

Source report:

Washington State Health Care Authority Health Technology Assessment Program. (2007). *Spinal fusion and discography for chronic low back pain and uncomplicated lumbar degenerative disc disease.* Olympia, WA: Health Technology Assessment Program. Retrieved from http://www.hta.hca.wa.gov/discography.html

Scanning results:

One review and one protocol were identified in the core sources that was published after the date of the WA HTA report. Summary results and/or conclusions are presented below:

Hayes. (2010). Discography for Diagnosis of Low Back Pain. Accessed on September 9, 2014, from https://www.hayesinc.com/subscribers/subscriberArticlePDF.pdf?articleId=1893

Conclusions: The available evidence indicates that lumbar discography can result in high false-positive rates in identifying pain-producing discs, although pressure-controlled injection and strict classification of results can reduce the false-positive rate to ≤ 10%. When surgical outcome was used as the reference standard, some studies found a high degree of correlation between discography findings and degree of pain relief following surgery, while others failed to find any contribution of discography to surgical outcome. Inconsistencies among studies may relate to the variable results of these surgical approaches and/or to differences in discography protocol. In the only study comparing discography with an alternate diagnostic approach, outcome after spinal fusion was worse in patients undergoing discography than in patients undergoing discoblock (intradiscal anesthesia) but the source of pain differed in the discography and discoblock groups. Therefore, available data do not clearly establish the efficacy of lumbar discography or the comparable value of lumbar discography relative to other methods in identifying the source of low back pain or determining surgical candidacy and do not clarify whether a positive discogram is sufficient to warrant surgery, particularly when using updated standards for defining positive discograms. Data do suggest that lumbar discography, as currently performed, is not commonly associated with serious adverse effects.

Based on available data, the following Hayes Ratings are assigned:

C – For lumbar discography using pressure-controlled injection and updated criteria for positive discograms in patients with chronic severe low back pain who are potential candidates for spinal surgery, when conservative care has failed, and other diagnostic tests have not clearly confirmed a suspected disc as the source of pain.
D – For lumbar discography in patients who have a contraindication to the procedure. This Rating reflects concerns regarding the safety of this procedure in these patients.

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

This guideline is in the process of being updated, with an anticipated publication date in 2015.

Summary:

The recently published evidence does not contradict the current coverage guidance recommendations.

Topic: ARTIFICIAL DISC REPLACEMENT

Coverage Recommendation (Box Language):

Artificial disc replacement should be a covered service 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 contra-indications. 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 contra-indications. 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.

Source report:

Washington State Health Care Authority Health Technology Assessment Program. (2008). HTA report: Artificial discs replacement (ADR). Olympia, WA: Health Technology Assessment Program. Retrieved from http://www.hta.hca.wa.gov/documents/adr_final091908.pdf

Scanning results:

Five reviews were identified in the core sources that were published after the date of the WA HTA, as well as two guidelines.

Blue Cross Blue Shield Association (2014). Artificial Intervertebral Disc Arthroplasty for Treatment of Degenerative Disc Disease of the Cervical Spine. Technology Evaluation Center Assessment Program. http://www.bcbs.com/blueresources/tec/vols/28/28_13.pdf

"Artificial intervertebral disc arthroplasty (AIDA) for the treatment of patients with cervical degenerative disc disease does not meet the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria."

- Has regulatory approval
- Evidence is insufficient to support conclusions about the comparative effect of AIDA on health outcomes
- While studies show non-inferiority to fusion (6 RCTs), however, the design of the trials allows some margin of inferiority.
- Similar clinical outcomes at 2 years, continued to 4-5 years but with high drop out in the longer studies, resulting in a lack of certainty about long term outcomes
- Have not been evaluated outside the investigational setting

---

Blue Cross Blue Shield Association (2014). Artificial Lumbar Disc Arthroplasty. Technology Evaluation Center Assessment Program. http://www.bcbs.com/blueresources/tec/vols/28/28_07.pdf

"the use of an artificial disc in lumbar spine arthroplasty for chronic symptomatic degenerative disc disease unresponsive to conservative management does not meet the TEC criteria."

- Has regulatory approval
- This evidence is insufficient to demonstrate a relative clinical benefit of ProDisc versus fusion (1 RCT), particularly because the effectiveness of the comparator— fusion—versus nonsurgical treatments is not well defined. Thus, the randomized trial of ProDisc is suspect as a valid noninferiority trial and does not prove superiority.
- The evidence is insufficient to determine whether use of ProDisc in lumbar spine arthroplasty improves the net health outcome of patients with symptomatic DDD.
- The evidence is insufficient to determine whether use of ProDisc in lumbar spine arthroplasty is as beneficial as lumbar spinal fusion. The artificial disc was not compared with nonsurgical approaches.
- Have not been evaluated outside the investigational setting

---

Hayes. (2012). Artificial Disc Replacement for Cervical Degenerative Disc Disease. Reviewed Dec 17, 2013. https://www.hayesinc.com/subscribers/subscriberArticlePDF.pdf?articleId=11387

Conclusions: Several moderate-size randomized controlled trials (RCTs) comparing different types of artificial cervical discs with anterior cervical discectomy and fusion (ACDF) have been published. Evidence to date demonstrates that total disc replacement (TDR) is at least as effective as ACDF in improving signs and symptoms associated with degenerative disease and improving quality of life (QOL)

for up to 2 years. The evidence also shows that total disc replacement (TDR) reduces the need for reoperation and reduces the incidence of dysphagia. Low-quality evidence suggests that TDR reduces the risk of new adjacent segment disease (ASD) but may have higher rates of intraoperative and perioperative complications. Reliable follow-up data for more than 3 years are lacking, which is an especially serious limitation regarding the evidence for the intended advantage of TDR (reduction in long-term ASD). Positive but sparse evidence suggests that bilevel TDR is less safe than single-level TDR, but a few studies with several limitations suggest that it is comparable to bilevel ACDF in safety and efficacy.

Hayes Rating (based on 12 RCTs): B - For single-level TDR for the treatment of cervical disc disease in patients who are candidates for ACDF and who do not have forms of degenerative disc disease, allergies, comorbidities, or concomitant treatments that are expected to interfere with successful arthroplasty.

D2 – For TDR in patients with multilevel cervical disc disease who are candidates for ACDF. This Rating is based on positive but very sparse evidence regarding the efficacy and safety of TDR for the treatment of multilevel disease.

Hayes. (2013). Lumbar Total Disc Replacement for Degenerative Disc Disease. https://www.hayesinc.com/subscribers/subscriberArticlePDF.pdf?articleId=6963

Conclusions: The available evidence suggests that, compared with spinal fusion, lumbar total disc replacement (LTDR) for degenerative disc disease (DDD) using the ProDisc or Charité may lead to improved outcomes lasting ≥ 5 years after surgery. However, the longer-term clinical outcome of LTDR is still unclear. The evidence from uncontrolled long-term studies suggests that potential degeneration of adjacent discs and facets and wear of the polyethylene part of the disc may occur and that, in some cases, revision surgery may be needed. Long-term follow-up results from randomized controlled studies are available from only 2 randomized trials, and it is, therefore, not known if the benefits of LTDR are maintained. Furthermore, patient selection criteria still need to be refined.

Hayes Rating (based on 9 RCTs): C For LTDR using the ProDisc or Inmotion (formerly Charité) in patients with DDD who would otherwise undergo lumbar spinal fusion. This Rating is based on the evidence suggesting that these discs may lead to improved outcomes compared with spinal fusion, the concern about potential degeneration of adjacent discs and wear of the disc itself, and the potential need for revision surgery.

