

**AGENDA**  
**BEHAVIORAL HEALTH ADVISORY PANEL (BHAP)**  
**September 16, 2015**  
**9:00-11:00 AM**

Wilsonville Training Center, Room 210

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

#	Time	Item	Presenter
1	9:00	Call to Order	David Pollack
2	9:05	Purpose of Meeting	Darren Coffman
3	9:10	Prioritized List issues 1) Integration of medical and mental health lines for child abuse and neglect 2) Guideline notes with differential treatment of children by age (GN 20, 25, 28, 42, 45) 3) SOI 3 INTEGRATED CARE 4) New line for substance abuse and acute substance intoxication and/or withdrawal	Ariel Smits
4	10:30	Coding/reimbursement issues with integrated care	Denise Taray
5	10:45	Other Business	David Pollack
6	10:55	Public Comment	
7	11:00	Adjournment	David Pollack

## Minutes

HEALTH EVIDENCE REVIEW COMMISSION  
Clackamas Community College  
Wilsonville Training Center, Rooms 111-112  
Wilsonville, Oregon  
August 13, 2015

**Members Present:** Som Saha, MD, MPH, Chair; Beth Westbrook, PsyD; Wiley Chan, MD; Vern Saboe, DC (teleconference-left early); Irene Crowell, RPh; Susan Williams, MD; Derrick Sorweide, DO.

**Members Absent:** Leda Garside, RN, MBA; Mark Gibson; Gerald Ahmann, MD, PhD.

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

**Also Attending:** Robyn Liu, MD, Adam Obley, MD, and Valerie King, MD, Center for Evidence-based Policy; Jesse Little, OHA Actuarial Services Unit; Kim R. Wentz, MD, MPH, and Laurie Theodorou, OHA Health Systems Division; Aiesha Moore, Aerocrine; Pam Keuneke, Providence; Joanne Rogovoy, March of Dimes; Kerry Kostman Bonilla, AstraZeneca; Bruce Croffy, FamilyCare; Ashlen Strong, Health Share; Courtney Johnston, COHO; Mellony Bernal, OHA Public Health Division; Jen Gilbert, Jonathan Modie, OHA Communications; Emily McLain, Nico Quintana, Basic Rights Oregon; Phillip L. Santa Maria, Avanir; Sharron Fuchs; Jeana Colabianchi, Pharm D, Sunovion; Maros Ferencik, SCCT; Teresa Everson, Will Nettleton, MD and Cristina Fuss, OHSU.

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### Call to Order

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

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### Minutes Approval

[Meeting Materials](#), page 4

***MOTION: To approve the minutes of the 3/12/2015 meeting as presented. CARRIES 7-0.***

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### Director's Report

Membership:

- Darren Coffman noted today is the first official meeting for recently confirmed Commissioner Dr. Derrick Sorweide. He is an osteopathic physician, a former family practice physician, is an Army Major, teaches at Western University of Health Sciences and is the current president of the Osteopathic Physicians & Surgeons of Oregon (OPSO).

***MOTION: To seat Sorweide on the Health Technology Assessment Subcommittee. CARRIES: 7-0.***

- Coffman noted the Governor’s office anticipates a Senate confirmation hearing in September to fill the vacant dental position.
- Recently, the EBGs CCO representative, Kattie Leuken, resigned.

Legislative update:

- Palliative Care and Quality of Life Interdisciplinary Advisory Council
  - Denise Taray will be lead staff
- Task Force on Researching the Medical and Public Health Properties of Cannabis
  - HERC Staff were initially tasked with staffing this group but found out this week staffing will come from elsewhere
- Report on diagnosis and treatment of Lyme disease
  - Ariel will be lead staff for this report to an interim legislative committee

Staff/organizational updates:

- Coffman introduced Dr. Kim Wentz, the new medical assistance program medical director. That organization has been renamed the “Health Systems Division.” HERC is now under Health Policy and Analytics Division, Clinical Services Improvement Unit. Jeanene Smith, CMO, is leaving state service.
- Coffman invited Val King to introduce Center for Evidence-based Policy staff. Adam Obley will take over Robyn Lui’s role, with Craig Mosbaek and Aasta Thielke acting as research assistants.

**Coverage Guidance Topic: Planned out-of-hospital birth**

[Meeting Materials](#), pages 26-197

No recommendation reached at the VbBS meeting held earlier in the day, therefore this topic was tabled until a future meeting.

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

[Meeting Materials](#), pages 198-271

Ariel Smits reported the VbBS met earlier in the day, August 13, 2015.

**Gender dysphoria discussion:**

Smits brought VbBS’s recommendations forward:

- Clarify which mental health provider appropriate for assessments/referrals
- Re-affirm no age limitations
- Do not specify provider type restrictions for gender dysphoria medication prescribing
- Issues tabled until the next meeting:
  - Changes to many surgery codes were tabled until a future meeting, including procedures for penile and testicular implants and chest surgery

Saha began the discussion by mentioning the onslaught of emails and phone calls staff received over a Fox news story in July. Most of them came from non-Oregon residents. What most struck Saha is that

we did not receive a single negative feedback/comment from someone who has gone through this as a patient or a parent. Every testimony from a patient, parent or provider implored the Commission to stick with the original decision.

Smits stated the new recommendations are based on the [World Professional Association for Transgender Health](#) (WPATH) guidelines. Williams pointed out that these guidelines have extensive requirements related to gender dysphoria training and experience, rather than limits on a particular type of provider degree type. Westbrook shared some concern with the language in the meeting materials regarding mental health professions. Smits stated VbBS adopted WPATH guidelines which specifically outlines necessary training (e.g. clinical training in psychiatry, mental health counselling, nursing or family therapy with specific training in behavioral health and a minimum of master's level degree or equivalent in a clinical behavioral health field by an accredited institution with continuing education in gender dysphoria).

Saha broached the issue of medical age of consent. He stated there is confusion over "age of procedure," when and who should be able to get it. In the case of gender dysphoria, it is disadvantageous clinically to wait until secondary sex characteristics are fully developed. There is no good clinical rationale to require patients to be 18 years old. Further, having heard from providers, advocates and patients, it is rare when the parents are not involved. It is not feasible to make parental involvement mandatory since this is a stigmatized condition where sometimes patients become estranged from their family and their parents don't approve. That becomes an issue of discriminating against people who have basically been disowned by their parents. It is a false idea that a child could just walk in and say "do this to me." There is a long list of criteria to meet, primary care doctor approval, multiple mental health evaluations, surgeon approval – plenty of adults involved in the discussion. A child is never making this decision alone, ever.

In Oregon, the age of medical consent is 15. This commission does not have the authority to change this state law. Without parental consent, a 15 -17 year old can have brain surgery, breast augmentation, or terminate a pregnancy. This policy has far more safeguards to help ensure a child isn't reaching a wrong decision than in the case of other surgeries.