D 2 – For LTDR using the Maverick, FlexiCore, or Kineflex discs in patients with DDD who would otherwise undergo lumbar spinal fusion. This Rating is based on the paucity of evidence for these types of artificial discs.

Jacobs W, Van der Gaag NA, Tuschel A, de Kleuver M, Peul W, Verbout AJ, Oner FC. (2012). Total disc replacement for chronic back pain in the presence of disc degeneration. Cochrane Database of Systematic Reviews. Issue 9. Art. No.: CD008326. DOI:10.1002/14651858.CD008326.pub2. http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD008326.pub2/pdf

Based on 7 RCTs.

"Although statistically significant, the differences between disc replacement and conventional fusion surgery for degenerative disc disease were not beyond the generally accepted clinical important differences with respect to short-term pain relief, disability and Quality of Life. Moreover, these analyses only represent a highly selected population. The primary goal of prevention of adjacent level disease and facet joint degeneration by using total disc replacement, as noted by the manufacturers and distributors, was not properly assessed and not a research question at all. Unfortunately, evidence from observational studies could not be used because of the high risk of bias, while these could have improved external validity assessment of complications in less selected patient groups. Non-randomised studies should however be very clear about patient selection and should incorporate independent, blinded outcome assessment, which was not the case in the excluded studies. Therefore, because we believe that harm and complications may occur after years, we believe that the spine surgery community should be prudent about adopting this technology on a large scale, despite the fact that total disc replacement seems to be effective in treating low-back pain in selected patients, and in the short term is at least equivalent to fusion surgery."

NICE. (2009). Prosthetic intervertebral disc replacement in the lumbar spine. http://www.nice.org.uk/guidance/ipg306/resources/guidance-prosthetic-intervertebral-disc-replacement-in-the-lumbar-spine-pdf

"Current evidence on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

NICE. (2010). Prosthetic intervertebral disc replacement in the cervical spine. http://www.nice.org.uk/guidance/ipg341/resources/guidance-prosthetic-intervertebral-disc-replacement-in-the-cervical-spine-pdf

"Current evidence on the efficacy of prosthetic intervertebral disc replacement in the cervical spine shows that this procedure is as least as efficacious as fusion in the short term and may result in a reduced need for revision surgery in the long term. The evidence raises no particular safety issues that are not already known in relation to fusion procedures. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit."

Summary:

The recently published evidence is conflicting, with two sources supporting the current coverage guidance recommendations for cervical artificial disc and one contradicting them. Similarly, one source supports the current coverage guidance recommendations for lumbar artificial disc and two sources contradict them. However, since the recommendations for this coverage guidance relied primarily on FDA indications rather than the evidence source, updating this guidance document may not be required.

Topic: HIP RESURFACING

Coverage Recommendation (Box Language):

Hip resurfacing should be a covered service for patients who are likely to outlive a traditional prosthesis and who would otherwise require a total hip replacement, and should only be done by surgeons with specific training in this technique.

The following criteria should be required:

- Diagnosis of osteoarthritis or inflammatory arthritis;
- Individual has failed nonsurgical management; and
- The device is FDA approved.

Patients who are candidates for hip resurfacing must not have FDA contraindications including:

- Patients with active or suspected infection in or around the hip joint, or sepsis
- Patients who are skeletally immature
- Patients with any vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery
- Patients with bone stock inadequate to support the device, including severe osteopenia or a family history of severe osteoporosis or osteopenia
- Patients with osteonecrosis or avascular necrosis with >50% involvement of the femoral head
- Patients with multiple cysts of the femoral head
- Females of childbearing age
- Patients with known moderate-to-severe renal insufficiency
- Patients who are immunosuppressed with diseases such as AIDS or persons receiving high doses of corticosteroids
- Patients who are severely overweight
- Patients with known or suspected metal sensitivity

Source report:

Washington State Health Care Authority Health Technology Assessment Program. (2009). *HTA final report: Hip resurfacing.* Olympia, WA: Health Technology Assessment Program. Retrieved from http://www.hta.hca.wa.gov/documents/hip_final_report_102309.pdf

Scanning results:

Two reviews were identified in the core sources that were published after the date of the WA HTA, one of which is an update to the WA HTA report, as well as a Cochrane protocol and one guideline.

CADTH. (2012). Metal on Metal Total Hip Replacements or Hip Resurfacing for Adults: A Review of Clinical Effectiveness and Cost Effectiveness. http://www.cadth.ca/media/pdf/htis/nov-2012/RC0405%20MOM%20Final.pdf

- Metal on metal (MOM) hip resurfacing arthroplasty (HRA) patients experienced higher rates of revision, femoral neck fractures and component loosening than total hip replacement (THR) patients.
- There was a reduced incidence of dislocation following HRA compared to THR.
- Stemmed MOM THR had survival rates of 71% and 100% at mean follow-ups ranging from 36 months to 336 months.
- MOM HRA had survival rates of 84% to 100% at mean follow-ups ranging from 39 to 89 months.
- No significant differences in the rates of mortality, dislocation or deep hip joint infection were found between groups.

Washington State Health Care Authority Health Technology Assessment Program. (2013). HTA final report: Hip resurfacing (Re-review). Olympia, WA: Health Technology Assessment Program. Retrieved from http://www.hca.wa.gov/hta/Documents/hip_final_report_100913.pdf

Efficacy (≤2 year): There is MODERATE evidence from three small randomized controlled trials that hip resurfacing (HR) is similar to total hip arthroplasty (THA - replacement) with respect to short-term (<2 year) functional, quality of life, and activity outcome.

Efficacy (>2 year): There are NO DATA available to assess efficacy beyond two-year follow-up.

Effectiveness (Short-term, <5 years): There is LOW evidence from studies directly comparing HR with THA to suggest that short term (≤5 years) patient-reported outcomes, clinician-based outcomes, and pain are similar comparing HR and THA. Activity scores tend to be slightly higher (better) in HR patients.

Effectiveness (Mid-term, 5-10 years): There is INSUFFICIENT evidence from one cohort study to suggest that at an average of 5.9 years follow-up, patients treated with HR may have better quality of life and activity outcome scores, but similar functional scores, compared with those treated with THA.

Revision (Short-term, ≤5 years): There is HIGH evidence from three large registry studies that short-term revision risks are higher in patients treated with HR compared with those treated with THA. At three years, there is between 20-50% higher risk of revision among those receiving HR vs. THA. The absolute risk is 3% in the HR group and between

2- 3% in the THA group. At five years, the higher risk is between 30-80%. The absolute risk ranges from 5 to 6% in the HR group and 1 to 4% in the THA group.

Revision (Mid-term, 6-10 years): There is HIGH evidence from three large registry studies that 7 and 10-year revision risks are higher ranging from 40-100% in patients receiving HR versus THA. The absolute risk at 7 years is between 6-9% in the HR group and between 3- 4% in the THA group.

Revision (Long-term, 10+ years): There is LOW evidence from one registry study that 11-year revision risks are higher in patients receiving HR (10%) versus THA (7%).

Complications: There is HIGH evidence from up to 3 RCTs and up to 6 observational studies that

- femoral component loosening occurs 8 times more frequently in HR patients than in THA patients, 2.7% vs. 0.3%
- heterotopic ossification occurs nearly twice as often in HR patients compared with THA patients, 19.8% vs. 11.4%.
- dislocation occurs less frequently in HR vs. THA patients, 0.5% vs. 2.8%.

There is MODERATE evidence that deep infection occurs less frequently in patients undergoing HR compared with THA, 0.4% vs. 1.8%. The risk of femoral neck fracture and avascular necrosis in HR patients is 2% and 1%, respectively.

Metal Ion Safety: There are consistently higher median concentrations of the primary metal ions cobalt and chromium in the blood or hair of HR patients compared with non-MoM THA (MoP and ceramic) patients in 5 studies with up to 3-year follow-up. High blood levels of cobalt and chromium are associated with poor outcomes (revision or poorly functioning hip) compared with low blood levels in patients receiving HR in 3 studies. Higher serum ion levels of cobalt and chromium are associated with pseudotumor formation following MoM HR and MoM THA in 3 studies. MoM hip prostheses (both HR and THA) are not associated with an increased risk of cancer compared with THA with other bearing surfaces in 3 registry studies. There is no negative impact on renal function across 6 studies evaluating patients following MoM HR or MoM THA.

Revisions: There is INSUFFICIENT evidence from one small study reporting similar functional and quality of life outcomes comparing HR revision with THA revision at final follow-up (range, 2-7 years).

Subpopulations: There is HIGH evidence from a large registry study that the diagnosis of developmental dysplasia (DD) modifies the rate of revision in HR and THA; those with DD receiving HR have significantly higher revision rates than those receiving THA or those with other diagnoses receiving HR or THA. There is HIGH evidence from a large registry study that gender modifies the rate of revision in HR and THA; females receiving HR have significantly higher revision rates than females receiving THA or males receiving HR or THA. Smaller femoral component head size results in significantly higher revision rates for those receiving HR while larger femoral component heads result in higher revision rates in those receiving THA.

NICE. (2014). Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip (review of technology appraisal guidance 2 and 44). http://www.nice.org.uk/guidance/ta304/resources/guidance-total-hip-replacement-and-resurfacing-arthroplasty-for-endstage-arthritis-of-the-hip-review-of-technology-appraisal-guidance-2-and-44-pdf

Prostheses for total hip replacement and resurfacing arthroplasty are recommended as treatment options for people with end-stage arthritis of the hip only if the prostheses have rates (or projected rates) of revision of 5% or less at 10 years.

Summary:
The recently published evidence does not contradict the current coverage guidance recommendations.

Topic: Management of Chronic Otitis Media with Effusion in Children

Coverage Recommendation (Box Language):

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

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

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

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

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

Source report:

Effros, R., & Little, A. (2010). *Pressure equalization tubes in children.* (Produced for the Medicaid Evidence-based Decision Project). Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

Key Sources Cited in MED Report:

American Academy of Family Physicians, American Academy of Otolaryngology – Head and Neck Surgery, & American Academy of Pediatrics (AAFP/AAOHNS/AAP) Subcommittee on Otitis Media with Effusion. (2004). Clinical Practice Guideline: Otitis Media with Effusion. *Pediatrics, 113*(5), 1412-1429.

Griffin, G., Flynn, C.A., Bailey, R.E., & Schultz, J.K. (2006). Antihistamines and/or decongestants for otitis media with effusion (OME) in children. *Cochrane Database of Systematic Reviews*, *4*(CD003423), 1-44.

Kay, D.J., Nelson, M., & Rosenfeld, R.M. (2001). Meta-analysis of tympanostomy tube sequelae. *Otolaryngology-Head and Neck Surgery*, *124*, 374-380.

Leach, A.J., & Morris, P.S. (2006). Antibiotics for the prevention of acute and chronic suppurative otitis media in children. *Cochrane Database of Systematic Reviews*, *4*(CD004401), 1-70.

Lous, J., Burton, M.J., Felding, J., Ovesen, T., Rovers, M., & Williamson, I. (2005). Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. *Cochrane Database of Systematic Reviews*, *1* (CD001801), 1-58.

Mandel, E.M., & Casselbrant, M.L. (2006). Recent developments in the treatment of otitis media with effusion. *Drug, 66*(12), 1545-1576.

McDonald, S., Langton Hewer, C.D., & Nunez, D.A. (2008). Grommets (ventilation tubes) for recurrent acute otitis media in children. *Cochrane Database of Systematic Reviews*, *4*(CD 004741), 1-14.

National Collaborating Centre for Women's and Children's Health. (2008). Surgical management of otitis media with effusion in children. London: National Institute for Health and Clinical Excellence (NICE). Retrieved July 6, 2012, from www.nice.org.uk/nicemedia/pdf/CG60NICEguideline.pdf

Perera, R., Haynes, J., Glasziou, P.P., & Heneghan, C.J. (2006). Autoinflation for hearing loss associated with otitis media with effusion. *Cochrane Database of Systematic Reviews, 4*(CD006285), 1-28.

Rovers, M.M., Black, N., Browning, G.G., Maw, R., Zielhuis, G.A., & Haggard, M.P. (2005). Grommets in otitis media with effusion: an individual patient data meta-analysis. *Archives of Diseases of Childhood*, *90*(5), 480-485.

Simpson, S.A., Thomas, C.L., van der Linden, M., MacMillan, H., van der Wouden, J.C., & Butler, C.C. (2007). Identification of children in the first four years of life for early treatment for otitis media with effusion. *Cochrane Database of Systemic Reviews*, *1*(CD004163), 1-24.

Thomas, C.L., Simson, S., Butler, C., & van der Voort, J. (2006). Oral or topical nasal steroids for hearling loss associated with otitis media with effusion in children. *Cochrane Database of Systemic Reviews*, *3*(CD001935), 1-26.

Scanning results:

Eight reviews were identified in the core sources that were published after the date of the MED report (some were updates of Cochrane reviews included in the guidance document). Summary results and/or conclusions are presented below:

Williamson, I. (2011). Otitis media with effusion in children. BMJ Clinical Evidence, 01(502), 1-30.

- Oral antibiotics, antihistamines plus oral decongestants, or mucolytics may be of no benefit in OME, and can cause adverse effects.
- Oral corticosteroids are unlikely to improve symptoms in OME, and can cause growth retardation.
- Intranasal corticosteroids are unlikely to be of benefit in children with bilateral otitis media with effusion.
- Ventilation tubes may improve short-term outcomes, but the clinical effect size is small. They may also increase the risk of tympanic membrane abnormalities. Ventilation tubes improve hearing for the first 2 years, but have no longer-term benefit, and may not improve cognition or language development.
- Adenoidectomy may improve hearing when performed with tympanostomy, but the clinical relevance of the improvements is unclear.
- Combination treatment with ventilation tubes plus adenoidectomy may be more effective than adenoidectomy alone.

van den Aardweg MTA, Schilder AGM, Herkert E, Boonacker CWB, Rovers MM. Adenoidectomy for otitis media in children. (2010). Cochrane Database of Systematic Reviews. Issue 1. Art. No.: CD007810. DOI: 10.1002/14651858.CD007810.pub2.

Main results:

Fourteen randomised controlled trials (2712 children) studying the effectiveness of adenoidectomy in children with otitis media were evaluated. Most of these trials were too heterogeneous to pool in a meta-analysis. Loss to follow up varied from 0% to 63% after two years.