Westbrook felt, for pre-surgery criteria, we should be even more cautious with minors, encouraging the group to consider adding criteria for a doctoral level person to complete any testing, especially a psycho-sexual developmental piece. Smits countered there are addition referrals required (1 for chest/breast surgery, 2 for genital surgery) from a provider with master's level or higher credentials.

Wentz said there is a shortage of child mental health care providers. Further, she mentioned there are currently ten active OHP discrimination cases pending over lack of appropriate care for transgender individuals; five are mental health cases. Hodges added the providers may be available in the community but may not be currently contracted by CCOs. Smits said Kaiser Permanente wrote her, objecting to any deviation from WPATH since doing so would cause them to treat their Medicaid patients differently, and potentially discriminately, than their "commercial" population. Saha wondered if the world-wide guidelines agree on this level, is changing anything necessary? Wentz added, if you ask for more scrutiny *only* for transgender patients you are discriminating on the basis of gender and you cannot do this in implementation. Further, Hodges shared there was an abundance of compelling testimony heard at VbBS to leave the 15-17 year-old coverage in place. Livingston said it may be in a patient's best interest to begin college as their identified gender.

*Public comment:*

Maura Roach, Basic Rights Oregon, urged the Commission to align with the world standard guidelines, WPATH, and to accept the VbBS recommendations.

Nico Quintana of Basic Rights Oregon testified that the lowest barriers possible for care should be adopted due to the marginalized nature of the transgender community, and their high risk of violence and suicide.

Census was reached to accept the VbBS proposal to modify the mental health evaluation sections to refer to the WPATH version 7 guidelines. The number of referrals required for chest/breast surgery was reduced from 2 to 1 to conform to WPATH guidelines, resulting in the following guideline.

**GUIDELINE NOTE 127, GENDER DYSPHORIA**

*Line 413*

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

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

1. have persistent, well-documented gender dysphoria
2. have the capacity to make a fully informed decision and to give consent for treatment
3. have any significant medical or mental health concerns reasonably well controlled
4. have a comprehensive mental health evaluation provided in accordance with Version 7 of the World Professional Association for Transgender Health (WPATH) Standards of Care ([www.wpath.org](http://www.wpath.org)).

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. for breast/chest surgeries, have one referral from a mental health professional provided in accordance with version 7 of the WPATH Standards of Care.
7. for genital surgeries, have two referrals from mental health professionals provided in accordance with the version 7 WPATH Standards of Care.

Electrolysis (CPT 17380) is only included on this line for surgical site electrolysis as part of pre-surgical preparation for chest or genital surgical procedures also included on this line. It is not included on this line for facial or other cosmetic procedures or as pre-surgical preparation for a procedure not included on this line.

#### **Other VbBS report items:**

Smits presented recommendations on other topics, but there was no discussion:

- Add certain procedure codes to the covered gender dysphoria line to better include all procedure codes for procedures previously approved for this line; remove 2 inappropriate codes from this line
- Make various straightforward coding changes
- Modify the left ventricular assist device guideline to allow destination therapy
- Modify the continuous blood glucose monitoring guideline to specify that recurrent hypoglycemia is defined as 3 or more events in the previous 6 months
- Adopt various straightforward guideline corrections

**MOTION: To accept the VbBS recommendations on Prioritized List changes not related to coverage guidances, as stated. See the VbBS minutes of August 13, 2015 for a full description. Carries: 6-0. (Absent: Saboe; Abstained: 0)**

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#### **Coverage Guidance Process Redesign**

[Meeting Materials](#), pages 273-285

Jason Gingerich reminded the group they had granted permission to change the literature search process and GRADE table format at a previous meeting. He reviewed the staff's proposed changes to the coverage guidance process including: 1) additional research prior to releasing the initial draft of the guidance, and 2) a brief 7-day comment period focused on insuring that the literature search strategy returns the correct information to guide the HERC's decision. He also presented examples of the new GRADE tables which will provide more quantitative information about key outcomes. There was minimal discussion.

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#### **Coverage Guidance Topic 2-Year Review**

[Meeting Materials](#), pages 286-302

Livingston led the discussion with help from Adam Obley, MD, of the Center for Evidence-based Policy. The new process now calls for the identification of Population, Intervention, Comparator, Outcomes (PICO) and Key Questions (KQ) for each topic, followed by posting for public comment for 7 days and a review of the literature search results at the September EbGS & HTAS meetings.

The Commission discussed the scope documents and made the changes shown in Appendix A.

- **Treatment of ADHD in Children (See Appendix A)**
- **Coronary Artery Calcium Scoring (See Appendix A)**

*Public comment:*

Maros Ferencik, MD, cardiologist and associate professor at OHSU, Board member of Society of Cardiovascular Computed Tomography. His stated conflict is that he is a practicing cardiologist who performs these tests and is a grant recipient for American Heart Associate to study coronary CTs. Dr. Ferencik said the current scope document partially mixes diagnostic uses with the test's preventive and prognostic value. He said the PICO should focus on the role of calcium scoring in predicting cardiovascular events and improving classification of the risk. Further, CACS should be compared to other tests or screening that lead to risk classification. She said that in certain cases adding a calcium score can help rule out further testing

- **Carotid Endarterectomy (See Appendix A)**
- **Coronary CT Angiography (See Appendix A)**

*Public comment:*

Cristina Fuss, MD is the section chief for cardiothoracic Imaging in the department of Diagnostic Radiology at OHSU. No conflicts declared. She said that studies have proven diagnostic accuracy and therefore the usefulness of this test is excellent. It does indeed prevent invasive tests in many cases and can help shorten the length of hospital stays. She said that in certain cases adding calcium score can help rule out further testing.

Maros Ferencik, MD spoke to urge the group to consider effects of radiation on the population. Also stressed the need to look at negative and positive effects of incidental findings.

At this point, with many more scope documents yet to review, Saha called a halt to reviewing the scope documents, as time for the topic had elapsed. He would like these discussions to take place at the subcommittee level in the future. Coffman and Gingerich added such a process change could result in a two-month delay. For this iteration, the scoping documents for all of the topics will be posted for public comment. The four reviewed at HERC today may then go on to a literature search, incorporating changes reflecting public comments as appropriate. The remainder will go to their originating subcommittee for additional discussion before proceeding with the literature search. After a literature search is conducted the subcommittee will review the results to see if revisiting the topic is warranted. Staff will work on a more stream-lined process for future topics.

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**Coverage Guidance Topic: Biomarker Tests of Cancer Tissue for Prognosis and Potential Response to Treatment**

[Meeting Materials](#), pages 303-368

Dr. Robyn Liu, Center for Evidence-based Policy, reviewed the evidence resulting in the draft coverage guidance recommended by HTAS. Livingston reviewed the GRADE table and box language and the proposed changes to the Prioritized List recommended by VbBS. There was no discussion.