Adenoidectomy in combination with a unilateral tympanostomy tube has a beneficial effect on the resolution of OME (risk difference (RD) 22% (95% CI 12% to 32%) and 29% (95% CI 19% to 39%) for the non-operated ear at six and 12 months, respectively (n = 3 trials)) and a very small (< 5 dB) effect on hearing, compared to a unilateral tympanostomy tube only. The results of studies of adenoidectomy with or without myringotomy versus non-surgical treatment or myringotomy only, and those of adenoidectomy in combination with bilateral tympanostomy tubes versus bilateral tympanostomy tubes only, also showed a small beneficial effect of adenoidectomy on the resolution of the effusion. The latter results could not be pooled due to large heterogeneity of the trials.

The effects of adenoidectomy on changes of the tympanic membrane or cholesteatoma have not been studied.

Authors' conclusions

Our review shows a significant benefit of adenoidectomy as far as the resolution of middle ear effusion in children with OME is concerned. However, the benefit to hearing is small and the effects on changes in the tympanic membrane are unknown. The risks of operating should be weighed against these potential benefits.

van Zon A, van der Heijden GJ, van Dongen TMA, Burton MJ, Schilder AGM. (2012). Antibiotics for otitis media with effusion in children. Cochrane Database of Systematic Reviews. Issue 9. Art. No.: CD009163. DOI: 10.1002/14651858.CD009163.pub2.

Main results:
We included 23 studies (3027 children) covering a range of antibiotics, participants, outcome measures and time points of evaluation. Overall, we assessed the studies as generally being at low risk of bias. Our primary outcome was complete resolution of OME at two to three months. The differences (improvement) in the proportion of children having such resolution (risk difference (RD)) in the five individual included studies ranged from 1% (RD 0.01, 95% CI -0.11 to 0.12; not significant) to 45% (RD 0.45, 95% CI 0.25 to 0.65). Results from these studies could not be pooled due to clinical and statistical heterogeneity. Pooled analysis of data for complete resolution at more than six months was possible, with an increase in resolution of 13% (RD 0.13, 95% CI 0.06 to 0.19). Pooled analysis was also possible for complete resolution at the end of treatment, with the following increases in resolution rates: 17% (RD 0.17, 95% CI 0.09 to 0.24) for treatment for 10 days to two weeks, 34% (RD 0.34, 95% CI 0.19 to 0.50) for treatment for four weeks, 32% (RD 0.32, 95% CI 0.17 to 0.47) for treatment for three months, and 14% (RD 0.14, 95% CI 0.03 to 0.24) for treatment continuously for at least six months.

We were unable to find evidence of a substantial improvement in hearing as a result of the use of antibiotics for otitis media with effusion; nor did we find an effect on the rate of ventilation tube insertion. We did not identify any trials that looked at speech, language and cognitive development or quality of life. Data on the adverse effects of antibiotic treatment reported in six studies could not be pooled due to high heterogeneity. Increases in the occurrence of adverse events varied from 3% (RD 0.03, 95% CI -0.01 to 0.07; not significant) to 33% (RD 0.33, 95% CI 0.22 to 0.44) in the individual studies.

Authors' conclusions:

The results of our review do not support the routine use of antibiotics for children up to 18 years with otitis media with effusion. The largest effects of antibiotics were seen in children treated continuously for four weeks and three months. Even when clear and relevant benefits of antibiotics have been demonstrated, these must be balanced against the potential adverse effects when making treatment decisions. Immediate adverse effects of antibiotics are common and the emergence of bacterial resistance has been causally linked to the widespread use of antibiotics for common conditions such as otitis media.

Griffin G, Flynn CA. Antihistamines and/or decongestants for otitis media with effusion (OME) in children. (2011). Cochrane Database of Systematic Reviews. Issue 9. Art. No.: CD003423. DOI: 10.1002/14651858.CD003423.pub3.

Main results:
Sixteen studies (1880 participants) were included in the review. No statistical or clinical benefit was found for any of the interventions or outcomes studied. However, treated study subjects experienced 11% more side effects than untreated subjects (number needed to treat to harm = 9).

Authors' conclusions:
The pooled data demonstrate no benefit and some harm from the use of antihistamines or decongestants alone or in combination in the management of OME, therefore we recommend against their use.

Perera R, Glasziou PP, Heneghan CJ, McLellan J, Williamson I. Autoinflation for hearing loss associated with otitis media with effusion. (2013). Cochrane Database of Systematic Reviews. Issue 5. Art. No.: CD006285. DOI: 10.1002/14651858.CD006285.pub2.

Main results:
Eight studies, with a total of 702 participants, met the inclusion criteria. Overall, the studies were predominantly assessed as being at low or unclear risk of bias; unclear risk was mainly due lack of information. There was no evidence of selective reporting. Pooled estimates favoured the intervention, but did not show a significant effect on tympanometry (type C2 and B) at less than one month, nor at more than one month. Similarly, there were no significant changes for discrete pure-tone audiometry and non-discrete audiometry. Pooled estimates favoured, but not significantly, the intervention for the composite measure of tympanogram or audiometry at less than one month; at more than one month the result became significant (RRI 1.74, 95% CI 1.22 to 2.50).

Subgroup analysis based on the type of intervention showed a significant effect using a Politzer device under one month (RRI 7.07, 95% CI 3.70 to 13.51) and over one month (RRI 2.25, 95% CI 1.67 to 3.04). None of the studies demonstrated a significant difference in the incidence of side effects between interventions.

Authors' conclusions:
All of the studies were small, of limited treatment duration and had short follow-up. However, because of the low cost and absence of adverse effects it is reasonable to consider autoinflation whilst awaiting natural resolution of otitis media with effusion. Primary care could prove a beneficial place to evaluate such interventions and there is ongoing research in this area. Further research should also consider the duration of treatment, the long-term impact on developmental outcomes in children and additional quality of life outcome measures for children and families.

Browning GG, Rovers MM, Williamson I, Lous J, Burton MJ. Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. (2010). Cochrane Database of Systematic Reviews. Issue 10. Art. No.: CD001801. DOI: 10.1002/14651858.CD001801.pub3.

Main results:
We included 10 trials (1728 participants). Some trials randomised children (grommets versus no grommets), others ears (grommet one ear only). The severity of OME in children varied between trials. Only one 'by child' study (MRC: TARGET) had particularly stringent audiometric entry criteria. No trial was identified that used long-term grommets.

Grommets were mainly beneficial in the first six months by which time natural resolution lead to improved hearing in the non-surgically treated children also. Only one high quality trial that randomised children (N = 211) reported results at three months; the mean hearing level was 12 dB better (95% CI 10 to 14 dB) in those treated with grommets as compared to the controls. Meta-analyses of three high quality trials (N = 523) showed a benefit of 4 dB (95% CI 2 to 6 dB) at six to nine months. At 12 and 18 months follow up no differences in mean hearing levels were found.

Data from three trials that randomised ears (N = 230 ears) showed similar effects to the trials that randomised children. At four to six months mean hearing level was 10 dB better in the grommet ear (95% CI 5 to 16 dB), and at 7 to 12 months and 18 to 24 months was 6 dB (95% CI 2 to 10 dB) and 5 dB (95% CI 3 to 8 dB) dB better. No effect was found on language or speech development or for behaviour, cognitive or quality of life outcomes.

Tympanosclerosis was seen in about a third of ears that received grommets. Otorrhoea was common in infants, but in older children (three to seven years) occurred in < 2% of grommet ears over two years of follow up.

Authors' conclusions:
In children with OME the effect of grommets on hearing, as measured by standard tests, appears small and diminishes after six to nine months by which time natural resolution also leads to improved hearing in the non-surgically treated children. No effect was found on other child outcomes but data on these were sparse. No study has been performed in children with established speech, language, learning or developmental problems so no conclusions can be made regarding treatment of such children.

Simpson SA, Lewis R, van der Voort J, Butler CC. Oral or topical nasal steroids for hearing loss associated with otitis media with effusion in children. (2011). Cochrane Database of Systematic Reviews. Issue 5. Art. No.: CD001935. DOI: 10.1002/14651858.CD001935.pub3.

Main results:
We included 12 medium to high-quality studies with a total of 945 participants. No study documented hearing loss associated with OME prior to randomisation. The follow-up period was generally limited, with only one study of intranasal steroid reporting outcome data beyond six months.

There was no evidence of benefit from steroid treatment (oral or topical) in terms of hearing loss associated with OME. Pooled data using a fixed-effect model for OME resolution at short-term follow up (< 1 month) showed a significant effect of oral steroids compared to control (RR 4.48; 95% CI 1.52 to 13.23; Chi^2 2.75, df = 2, P = 0.25; I^2 = 27%). Oral steroids plus antibiotic also resulted in an improvement in OME resolution compared to placebo plus antibiotic at less than one month follow up, using a random-effects model (RR 1.99; 95% CI 1.14 to 3.49; five trials, 409 children). However, there was significant heterogeneity between studies (P < 0.01, I^2 = 69%). There was no evidence of beneficial effect on OME resolution at greater than one month follow up with oral steroids (used alone or with antibiotics) or intranasal steroids (used alone or with antibiotics) at any follow-up period. There was also no evidence of benefit from steroid treatment (oral or topical) in terms of symptoms.

Authors' conclusions:
While oral steroids, especially when used in combination with an oral antibiotic, lead to a quicker resolution of OME in the short term, there is no evidence of longer-term

benefit and no evidence that they relieve symptoms of hearing loss. We found no evidence of benefit from treatment of OME with topical intranasal steroids, alone or in combination with an antibiotic, either at short or longer term follow up.

Berkman ND, Wallace IF, Steiner MJ, Harrison M, Greenblatt AM, Lohr KN, Kimple A, Yuen A. (2013). Otitis Media With Effusion: Comparative Effectiveness of Treatments. Comparative Effectiveness Review No. 101. (Prepared by the RTI-UNC Evidence-based Practice Center under Contract No. 290-2007-10056-I.) AHRQ Publication No. 13-EHC091-EF. Rockville, MD: Agency for Healthcare Research and Quality.

Results:

We identified 59 studies through the earlier reviews and our independent searches. Generally, studies examined interventions in otherwise healthy, non-infant children. We did not find any eligible studies covering complementary and alternative medicine. Findings are reported for clinical and functional outcomes, and harms. Variation in length of tympanostomy tube (TT) retention corresponded to whether TT were designed to be short versus long term, but variation in TT type was not related to improved OME and hearing outcomes. Tympanostomy tubes decreased OME for 2 years compared with watchful waiting (WW) or myringotomy, and improved hearing for 6 months compared with WW. OME resolution was more likely with adenoidectomy than no treatment at 12 months. Adenoidectomy and myringotomy were superior to myringotomy alone in relation to OME and hearing outcomes at 24 months. Adenoidectomy and TT were superior to WW for hearing outcomes at 24 months. Autoinflation was superior to standard treatment at improving OME at 1 month. We found no benefits from oral steroids at 2 months, or topical steroids at 9 months. In relation to functional outcomes, TT and WW did not differ in long-term language, cognitive or academic outcomes. Tympanosclerosis and otorrhea were more common in ears with TT. Adenoidectomy increased the risk of postsurgical hemorrhage. In one study of a subgroup, adults receiving autoinflation were more likely to recover from OME than those in the control group at one month. We found no studies examining the influence of any health care factors on treatment effectiveness.

Conclusions:

There is evidence that both TT and adenoidectomy reduce OME and improve hearing in the short term, but both treatments also have associated harms. Large, well-controlled studies could help resolve the risk-benefit ratio by measuring AOM recurrence, functional outcomes, quality of life measures, and long-term outcomes. Finally, additional research is needed to support treatment decisions in subpopulations,

particularly those with comorbidities and those who have received a pneumococcal vaccine inoculation.

Summary:

The recently published evidence does not contradict the current coverage guidance recommendations.

Topic: INDICATIONS FOR PLANNED CESAREAN SECTION

Coverage Recommendation (Box Language):

Planned cesarean section (CS) should be covered for:

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

Planned CS should not be covered for:

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

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

Source reports:

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

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

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

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

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

Risser, A., & King, V. (2010). Rapid review: Elective cesarean section. Portland: Center for Evidence-based Policy. Retrieved from http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/upload/Elective-Delivery-Elective-Cesarean_PUBLIC_Rapid-Review_Final_12_1_10.pdf

Scanning results:

Seven Cochrane reviews published or updated in 2010 or later were identified. Two were published prior to 2010 and assessed as up to date without changes after 2010. Of the remaining five, two identified no RCTs, and hence were empty reviews. The other three addressed cesarean section for a variety of conditions; main results and author's conclusions are reported below:

Dodd JM, Crowther CA, Huertas E, Guise JM, Horey D. Planned elective repeat caesarean section versus planned vaginal birth for women with a previous caesarean birth. (2013). Cochrane Database of Systematic Reviews. Issue 12. Art. No.: CD004224. DOI: 10.1002/14651858.CD004224.pub3.

> Main results:
> Two randomised trials involving 320 women and their infants were included. However, data for maternal and infant clinical outcomes were available from one trial with very low event rates, involving 22 women only. For the primary outcomes maternal death or serious morbidity (one study; 22 women; risk ratio (RR) not estimable), and infant death or serious morbidity (one study; 22 women; RR not estimable), there were no statistically significant differences between planned caesarean birth and planned vaginal birth identified.

Authors' conclusions:
Planned elective repeat caesarean section and planned VBAC for women with a prior caesarean birth are both associated with benefits and harms. Evidence for these care practices is largely drawn from non-randomised studies, associated with potential bias. Any results and conclusions must therefore be interpreted with caution. Randomised controlled trials are required to provide the most reliable evidence regarding the benefits and harms of both planned elective repeat caesarean section and planned vaginal birth for women with a previous caesarean birth.

Alfirevic Z, Milan SJ, Livio S. Caesarean section versus vaginal delivery for preterm birth in singletons. (2013). Cochrane Database of Systematic Reviews. Issue 9. Art. No.: CD000078. DOI: 10.1002/14651858.CD000078.pub3.

Main results:
We included six studies (involving 122 women) but only four studies (involving only 116 women) contributed data to the analyses.