**MOTION: To approve the proposed coverage guidance for Biomarker Tests of Cancer Tissue as recommended by HTAS. Carries 6-0.**

**MOTION: To approve the proposed guideline and coding changes for the Prioritized List as recommended by VbBS. Carries 6-0.**

**HERC APPROVED COVERAGE GUIDANCE**

**BIOMARKER TESTS OF CANCER TISSUE FOR PROGNOSIS AND POTENTIAL RESPONSE TO TREATMENT**

Oncotype DX is recommended for coverage in early stage breast cancer when used to guide adjuvant chemotherapy treatment decisions for women who are lymph node negative (*strong recommendation*).

The following genetic tests of cancer tissue are recommended for coverage (*strong recommendation*):

- BRAF gene mutation testing for melanoma
- Epidermal growth factor receptor (EGFR) gene mutation testing for non-small-cell lung cancer
- KRAS gene mutation testing for colorectal cancer

The following genetic tests of cancer tissue are not recommended for coverage (*weak recommendation*):

- MammaPrint, ImmunoHistoChemistry 4 (IHC4), and Mammostrat for breast cancer
- Prolaris and Oncotype DX for prostate cancer
- BRAF, microsatellite instability (MSI), and Oncotype DX for colorectal cancer
- KRAS for lung cancer
- Urovysion for bladder cancer
- Oncotype DX for lymph node-positive breast cancer

The use of multiple molecular testing to select targeted cancer therapy is not recommended for coverage (*weak recommendation*).

**Changes to the Prioritized List of Health Services:**

1) Coding changes:

- a. Add S3854 (Gene expression profiling panel for use in the management of breast cancer treatment) to Line 195 (breast cancer).
  - i. Advise the Health Systems Division to remove S3854 from Ancillary Codes File
- b. Place 81275 (KRAS) on Line 161 (colon cancer)
  - i. Advise the Health Systems Division to remove 81275 from the Diagnostic File
- c. Place 81210 (BRAF) on Line 233 (malignant melanoma)
  - i. Advise the Health Systems Division to remove 81210 from Diagnostic File
- d. Add the following to the Services Recommended for Non-coverage Table (all represented by nonspecific CPT codes unless otherwise indicated)
  - MammaPrint
  - ImmunoHistoChemistry 4 (IHC4)
  - Mammostrat
  - Microsatellite instability (MSI)
  - Urovysion

- Prolaris
- Multiple molecular testing (81504)

2) Adopt a new Guideline Note:

**GUIDELINE NOTE 148, BIOMARKER TESTS OF CANCER TISSUE**

*Lines 161, 188, 195, 233, 266, 274, 333*

The use of multiple molecular testing to select targeted cancer therapy (CPT 81504) is included on the Services recommended for non-coverage table.

For breast cancer, Oncotype Dx testing (CPT 81519, HCPCS S3854) is included on line 195 only for early stage breast cancer when used to guide adjuvant chemotherapy treatment decisions for women who are lymph node negative. Oncotype Dx is not included on this line for lymph node-positive breast cancer. Mammaprint, ImmunoHistoChemistry 4 (IHC4), and Mammostrat for breast cancer are included on the Services recommended for noncoverage table.

For melanoma, BRAF gene mutation testing (CPT 81210) is included on line 233.

For lung cancer, epidermal growth factor receptor (EGFR) gene mutation testing (CPT 81235) is included on line 266 only for non-small cell lung cancer. KRAS gene mutation testing (CPT 81275) is not included on this line.

For colorectal cancer, KRAS gene mutation testing (CPT 81275) is included on line 161. BRAF (CPT 81210) and Oncotype DX are not included on this line. Microsatellite instability (MSI) is included on the Services recommended for noncoverage table.

For bladder cancer, Urovysion testing is included on Services recommended for noncoverage table.

For prostate cancer, Oncotype DX is not included on line 333 and Prolaris is included on the Services recommended for noncoverage table.

The development of this guideline note was informed by a HERC coverage guidance. See [website](#).

**Advisory Panels Update**

Coffman said the three advisory panels to help VbBS with a variety of issues have been revitalized and will meet in September and October. Membership has been updated to ensure current CCO/DCO representation on the Behavioral Health Advisory Panel, Oral Health Advisory Panel, and Genetics Advisory Panel.

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## **Best Practices, Evidence-based Toolkits**

Livingston said there is a need for a way for HERC to make a statement on effectiveness and appropriateness of services that do not fit within the current constructs of the Prioritized List. These would be strategies for population health management on topics such as obesity, chronic pain, and tobacco use for services not traditionally billed as medical services. The product might be a stand-alone document and/or could be embedded in the Prioritized List.

Saha agreed there is a need to break down barriers between medical care and public health in support of our biggest stake holder, the CCOs. Discussion centered on the scope of the new venture, whether a task force should be convened for each topic or if adopting another group's practices was desired. Staff will bring back options at the next meeting in October, possibly focused on tobacco cessation.

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## **2016 Biennial Review**

Livingston asked for permission to convene a task force on obesity management which would include a wide variety of providers including primary care, CCO representatives, and endocrinology. This will take a look at HTAS recommendations on surgical indications as well as a comprehensive look at non-surgical approaches.

**MOTION to create a task force on obesity management. CARRIES: 6-0.**

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## **Next Steps**

I was determined that the next VbBS/HERC meeting date needs to be moved to October 1st or 22nd. Staff will poll the members for availability by email and confirm the date and location as soon as able.

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## **Adjournment**

The meeting was adjourned at 4:30 pm.

## Appendix A

### PICO & Key Questions for Literature Search on Coverage Guidance Topics Last Reviewed in 2013

#### Treatment of ADHD in Children

##### Populations

Children 6 years of age or older diagnosed with ADHD, or  
Children under 6 years of age deemed at-risk for ADHD

##### Interventions

Parent behavior training, teacher consultation, pharmacotherapy (methylphenidate, amphetamine salts, non-stimulant medications, atypical antipsychotics) other pharmacologic treatments, psychosocial and behavioral interventions

##### Comparators

Usual care, no intervention

##### Outcomes

*Critical:* Academic achievement, measures of social functioning

*Important:* Measures of impulsiveness, grade retention, growth restriction

*Outcomes considered but not selected for GRADE table:* Measures of inattention, overactivity, non-specific harms

##### Key Questions

KQ1: What is the effectiveness of pharmacologic, behavioral, and psychosocial interventions for children with ADHD?

1a. Does effectiveness vary based on patient characteristics?

KQ2: Is there comparative effectiveness evidence for interventions for children with ADHD?

KQ3: What is the effectiveness of interventions for children under 6 years of age deemed at-risk for ADHD?

KQ4: What is the evidence of harms associated with the interventions for ADHD in children?