Infant
There were very little data of relevance to the three main (primary) outcomes considered in this review: There was no significant difference between planned immediate caesarean section and planned vaginal delivery with respect to birth injury to infant (risk ratio (RR) 0.56, 95%, confidence interval (CI) 0.05 to 5.62; one trial, 38 women) or birth asphyxia (RR 1.63, 95% CI 0.84 to 3.14; one trial, 12 women). The only cases of birth trauma were a laceration of the buttock in a baby who was delivered by caesarean section and mild bruising in another allocated to the group delivered vaginally. The difference between the two groups with regard to perinatal deaths was not significant (0.29, 95% CI 0.07 to 1.14; three trials, 89 women) and there were no data specifically relating to neonatal admission to special care and/or intensive care unit. There was also no difference between the caesarean or vaginal delivery groups in terms of markers of possible birth asphyxia (RR 1.63, 95% CI 0.84 to 3.14; one trial, 12 women) or Apgar score less than seven at five minutes (RR 0.83, 95% CI 0.43 to 1.60; four trials, 115 women) and no difference in attempts at breastfeeding (RR 1.40, 95% 0.11 to 17.45; one trial, 12 women). There was also no difference in neonatal fitting/seizures (RR 0.22, 95% CI 0.01 to 4.32; three trials, 77 women), hypoxic ischaemic encephalopathy (RR 4.00, 95% CI 0.20 to 82.01; one trial, 12 women) or respiratory distress syndrome (RR 0.55, 95% CI 0.27 to 1.10; three trials, 103 women). There were no data reported in the trials specifically relating to meconium aspiration. There was

also no significant difference between the two groups for abnormal follow-up in childhood (RR 0.65, 95% CI 0.19 to 2.22; one trial, 38 women) or delivery less than seven days after entry (RR 0.95, 95% CI 0.73 to 1.24; two trials, 51 women).

Mother

There were no data reported on maternal admissions to intensive care. However, there were seven cases of major maternal postpartum complications in the group allocated to planned immediate caesarean section and none in the group randomised to vaginal delivery (RR 7.21, 95% CI 1.37 to 38.08; four trials, 116 women). There were no data reported in the trials specifically relating to maternal satisfaction (postnatal). There was no significant difference

between the two groups with regard to postpartum haemorrhage. A number of non-prespecified secondary outcomes were also considered in the analyses. There was a significant advantage for women in the vaginal delivery group with respect to maternal puerperal pyrexia

(RR 2.98, 95% CI 1.18 to 7.53; three trials, 89 women) and other maternal infection (RR 2.63, 95% CI 1.02 to 6.78; three trials, 103 women), but no significant differences in wound infection (RR 1.16, 95% CI 0.18 to 7.70; three trials, 103 women), maternal stay more than 10 days (RR 1.27, 95% CI 0.35 to 4.65; three trials, 78 women) or the need for blood transfusion (results not estimable).

Authors' conclusions:

There is not enough evidence to evaluate the use of a policy of planned immediate caesarean delivery for preterm babies. Further studies are needed in this area, but recruitment is proving difficult.

Hofmeyr GJ, Barrett JF, Crowther CA. Planned caesarean section for women with a twin pregnancy. Cochrane Database of Systematic Reviews. (2011). Issue 12. Art. No.: CD006553. DOI: 10.1002/14651858.CD006553.pub2

Main results:

One small trial with unconfirmed allocation concealment compared caesarean section with planned vaginal birth in 60 women with vertex/non-vertex twin pregnancies. There were no differences in perinatal outcome. The trial was too small to exclude the possibility of clinically meaningful benefits of either approach. There is one additional trial currently ongoing.

Authors' conclusions:

There is a lack of robust evidence to guide clinical advice regarding the method of birth for twin pregnancies. Women should be informed of possible benefits and risks of either approach, including short-term and long-term consequences for both mother and babies. Future research should aim to provide unbiased evidence, including long-term outcomes.

Summary:

The recently published evidence does not contradict the current coverage guidance recommendations.

Topic: Knee arthroscopy for osteoarthritis

Coverage Recommendation (Box Language):

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

Source report:

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

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

Scanning results:

One review was identified in the core sources that was published after the date of the WA HTA report. Summary results and/or conclusions are presented below:

Reichenbach S, Rutjes AWS, Nüesch E, Trelle S, Jüni P. Joint lavage for osteoarthritis of the knee. (2010). Cochrane Database of Systematic Reviews. Issue 5. Art. No.: CD007320. DOI: 10.1002/14651858.CD007320.pub2.

> Main results:
> We included seven trials with 567 patients. Three trials examined arthroscopic joint lavage, two non-arthroscopic joint lavage and two tidal irrigation. The methodological quality and the quality of reporting was poor and we identified a moderate to large degree of heterogeneity among the trials (I2 = 65%). We found little evidence for a benefit of joint lavage in terms of pain relief at three months (SMD -0.11, 95% CI -0.42 to 0.21), corresponding to a difference in pain scores between joint lavage and control of 0.3 cm on a 10-cm visual analogue scale (VAS). Results for improvement in function at three months were similar (SMD -0.10, 95% CI -0.30 to 0.11), corresponding to a difference in function scores between joint lavage and control of 0.2 cm on a WOMAC disability sub-scale from 0 to 10. For pain, estimates of effect sizes varied to some degree depending on the type of lavage, but this variation was likely to be explained by differences in the credibility of control interventions: trials using sham interventions to closely mimic the process of joint lavage showed a null-effect. Reporting on adverse events and drop out rates was unsatisfactory, and we were unable to draw conclusions for these secondary outcomes.

Authors' conclusions:

Joint lavage does not result in a relevant benefit for patients with knee osteoarthritis in terms of pain relief or improvement of function.

Summary:

The recently published evidence does not contradict the current coverage guidance recommendations.

Topic: Neuroimaging in Dementia

Coverage Recommendation (Box Language):

Screening of asymptomatic patients for dementia with neuroimaging should not be covered.

Structural neuroimaging should be covered to rule out reversible causes of dementia.*

In patients with mild cognitive impairment, imaging should not be used to predict progression of the risk of developing dementia.

Functional neuroimaging (PET, SPECT or fMRI) should not be covered for screening, diagnosis, or monitoring of dementia.

Source report:

Clark, E.E., & Little, A., (2010). Imaging in dementia. Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

Sources Cited in MED Report:

Boustani, M., Peterson, B., Harris, R., Lux, L.J., Krasnov, C., Sutton, S.F., et al. (2003). Screening for dementia: Systematic evidence review. Rockville, MD: Agency for Healthcare Research and Quality.

Chui, H. & Zhang, Q. (1997). Evaluation of dementia: A systematic study of the usefulness of the American Academy of Neurology's Practice Parameters. Neurology, 49, 925-935.

Dougall, N.J., Bruggink, S., & Ebmeier, K.P. (2004). Systematic review of the diagnostic accuracy of 99m Tc-HMPAO-SPECT in dementia. American J. Geriatric Psychiatry, 12, 554-570.

Foster, G.R., Scott, D.A., & Payne, S. (1999). The use of CT scanning in dementia: A systematic review. International Journal of Technology Assessment in Health Care, 15(2), 406-423

Gifford, D.R., Holloway, R.G., & Vickery, B.G. (2000). Systematic review of clinical prediction rules for neuroimaging in the evaluation of dementia. Archives of Internal Medicine, 160, 2855-2862.

Knopman, D.S., DeKosky, S.T., Cummings, J.L., Chui, H., Corey-Bloom, J., Relkin, N., et. al. (2006). Practice parameter: Diagnosis of dementia (an evidence-based review). American Academy of Neurology. Retrieved from http://www.neurology.org/cgi/reprint/56/9/1143.pdf

Matchar, D.B., Kulasingam, S.L., Huntington, A., Patwardhan, M., Mann, L.O. (2004). Positron emission tomography, single photon emission computed tomography, computed tomography,

functional magnetic resonance imaging and magnetic resonance spectroscopy for the diagnosis and management of Alzheimer's disease. Rockville, MD: Agency for Health Care Research and Quality. Retrieved from http://www.cms.gov/coverage/download /id104b.pdf

Matchar, D.B., Kulasingam, S.L., McCrory, D.C., Patwardhan, M.B., Rutschmann, O.T., Samsa, G.P., et al. (2001). Use of positron emission tomography and other neuroimaging techniques in the diagnosis and management of Alzheimer's disease and dementia. Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from http://www.cms.gov/determination process /downloads/id9TA.pdf

National Collaborating Centre for Mental Health. (2006). Dementia: A NICE–SCIE guideline on supporting people with dementia and their carers in health and social care. Social Care Institute for Excellence. London: National Institute for Health and Clinical Excellence. Retrieved from http://www.nice.org.uk/nicemedia/live/10998/30318/30318.pdf

Scottish Intercollegiate Network of Guidelines (SIGN). (2006). Management of patients with dementia: update. Edinburg: Scottish Intercollegiate Network of Guidelines. Retrieved from http://www.sign.ac.uk/pdf/sign86.pdf

U.S. Preventive Services Task Force. (2003). Screening for Dementia, Topic Page. Retrieved from http://www.uspreventiveservicestaskforce.org/uspstf/uspsdeme.htm

Waldemar, G., Dubois, B., Emre, M., Georges, J., McKeith, I.G., Rossor, M., et al. (2007). Recommendations for the diagnosis and management of Alzheimer's disease and other disorders associated with dementia: EFNS guideline. Eur J Neurol, 14(1), e1-26.

Yuan, Y., Gu, Z.X., & Wei, W.S. (2009). FDG-positron emission tomography, single-photon emission tomography and structural imaging for prediction of rapid conversion to Alzheimer disease in patients with mild cognitive impairment: A meta-analysis. Am J Neuroradiology, 30, 404-410.

Scanning results:

Two reviews and two Cochrane protocols were identified in the core sources that were published after the date of the MED report. In addition, a WA HTA report is in progress and due for publication in December 2014. Summary results and/or conclusions of the two completed reviews are presented below:

Zhang S, Smailagic N, Hyde C, Noel-Storr AH, Takwoingi Y, McShane R, Feng J. 11C-PIB-PET for the early diagnosis of Alzheimer's disease dementia and other dementias in people with mild cognitive impairment (MCI). (2014) Cochrane Database of Systematic Reviews. Issue 7. Art. No.: CD010386. DOI: 10.1002/14651858.CD010386.pub2.

Main results:
Conversion from MCI to Alzheimer's disease dementia was evaluated in nine studies. The quality of the evidence was limited. Of the 274 participants included in the meta-analysis, 112 developed Alzheimer's dementia. Based on the nine included studies, the median proportion converting was 34%. The studies varied markedly in how the PIB scans were done and interpreted.

The sensitivities were between 83% and 100% while the specificities were between 46% and 88%. Because of the variation in thresholds and measures of 11C-PIB amyloid retention, we did not calculate summary sensitivity and specificity. Although subject to considerable uncertainty, to illustrate the potential strengths and weaknesses of 11C-PIB-PET scans we estimated from the fitted summary ROC curve that the sensitivity was 96% (95% confidence interval (CI) 87 to 99) at the included study median specificity of 58%. This equated to a positive likelihood ratio of 2.3 and a negative likelihood ratio of 0.07. Assuming a typical conversion rate of MCI to Alzheimer's dementia of 34%, for every 100 PIB scans one person with a negative scan would progress and 28 with a positive scan would not actually progress to Alzheimer's dementia.

There were limited data for formal investigation of heterogeneity. We performed two sensitivity analyses to assess the influence of type of reference standard and the use of a pre-specified threshold. There was no effect on our findings.

Authors' conclusions:
Although the good sensitivity achieved in some included studies is promising for the value of 11C-PIB-PET, given the heterogeneity in the conduct and interpretation of the test and the lack of defined thresholds for determination of test positivity, we cannot recommend its routine use in clinical practice.11C-PIB-PET biomarker is a high cost investigation, therefore it is important to clearly demonstrate its accuracy and standardise the process of the 11C-PIB diagnostic modality prior to it being widely used.

<u>BCBS. (2013). Beta Amyloid Imaging with Positron Emission Tomography (PET) for Evaluation of Suspected Alzheimer's Disease or Other Causes of Cognitive Decline.</u>

"beta amyloid imaging with positron emission tomography (PET) to evaluate suspected Alzheimer's disease (AD) and other causes of cognitive decline does not meet the TEC criteria."

- Has regulatory approval

- Evidence is insufficient to support conclusions concerning the impact of beta amyloid PET imaging with florbetapir F18 on health outcomes. The evidence to date focuses solely on the correlation between the results of beta amyloid PET imaging and other indicators of cognitive decline, clinical diagnoses, and histopathologic results. Studies are needed to define the accuracy of beta amyloid imaging according to age (since beta amyloid deposition increases with age in cognitively normal individuals). Further evidence is also needed on the link between the test results and improving health outcomes.
- Because evidence is insufficient to permit conclusions on the effect of beta amyloid PET imaging on health outcomes, any improvement cannot be established.
- Comparative benefit cannot be established lacking sufficient evidence.
- Have not been evaluated outside the investigational setting.

Summary:

The recently published evidence does not contradict the current coverage guidance recommendations. Given three reviews currently in progress, it may be reasonable to consider updating this guidance once those reviews have been completed.

Topic: Routine Ultrasound in Pregnancy

Coverage Recommendation (Box Language):

Routine ultrasound for average risk pregnant women should be covered only: Once in the first trimester for the purpose of identifying fetal aneuploidy or anomaly (between 11 and 13 weeks of gestation) and/or dating confirmation. In some instances, if a patient's LMP is truly unknown, a dating ultrasound may be indicated prior to an aneuploidy screen.

Once for the purpose of anatomy screening after 18 weeks gestation

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

Source report:

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

Scanning results:

The only review identified in the core sources that was published after the date of the WA HTA report was a Hayes report, which was published just three months after the WA HTA report. Hayes was the author of the WA HTA report, and the document contains essentially the same information.

Summary:

No evidence has been published in the trusted sources since this guidance document was created. Therefore, it appears unlikely to need updating.

Topic: Non-pharmacologic Interventions for Treatment Resistant Depression

Coverage Recommendation (Box Language):

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

In patients with an episode of major depressive disorder who have failed at least two or more pharmacologic treatments the following treatments should be covered:

1) Repetitive transcranial magnetic stimulation

2) Electroconvulsive therapy

Vagus nerve stimulation should not be covered.