#### Coronary Artery Calcium Scoring

##### Populations

Asymptomatic adults with coronary heart disease (CHD) risk, adults with acute chest pain with normal EKG and negative cardiac enzymes, adults with chronic stable chest pain

##### Intervention

Coronary artery calcium scoring (CACS)

##### Comparators

No further risk stratification, other forms of risk stratification (including serial monitoring (EKG, troponins), exercise EKG, stress echocardiography, stress myocardial perfusion scanning, coronary angiography, clinical risk prediction tools

##### Outcomes

*Critical:* All-cause mortality, major adverse cardiovascular events

*Important:* Incidental findings, avoidance of invasive procedure

*Outcomes considered but not selected for GRADE table:* Length of stay

##### Key Questions

KQ1: What is the comparative effectiveness of CACS in improving outcomes for asymptomatic patients with CHD risk or patients with chest pain (either acute chest pain with normal EKG and negative cardiac enzymes or chronic stable chest pain)?

KQ2: What is the cost-effectiveness of CACS?

KQ3: What are the harms of CACS?

## Appendix A

### PICO & Key Questions for Literature Search on Coverage Guidance Topics Last Reviewed in 2013

#### Coronary CT Angiography

##### Population

Adults with acute chest pain or chronic stable chest pain

##### Intervention

Coronary CT angiography (CTA)

##### Comparators

Usual care (including no additional testing, exercise EKG, stress echocardiography, stress myocardial perfusion scanning, coronary angiography; serial monitoring with EKG/troponin)

##### Outcomes

*Critical:* All-cause mortality, Major Adverse Cardiac Events (MACE)

*Important:* Contrast-induced nephropathy, avoidance of invasive procedures

*Outcomes considered but not selected for GRADE table:* radiation exposure; need for revascularization procedure

##### Key Questions

KQ1: What is the comparative effectiveness of coronary CTA for improving outcomes among adults with chest pain?

1a. Are there patient characteristics that modify the utility?

KQ2: What are the harms of coronary CTA (including incidental findings)?

KQ3: What are the comparative costs and/or cost-effectiveness of coronary CTA?

#### Coronary Endarterectomy

##### Populations

Adults with carotid stenosis with or without recent symptoms of cerebral ischemia

##### Intervention

Carotid endarterectomy

##### Comparators

Optimal medical therapy, carotid stenting

##### Outcomes

*Critical:* All-cause mortality, cerebrovascular accidents

*Important:* Transient ischemic attacks, development/progression of vascular dementia, quality of life

*Outcomes considered but not selected for GRADE table:* Need for reintervention

##### Key Questions

KQ1: What is the comparative effectiveness of carotid endarterectomy for treatment of symptomatic or asymptomatic carotid stenosis?

1a. What degree of carotid stenosis predicts clinical utility of carotid endarterectomy?

KQ2: What are the harms of carotid endarterectomy?

KQ3 Under what circumstances should carotid endarterectomy be covered for asymptomatic patients (i.e. when stenosis is found as an incidental finding?)

# HEALTH EVIDENCE REVIEW COMMISSION (HERC)

## COVERAGE GUIDANCE: NITROUS OXIDE FOR LABOR PAIN

**DRAFT for EbGS Meeting Materials 9/3/2015**

### HERC Coverage Guidance

Nitrous oxide for labor pain is recommended for coverage (*weak recommendation*).

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

### PLAIN LANGUAGE SUMMARY

[Staff will insert lay language summary once the coverage guidance has been reviewed by subcommittee]

### RATIONALE FOR GUIDANCE DEVELOPMENT

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

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

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

### EVIDENCE OVERVIEW

#### Clinical background

Annually, approximately 45,000 births occur in Oregon (Oregon Health Authority, 2015) and childbirth pain is a major concern among women (Likis et al., 2012). Pain relief is most commonly delivered through epidural anesthesia in the United States, with 61% of women who had singleton births through vaginal delivery electing an epidural anesthesia (Centers for Disease Control and Prevention, 2011; Likis, et al., 2012). For women interested in other types of pain relief or in delaying the timing of an epidural, there are several options including inhaled nitrous oxide (N<sub>2</sub>O, also known as "laughing gas"), other

inhaled anesthetic gases, opioids, paracervical or pudendal block, transcutaneous electrical nerve stimulation, hydrotherapy, sterile water injections, and psychoprophylaxis (Likis et al., 2012).

Inhaled nitrous oxide is a non-invasive form of pain relief. Commonly used in dentistry, nitrous oxide provides a diminished sense of pain and provides some antianxiety effects (Likis et al., 2012). In comparison to epidural anesthesia, women using nitrous oxide for pain management retain their full mobility. Individuals experience the maximum effect of nitrous oxide 30 to 60 seconds after inhalation. The effects of nitrous oxide wear off quickly and other types of pain management methods can be used in a relatively short time period after the use of nitrous oxide (Likis et al., 2012).

In the Portland-Metro region, an epidural adds an additional \$1,050 to \$2,400 to the cost of a hospital birth (Providence Health Services, 2015). The use of nitrous oxide costs significantly less with estimates ranging from \$15 to \$100 per patient.

## Indications

Inhaled nitrous oxide can be used in the first or second stages of labor and is indicated for pregnant women in labor intending a vaginal birth. Nitrous oxide can also be used in the third stage of labor to assist with managing pain that may occur during immediate postpartum procedures (e.g., perineal repair, manual placenta removal).

## Technology description

Inhaled nitrous oxide is widely used for childbirth pain relief outside of the United States and is a common form of non-invasive pain relief during childbirth (Klomp, van Poppel, Jones, Lazet, Di Nisio & Lagro-Janssen, 2012). Nitrous oxide is a non-flammable, tasteless, odorless gas that is self-administered on demand by laboring women through a mouth piece or facemask (Collins, Starr, Bishop, Baysiner, 2012; Klomp et al., 2012). Inhaled nitrous oxide is typically administered as a 50% nitrous oxide / 50% oxygen combination. It can be administered at this concentration using a blender device (e.g., Nitronox®) or as a premixed gas (e.g., Entonox®). Entonox® is not currently available in the U.S., but appropriate types of blender equipment are available for hospital and out-of-hospital use.

## Key questions

The following key questions (KQ) guided the evidence search and review described below. For additional details about the review scope and methods please see Appendix B.

KQ1: What are the effects on mode of birth, use of neuraxial (e.g. epidural) analgesia and maternal satisfaction when nitrous oxide is used for labor analgesia?

KQ2: What are the maternal and fetal/neonatal harms of nitrous oxide used for labor pain?

## Evidence review

Two systematic reviews (SR) (Klomp et al., 2012; Likis et al., 2012) identified in the core source search address the use of nitrous oxide for pain management during labor. Both SRs were of good methodological quality. The AHRQ SR (Likis, 2012; Likis, 2014) was selected as the index SR and is the

primary evidence source for this coverage guidance because it is more comprehensive and matches the scope of the HERC’s key questions better. In addition, the Cochrane SR (Klomp, 2012) did not add eligible studies or other information which were not included in the AHRQ SR. For further details on the methods of this evidence review please see Appendix B. The included study characteristics for the AHRQ SR are outlined below in Table 1.

**Table 1. Overview of Index Systematic Review**

<b>Citation</b>	<b>Total Studies Included</b>	<b>Included Studies Specifically Addressing Coverage Guidance Scope</b>
Likis et al (2012, 2014) [AHRQ SR]	59 studies (13 RCTs, 7 crossover RCTs, 4 non-randomized clinical trials, 14 prospective cohorts, 1 retrospective cohorts, 3 case series, 4 case-control studies, 11 cross sectional studies, and 2 trend studies)	<ul style="list-style-type: none"> <li>• 14 studies (5 RCTs; 8 prospective cohorts 1 case-series) for fetal/neonatal harms</li> <li>• 3 studies (2 prospective cohort studies, 1 cross-sectional study) for mode of delivery</li> <li>• 10 studies (7 RCTs; 2 prospective cohorts; 1 cross-sectional study) for maternal adverse effects</li> <li>• 2 studies (both cross-sectional studies) for use of neuraxial (e.g. epidural) anesthesia</li> </ul>

### Evidence from additional sources

No additional evidence sources were included in this review. A MEDLINE® (Ovid) search based on the search strategy of the AHRQ SR did not locate any additional eligible studies.

### EVIDENCE SUMMARY

The AHRQ SR (Likis, 2012) included a total of 59 studies reported in 58 publications (13 RCTs, 7 crossover RCTs, 4 non-randomized clinical trials, 14 prospective cohorts, 1 retrospective cohorts, 3 case series, 4 case-control studies, 11 cross sectional studies, and 2 trend studies) to answer five key questions on the following issues: 1) effectiveness for pain (21 studies); 2) comparative effectiveness for women’s satisfaction with their birth experience and pain management (9 studies); 3) effect on mode of birth (6 studies); 4) maternal and fetal/neonatal adverse effects (49 studies); and 5) health system factors influencing the use of nitrous oxide (no studies). Key Questions 2, 3 and 4 are directly applicable to this coverage guidance.

Most of the studies in the full AHRQ SR included comparator interventions that are not of interest for this guidance (comparators included other inhaled anesthetic gasses, most of which are not used in the U.S., alternative concentrations of N2O; parenteral opioids and non-pharmacologic techniques not widely available or used in the U.S.). Many of the studies used different concentrations of N2O compared to the 50% N2O/50% oxygen mix that is used in most labor and delivery settings in countries such as the United Kingdom (U.K.) and which is the concentration used in U.S. settings that have

adopted it for obstetric use. Most included studies did not report on populations or outcomes of interest for this guidance (e.g. pain scores, occupationally exposed workers). Some populations of interest (e.g. women in the third stage of labor requiring procedural analgesia such as for manual placental removal) were not explicitly included among the studies identified in the AHRQ SR. No study directly addressed or was designed to address whether use of N2O reduces the use of neuraxial (e.g. epidural) analgesia; we were only able to address this outcome descriptively. None of the included studies that did address the questions of interest for this evidence review were conducted in the U.S., although all were conducted in developed countries with modern maternity care systems. However, differences in health systems, provider training, hospital routines and patient expectations may limit the applicability of these studies to the U.S. context.

Although pain was not selected as a key outcome for this guidance, for background context, the AHRQ SR found that N2O is less effective than epidural anesthesia for measures of pain in labor, but that the evidence was insufficient to determine the effectiveness compared with other, non-epidural pain management interventions. The studies are limited because of poor quality, use of varying outcome measures, and inconsistency. The review found no studies that met inclusion criteria and studied the systems factors related to using N2O for management of labor pain, including provider preferences, availability, settings and resource utilization.

### **Critical Outcome: Fetal/neonatal adverse effects**

The AHRQ SR (Likis, 2012) noted that while 49 studies reported on maternal, fetal, neonatal, or occupational harms associated with N2O use in labor, that 16 of these were conducted prior to 1980 when it was usual practice to combine N2O with other sedative, tranquilizing and anesthetic agents. Although N2O is transmitted via the placenta to the fetus, it is also quickly eliminated via maternal circulation and neonatal respiration. Twenty-nine studies included fetal or neonatal harms as outcomes. The SR found no significant differences between any comparison groups in Apgar scores at either one or five minutes after birth. Eight studies reported umbilical cord blood gasses. There was one study that compared infants of women using 50% N2O/50% oxygen to epidural anesthesia. It found that 7% of the N2O group had Apgar scores less than or equal to seven at one minute after birth compared to 6% of infants of women who used epidurals. At five minutes, the proportions with low Apgar scores were 1% and 4%, respectively (p values not reported). There was a statistically significant finding in one study of lower arterial cord blood gasses among infants of primiparous women who used N2O plus meperidine (a parenteral opioid) compared to those who used an epidural (pH 7.21 vs. pH 7.29, p<0.01). Use of meperidine alone has been associated with lower umbilical cord gasses and so it is not clear whether this finding can be attributed to N2O use or only to use of meperidine. The AHRQ SR was unable to analyze neonatal intensive care unit admission because of the varying definitions of intensive care across countries and lack of reporting of this outcome.

Only one study included in the AHRQ SR compared neonatal neurobehavioral outcomes among infants of women using N2O and who used other methods of labor pain management, including epidurals, opioids, TENS, and non-pharmacologic methods. This study reported no significant differences between groups in neonatal adaptive capacity scores (NACS).

## Critical Outcome: Mode of birth

Six studies in the AHRQ review compared the mode of birth among women who used N2O to women who used other methods of pain relief and determined that there was insufficient evidence, primarily due to poor quality studies and inconsistent results. However, only three studies compared the intervention and comparator of interest for this guidance. One prospective cohort study from Ireland, published in 1987, enrolled primiparous women in an academic hospital. Twenty women used N2O and 50 women used epidural anesthesia. Other comparison groups in the study used TENS or parenteral opioids. Another prospective cohort study from Finland, published in 1994, included 210 women (27% primiparas) using N2O and 82 women (71% primiparas) using epidural anesthesia. This study also found higher rates of vaginal birth among women using N2O. No analysis of the results by parity was provided in the AHRQ SR. These two studies found the following proportions of women with vaginal, assisted vaginal (vacuum or forceps), Cesarean, or vaginal breech births as described in Table 2 below. No statistical testing of differences between pain management groups were reported in either study.

**Table 2. Mode of Birth According to Pain Management Approach**

Mode of Birth	Nitrous Oxide*	Epidural*
Vaginal	60%/95%	26%/80%
Assisted	35%/2%	62%/11%
Cesarean	0%/3%	6%/9%
Breech	5%/NR	6%/NR

NR: not reported

\* The first percentage in each cell represents the Irish study and the second percentage is from the Finnish study.

One cross sectional study conducted in the U.K. and published in 1982 also reported the mode of birth. This U.K.-based study included women (51.4% primiparous) who had vaginal births and found that women who used N2O (n=128) were more likely to have a spontaneous vaginal birth and less likely to have an assisted vaginal birth compared with women who used epidural anesthesia (n=423) or women who used an epidural and N2O together (n=38). Proportions who had a vaginal birth for each of these three groups were 93.7%, 48.7%, and 60.5% and for assisted vaginal birth the proportions were 6.3%, 51.3%, and 39.5%.