Source report:

Gaynes, B.N., Lux, L., Lloyd, S., Hansen, R.A., Gartlehne, G., Thieda, P., et al. (2011). Nonpharmacologic interventions for treatment-resistant depression in adults. Comparative effectiveness review no. 33. (Prepared by RTI International-University of North Carolina [RTI-UNC] Evidence-Based Practice Center under Contract No. 290-02-0016I.) AHRQ Publication No. 11-EHC056-EF. Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from www.effectivehealthcare.ahrq.gov/reports/final.cfm

Trivedi, R.B., Nieuwsma, J.A., Williams, J.W., & Baker, D. (2009). Evidence synthesis for determining the efficacy of psychotherapy for treatment resistant depression. Washington, DC: Department of Veterans Affairs Veterans Health Administration Health Services Research & Development Service. Retrieved from http://www.hsrd.research.va.gov/publications/esp/Depression-Q3.pdf

Scanning results:

Two reviews were identified in the core sources that were published after the date of the AHRQ report. Summary results and/or conclusions are presented below:

Nonpharmacological Treatments for Treatment Resistant Depression. (2014) http://www.hca.wa.gov/hta/Documents/TRD_final_report_022114.pdf

Summary:
Electroconvulsive therapy (ECT) has been in use for decades, but its efficacy has not been extensively investigated in recent decades. Only 2 small sham-controlled trials of ECT published in 1980 and 1981 and a comparison of ECT with new pharmacotherapy

published in 1997 were reviewed for this report. Trials published prior to 1980 were excluded from the 2011 AHRQ evidence report on Nonpharmacologic Interventions for Treatment-Resistant Depression in Adults and hence were also excluded from the present report. Even the included RCTs of ECT may have limited generalizability to current practice because of differences in standard antidepressant (AD) medication regimens.

Some investigators have considered ECT the standard treatment for TRD against which to compare repetitive transcranial magnetic stimulation (rTMS) as an alternative more acceptable to patients. A large body of evidence has demonstrated the efficacy of rTMS compared with sham stimulation in patients with TRD. There is no evidence suggesting that rTMS is more effective than ECT, and the comparability of the 2 treatments has not been conclusively established. Although sham-controlled studies of rTMS showed no adverse effect on cognitive function, comparator trials did not prove rTMS to be safer than ECT in this regard. No serious safety issues were identified in trials of rTMS. Several variations are possible for the way ECT and rTMS are delivered, but optimal treatment parameters have not been identified. There is no evidence of at least moderate quality that establishes an association between the treatment effect of ECT or rTMS and the type of subgroup characteristics listed in Key Question #3.

These conclusions regarding ECT and rTMS are consistent with the conclusions of the 2011 Agency for Healthcare Research and Quality (AHRQ) evidence review, although the AHRQ conclusions were based only on studies in which patients had experienced ≥ 2 failed antidepressant (AD) trials. The authors of the AHRQ review noted that findings from the overall evidence base were consistent with findings specific to studies defining TRD as ≥ 2 AD failures but that the effect of combining patients meeting different definitions of TRD was unclear. The AHRQ review did not address treatment parameters and addressed only a limited number of patient characteristics (see Appendix V).

There is some positive evidence suggesting that transcranial direct current stimulation (tDCS) is efficacious as a treatment for TRD, but pooled estimates of response and remission were nonsignificant. Deep brain stimulation (DBS) has been studied only in very small case series with pretest/posttest (before-and-after) analyses; although mean improvement was demonstrated, no conclusion regarding causality may be made. DBS can result in serious complications.

The literature provides very little direct evidence of improvement in quality of life (QOL) or functional status attributable to the technologies of interest. However, there is some

evidence that lower symptom scores are associated with better function and QOL (this issue was not systematically investigated for this report). Thus, improvement in depression symptoms may also result in improvement in QOL and general function. Evidence of the durability of post-treatment benefits is sparse or missing for all of the technologies of interest.

One of the deficiencies of existing research evidence is the lack of a standard definition of TRD. The literature suggests a growing consensus that failure of 2 prior adequate trials of AD medication is an appropriate definition of TRD. The evidence reviewed for this report suggests that rTMS and ECT are effective even when TRD is defined as ≥ 1 failed AD trial. There was low-quality evidence suggesting that the effectiveness of ECT diminishes as medication resistance increases. The oft-cited STAR*D trial demonstrated that the effectiveness of new AD medication also diminishes with each round of failed treatment. No studies directly assessed the effectiveness of rTMS according to degree of medication resistance. Where reported in studies of tDCS, patients had generally failed ≥ 2 AD trials in their lifetime, but the evidence does not permit a conclusion regarding the effectiveness of tDCS by degree of medication. Studies of DBS required a failure of ≥ 3 prior AD trials.

Related to the lack of a standard definition of TRD is the need for greater standardization in the manner in which the adequacy of AD trials is defined and whether medication resistance should be demonstrated in the current episode. Regarding the duration of an adequate AD trial, ≥ 6 weeks was the most common threshold in studies that addressed this issue in inclusion criteria, American Psychiatric Association guidelines on the management of MDD advise that an AD trial should be continued 4 to 8 weeks, and other sources suggest 10 to 12 weeks for an adequate trial. No distinction was made in the studies reviewed for this report between patients who were and were not compliant in previous AD treatment. Very few studies clarified whether patients were enrolled on the basis of AD failure at any time in the past or on the basis of failure during the current episode.

No studies of any of the technologies of interest compared the technology with usual care or evaluated the technology as an add-on to usual care. Only 2 comparisons of nonpharmacologic treatment (ECT in 1 study, tDCS in the other) with a new AD medication as the control were identified. More studies providing a comparison with real-world alternatives are needed, ideally with a sham-controlled arm as well as a new pharmacotherapy or usual care arm.

BCBS. (2014). Transcranial Magnetic Stimulation for Depression.
http://www.bcbs.com/blueresources/tec/vols/28/28_09.pdf

- Has regulatory approval
- Three large, and many small, trials have compared TMS with sham for treatment-resistant depression. Two of the large trials employed a "duration adaptive design" that enforces dropout of patients failing to improve after 3 weeks. Effect estimates after the initial 3-week follow-ups are potentially biased and longer term follow-up of these trials is difficult to interpret. Limited data have been reported from the third trial because it is unpublished. No significant results were reported in the intention-to-treat analyses after 6 or 16 weeks of TMS. Results from other small trials, along with the 2 large published trials, have been included in meta-analyses. Although pooled effect estimates from the meta-analyses favor TMS, results from the later and potentially biased follow-up of the 2 large trials were used. Only one of the 7 meta-analyses reviewed evaluated study quality. A search of ClinicalTrials.gov identified unpublished completed studies. The available evidence does not permit conclusions regarding the effect of TMS on health outcomes.
- The available evidence does not permit conclusions on whether TMS improves the net health outcome.
- Lacking evidence to support conclusions about the effect of TMS on health outcomes, it is not possible to compare with established alternatives.
- Have not been evaluated outside the investigational setting.

Summary:
The recently published evidence is conflicting, with the WA HTA review supporting the current coverage guidance recommendations and the BCBS technology evaluation contradicting it. The primary discrepancy appears to be that BCBS believes that two of three large trials may be biased because of the trial design, and in addition, they are concerned about the existence of unpublished studies.

Topics: Advanced Imaging for Low Back Pain

Low back pain: Pharmacologic Interventions

Low back pain: Non-pharmacologic/ Non-invasive Interventions

Source report:

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

Additional Information:

This report is in the process of being updated. The update process has just begun, and it is expected to be finalized next year or possibly 2016.

Topic: Percutaneous interventions for low back pain

Source report:

Chou, R., Loesser, J.D., Owens, D.K., Rosenquist, R.W., Atlas, S.J., Baisden, J., et al. (2009). Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: An evidence-based clinical practice guideline from the American Pain Society. Spine, 34(10), 1066-1077. – Accompanied by:
Chou, R., Atlas, S.J., Stanos, S.P., & Rosenquist, R.W. (2009). Nonsurgical interventional therapies for low back pain: A review of the evidence for an American Pain Society clinical practice guideline. Spine, 34(10), 1078-1094.

Additional Information:

This report is in the process of being updated. It is in the final stages, and is expected to be finalized later this year or early 2015.