Consistent with reported mode of birth outcomes, three of these studies (two prospective cohort studies and one cross sectional study) also reported shorter duration of labor for women in the N2O groups compared to the epidural groups. The reported duration of labor in the N2O groups ranged from a mean of 5.2 hours +/- 1.7 (standard deviation [S.D.]) to 6.7 +/- 3.0 hours. The reported range among women using epidural anesthesia was 7.7 +/- 2.4 hour to 10.8 +/- 4.9 hours.

## Important Outcome: Maternal adverse effects

Most harms reported by studies included in the AHRQ SR were unpleasant side effects of N2O such as nausea, vomiting, dizziness and drowsiness. Some commonly reported adverse effect outcomes (e.g.

nausea and oxygen desaturation) are reported often among women in labor regardless of pain management strategies used. Studies did not have adequate power to detect rare outcomes. Eight studies of women receiving N2O as the sole pain management agent report rates of nausea from 0% to 28%. Four of these studies also reported vomiting with a range of 0% to 14%. Four studies of women using N2O as the sole analgesia agent reported dizziness or lightheadedness, with rates ranging from 3% to 23%. Four studies reported drowsiness or sleepiness with sole use of N2O and proportions ranged from 0% to 67%.

## **Important Outcome: Maternal satisfaction**

Nine studies in the AHRQ SR evaluated women's satisfaction with their birth experience or pain management, although most were of poor quality and reported varying outcome measures, making it difficult to synthesize results. However, the AHRQ authors concluded that there was low strength of evidence to support the equivalence or superiority of N2O relative to maternal satisfaction outcomes. Among the three studies that specifically evaluated use of 50% N2O / 50% oxygen compared with epidural anesthesia, two studies (two prospective cohorts) evaluated women's satisfaction with labor pain management at various points in time between one hour and three days post-delivery. They both reported that women who used N2O were somewhat less satisfied with the adequacy of pain relief for N2O compared to epidural anesthesia. Satisfaction scores ranged from 60% to 90% for the N2O group and 98% to 100% for the epidural group in the prospective cohort study. Because N2O is not assumed or designed to achieve the same degree of pain relief as epidural anesthesia this is not considered by the AHRQ researchers to be as robust of an outcomes as is women's assessment of whether they would use the method again. One prospective cohort study conducted in Ireland found that 80% of women who used N2O would request the method again in a subsequent pregnancy compared with 88% of women who used an epidural. In a cross-sectional study performed in Sweden that evaluated this outcome, 69.9% of women who used N2O would request it in another pregnancy compared to 45.3% of women who used an epidural.

## **Important Outcome: Use of neuraxial analgesia in labor**

The AHRQ SR did not report on this outcome. However, the two cross sectional studies (one from the U.K. and one from Sweden) that reported outcomes for groups of women choosing N2O and epidural anesthesia, respectively, do give some information on the methods that women choose when both choices are freely available. The U.K. based study, published in 1982, included only women who had a vaginal birth and approximately half were primiparous. Of 1000 women, about 13% used N2O, 42% used epidurals, and 4% used both methods. Other methods used in this study included parenteral opioids, pudendal or regional anesthetic blocks, no pharmacologic pain management, and combinations of these methods. The Swedish cross-sectional study, published in 1996, gathered data on women who had used N2O, epidural, local anesthesia, acupuncture, hydrotherapy, and breathing techniques as their primary pain management technique. About 79% of women used N2O and 34% used epidural (categories were not mutually exclusive and thus some women who started with N2O may have also used epidurals or other techniques).

## **OTHER DECISION FACTORS**

### **Resource Allocation**

The cost of N2O for labor is low (\$15 to \$100 per patient). The major cost is for the delivery equipment, which is borne by the facility or provider. The costs of the comparator intervention are relatively high (\$1,050 to \$2,400 per patient per epidural in the Portland metropolitan area). Use of N2O is associated with lower rates of assisted vaginal birth and cesarean delivery which would potentially result in significantly lower intrapartum costs. For some women who use both N2O and an epidural during the same labor, anesthesia costs of care could increase over use of an epidural alone. However, this combination may still result in higher vaginal birth rates and thus lower total costs of care. The literature review found that the length of labor was consistently shorter (about 2 to 4 hours shorter) among women using N2O analgesia compared to women using epidural anesthesia such that increased use of N2O may also result in somewhat shorter length of stay on labor and delivery units.

### **Values and preferences**

Some women and clinicians have a strong preference to avoid or delay neuraxial anesthesia and would potentially desire an intervention that may decrease their risk of assisted vaginal delivery or cesarean section. If N2O were available in Oregon facilities, many women would likely try it. Most women would not be concerned about potential harms because there do not appear to be adverse fetal/neonatal harms and women who experience adverse effects themselves can stop using N2O and their symptoms would resolve. Its quick onset would also be desired by women who are waiting for an epidural in labor and who would use it as a bridging technology. However, other women may strongly prefer neuraxial anesthesia (epidural) because of its greater effect in reducing labor pain, so the net assessment is that values and preferences would be highly variable.

### **Other considerations**

There is currently no specific CPT code for N2O use in labor except for an anesthesia-specific code. Benefit plans may need to consider alternative payment methodologies and/or innovative mechanisms to encourage use by providers. Facilities and clinicians may have to invest in equipment and staff training to implement N2O for labor pain. Facilities may experience shorter length of stay on labor and delivery units with increased use of N2O that may result in higher bed availability and/or decreased staffing needs in some hospitals.

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## GRADE-INFORMED FRAMEWORK

The HERC develops recommendations by using the concepts of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are several 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. Estimates of effect are derived from the evidence presented in this document. The level of confidence in the estimate is determined by the Commission based on assessment of two independent reviewers from the Center for Evidence-based Policy. Unless otherwise noted, estimated resource allocation, values and preferences, and other considerations are assessments of the Commission.

<b>Coverage question: Should nitrous oxide (50% N2O) be recommended for coverage for labor pain management?</b>				
<b>Outcomes</b>	<b>Estimate of Effect for Outcome/ Confidence in Estimate</b>	<b>Resource allocation</b>	<b>Values and Preferences</b>	<b>Other considerations</b>
<b>Fetal/neonatal adverse effects</b> <i>(Critical outcome)</i>	No significant differences in Apgar scores at 1 and 5 minutes, or umbilical cord gasses after birth when maternal N2O is compared to epidural anesthesia use.  ●●●○ <i>(Moderate certainty, based on multiple RCTs and other studies with consistent findings)</i>	Use of N2O is likely to be cost-saving compared to epidural anesthesia. The cost of N2O is low. Use of N2O is associated with lower rates of assisted vaginal birth and cesarean delivery, and shorter length of stay on labor and delivery units.	High variability: Some women would want this additional option because of the reduced risk of caesarean section or assisted delivery. Concerns about harms would be mitigated because they could easily discontinue it and	There is no specific CPT code for this service, other than an anesthesia code, so reimbursement to providers may require use of a non-specific code that may require manual review.

Coverage question: Should nitrous oxide (50% N2O) be recommended for coverage for labor pain management?				
Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>	Resource allocation	Values and Preferences	Other considerations
<b>Mode of birth</b> <i>(Critical outcome)</i>	15 to 34 more women per 100 are likely to have a vaginal birth when using N2O compared to those using epidural anesthesia for labor pain. 9 to 27 fewer women per 100 would experience assisted vaginal (forceps/vacuum) birth, and there would be about 6 fewer Cesarean births per 100.  ●●○○ (Low certainty based on prospective cohort and cross sectional studies with consistent findings)		consider an epidural if adverse events occur or if analgesia is insufficient. Other women may prefer epidural anesthesia because of its greater effect in reducing labor pain.	
<b>Maternal adverse effects</b> <i>(Important outcome)</i>	Women may experience unpleasant side effects when using N2O. Nausea (0-28%), vomiting (0-14%), dizziness/lightheadedness (3-23%), and drowsiness/sleepiness (0-67%) were commonly reported side effects. Effects dissipated quickly when N2O use is stopped.  ●●●○ (Moderate certainty based on multiple RCTs and other studies with consistent findings)			
<b>Maternal satisfaction</b> <i>(Important outcome)</i>	70 to 80% of women who used N2O said they would want to use it in a subsequent pregnancy compared to 45 to 88% of women who would request an epidural again.  ●●○○ (Low certainty based on prospective cohort and cross-sectional studies with consistent findings)			

Coverage question: Should nitrous oxide (50% N2O) be recommended for coverage for labor pain management?				
Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>	Resource allocation	Values and Preferences	Other considerations
Use of neuraxial (e.g., epidural) anesthesia <i>(Important outcome)</i>	When multiple pain management methods are available for women 13% to 79% will use N2O, compared to 34 to 42% who will select epidural anesthesia. There is no direct evidence on whether use of N2O changes the use of neuraxial anesthesia.  ●○○○ ( <i>Very low certainty based on cross-sectional studies with consistent findings</i> )			
<p><b>Rationale:</b> On balance, there are potential benefits to the use of N2O and no serious harms to its use. Costs are low and variable maternal preferences argue for increased availability of N2O for management of labor pain. Coverage is recommended because of the potential benefits of fewer cesarean and assisted deliveries, the lack of significant harms, maternal preferences, and low costs. The recommendation is a weak recommendation because there are few studies available for benefit outcomes, and the external validity of the data and its applicability in U.S. settings is limited. The confidence in the quality of evidence for most outcomes is low to moderate certainty.</p> <p><b>Recommendation:</b> Nitrous oxide for labor pain is recommended for coverage (<i>weak recommendation</i>).</p>				

Note: GRADE framework elements are described in Appendix A

## POLICY LANDSCAPE

### Quality measures

No quality measures related to the use of nitrous oxide during labor were identified when searching the [National Quality Measures Clearinghouse](#).

### Payer coverage policies

No public or private payer coverage policies<sup>1</sup> were identified for the use of nitrous oxide during labor.

### Professional society guidelines

The National Institute for Health and Care Excellence (NICE) found there to be moderate evidence of benefit for the use of nitrous oxide during labor (NICE, 2014). The guideline notes that nitrous oxide can cause nausea and light-headedness for the mother. NICE did not find any evidence of harm to the baby. The use of 50:50 mixture oxygen and nitrous oxide is recommended to be available in all birth settings in the United Kingdom.

The American College of Nurse-Midwives (ACNM) has a Position Statement that supports the increased availability and use of nitrous oxide analgesia (ACNM, 2011).

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

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<sup>1</sup> Washington Medicaid, Aetna, Cigna, Regence Blue Cross Blue Shield, and Moda

## APPENDIX A. GRADE INFORMED FRAMEWORK - 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
Other considerations	Other considerations include issue about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon.

### Confidence in the quality of the evidence, across studies, about an outcome

**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.

### 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.

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## APPENDIX B. METHODS

### Scope Statement

#### Populations

Pregnant women intending a vaginal birth in the first and second stages of labor and their fetus/neonate, women in the third stage of labor or immediate postpartum period

Population scoping notes: *Exclude women planning a Cesarean birth*

#### Interventions

Self-administered nitrous oxide used for labor analgesia or third stage/immediate postpartum management

Intervention exclusions: *Concentration of nitrous oxide blended with oxygen for analgesia other than 50%; non-self-administration of nitrous oxide*

#### Comparators

Neuraxial analgesia (e.g. epidural, combined spinal/epidural)

#### Outcomes

Critical: Mode of birth; Fetal/neonatal adverse effects (e.g. low Apgar score, low cord blood gasses)

Important: Maternal adverse effects (e.g. nausea/vomiting, dizziness, loss of consciousness); Use of neuraxial (e.g. epidural) analgesia; Maternal satisfaction

*Considered but not selected for the GRADE table*: Use of non-neuraxial analgesia

#### Key Questions

KQ1: What are the effects on mode of birth, use of neuraxial (e.g. epidural) analgesia and maternal satisfaction when nitrous oxide is used for labor analgesia?

KQ2: What are the maternal and fetal/neonatal harms of nitrous oxide used for labor pain?

#### Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, technology assessments, and clinical practice guidelines using the terms “nitrous oxide,” and “labor pain management.” Searches of core sources were limited to citations published after 2004.

The core sources searched included:

- Agency for Healthcare Research and Quality (AHRQ)
- Blue Cross/Blue Shield Health Technology Assessment (HTA) program
- BMJ Clinical Evidence
- Canadian Agency for Drugs and Technologies in Health (CADTH)

Cochrane Library (Wiley Interscience)  
Hayes, Inc.  
Institute for Clinical and Economic Review (ICER)  
Medicaid Evidence-based Decisions Project (MED)  
National Institute for Health and Care Excellence (NICE)  
Tufts Cost-effectiveness Analysis Registry  
Veterans Administration Evidence-based Synthesis Program (ESP)  
Washington State Health Technology Assessment Program

Based on this initial search, the AHRQ report (Lakis, 2012) was selected as the index systematic review.

We also identified another good quality SR from the Cochrane Collaboration in the core source search. The Cochrane SR (Klomp, 2012) included four RCTs that were not included in the AHRQ SR. They were excluded from the AHRQ SR because they were not published in English. In total, five RCTs in the Cochrane SR, compared varying or unspecified concentrations of N<sub>2</sub>O to oxygen alone or no treatment. Only one of these RCTs evaluated the comparison, relevant to this coverage guidance, of 50% N<sub>2</sub>O/50% oxygen with epidural anesthesia. This RCT also included a no treatment control group. The Cochrane SR did not present outcomes for the comparison of N<sub>2</sub>O vs. epidural groups, but only the comparison of the N<sub>2</sub>O and no treatment groups. We were unable to incorporate the results of the N<sub>2</sub>O vs. epidural comparison to this evidence report due to this RCT being published in Chinese.

A MEDLINE® (Ovid) search was then conducted to identify systematic reviews, meta-analyses, and technology assessments published after the search dates of the AHRQ report (Lakis, 2012). The search was limited to publications in English published after 2010 (the end search date for the AHRQ SR).

Searches for clinical practice guidelines were limited to those published since 2010. A search for relevant clinical practice guidelines was also conducted, using the following sources:

Australian Government National Health and Medical Research Council (NHMRC)  
Centers for Disease Control and Prevention (CDC) – Community Preventive Services  
Choosing Wisely  
Institute for Clinical Systems Improvement (ICSI)  
National Guidelines Clearinghouse  
New Zealand Guidelines Group  
NICE  
Scottish Intercollegiate Guidelines Network (SIGN)  
United States Preventive Services Task Force (USPSTF)  
Veterans Administration/Department of Defense (VA/DOD)

## **Inclusion/Exclusion Criteria**

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, or clinical practice guidelines.

## APPENDIX C. GRADE EVIDENCE PROFILE

Quality Assessment (Confidence in Estimate of Effect)							
No. of Studies	Study Design(s)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Factors	Quality
<b>Fetal/Neonatal Adverse Effects (Apgar scores, Cord gasses)<sup>1</sup></b>							
14	5 RCTs; 8 Prospective cohorts; 1 Case-series	High	Consistent	Direct	Imprecise	None	Moderate confidence in estimate of effect ●●●○
<b>Mode of Birth<sup>3</sup></b>							
3	2 Prospective cohort; 1 Cross-sectional	High	Consistent	Direct	Imprecise	Moderate magnitude of effect and some evidence of dose-response relationship	Low confidence in estimate of effect ●●○○
<b>Maternal Adverse Effects (Nausea, Vomiting, Dizziness/Lightheadedness, Drowsiness/Sleepiness)<sup>2</sup></b>							
10	7 RCTs; 2 Prospective cohorts; 1 Cross-sectional	High	Consistent	Direct	Imprecise	None	Moderate confidence in estimate of effect ●●●○
<b>Maternal Satisfaction<sup>3</sup></b>							
4	2 Prospective cohort; 2 Cross-sectional	High	Consistent	Direct	Imprecise	None	Low confidence in estimate of effect ●●○○

Quality Assessment (Confidence in Estimate of Effect)							
No. of Studies	Study Design(s)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Factors	Quality
<b>Use of Neuraxial Anesthesia<sup>3</sup></b>							
2	2 Cross-sectional	High	Consistent	Indirect	Imprecise	None	Very low confidence in estimate of effect (●○○○)

<sup>1</sup>Studies from Tables 9, 10, 11 (AHRQ, 2012). Strength of evidence assessment based on AHRQ SR, Table 12 (AHRQ, 2012).

<sup>2</sup>Studies from Table 8 (AHRQ, 2012). Strength of evidence assessment based on AHRQ SR, Table 12 (AHRQ, 2012).

<sup>3</sup>Studies for benefit outcomes selected from AHRQ SR based on HERC review PICO only (neuraxial anesthesia comparator studies only) (AHRQ, 2012). Strength of evidence based on risk of bias assessments included for individual studies in AHRQ SR, Table 6 (AHRQ, 2012) and assessment of other GRADE elements by staff.

## APPENDIX D. APPLICABLE CODES

CODES	DESCRIPTION
<b>ICD-9 Diagnosis Codes</b>	
<b>ICD-10 Diagnosis Codes</b>	
<b>ICD-9 Volume 3 (Procedure Codes)</b>	
<b>CPT Codes</b>	
<b>HCPCS Level II Codes</b>	

Note: Inclusion on this list does not guarantee coverage

**AGENDA**  
**ORAL HEALTH ADVISORY PANEL (OHAP)**  
**September 22, 2015**  
Wilsonville Training Center, Room 210  
8:00 – 10:00 am

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

<b>#</b>	<b>Time</b>	<b>Item</b>	<b>Presenter</b>
1	8:00 AM	Call to Order & Introductions	Bruce Austin
2	8:05 AM	Purpose of Meeting	Ariel Smits
3	8:10 AM	<ol style="list-style-type: none"> <li>1. 2016 CDT code placement</li> <li>2. Placement of CDT codes on the Prioritized List and on another list</li> <li>3. Denture code placement review</li> <li>4. Guideline for crowns</li> </ol>	Ariel Smits
4	9:15 AM	Medicaid dental access issues	Bruce Austin
5	9:30 AM	Update on restoration of benefits for adults -dentures -crowns -interval for scaling and root planing	Bruce Austin
6	9:45 AM	Dental metrics?	?
7	9:55 AM	Public Comment	
8	10:00 AM	Adjournment	Bruce Austin

**Value-based Benefits Subcommittee Recommendations Summary**  
**For Presentation to:**  
**Health Evidence Review Commission on August 13, 2015**

*For specific coding recommendations and guideline wording, please see the text of the 8-13-2015 VbBS minutes.*

**RECOMMENDED CODE MOVEMENT (effective 10/1/15)**

- Add several procedure codes to the covered gender dysphoria line to better include all procedure codes for procedures previously approved for this line; delete 2 inappropriate codes from this line
- Delete several tests for genetic changes in tumors to the Services Recommended for Non-Coverage Table and add several others to covered cancer lines in accordance with the recommendations in the coverage guidance for biomarker tests of cancer tissue
- Add and delete several straightforward coding changes

**ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE**

- No age restrictions were added for gender dysphoria services
- No restrictions on prescriber type were added for gender dysphoria medications
- No change was made to non-coverage of exhaled nitric oxide testing for asthma

**RECOMMENDED GUIDELINE CHANGES (effective 10/1/15)**

- Edit the left ventricular assist device guideline to allow destination therapy
- Edit the gender dysphoria guideline to have the mental health evaluation sections refer to the WPATH version 7 guidelines. The number of referrals required for chest/breast surgery was reduced from 2 to 1 to conform to WPATH guidelines.
- Edit the continuous blood glucose monitoring guideline to specify that recurrent hypoglycemia is defined as 3 or more events in the previous 6 months
- Add a new guideline based on the new coverage guidance for biomarker tests of cancer tissue
- Make various straightforward guideline corrections

**VALUE-BASED BENEFITS SUBCOMMITTEE**  
**Clackamas Community College**  
**Wilsonville Training Center, Rooms 111-112**  
**Wilsonville, Oregon**  
**August 13, 2015**  
**8:00 AM – 1:30 PM**

**Members Present:** Kevin Olson, MD, Chair; David Pollack, MD; Susan Williams, MD; Irene Croswell, RPh; Holly Jo Hodges, MD.

**Members Absent:** Laura Ocker, LAc; Mark Gibson.

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

**Also Attending:** Jenn Burleton and Kate Kauffman, TransActive Gender Center; Jim Mudd, MD, Amy Kerfoot, Amy Perkin, Dr. Christina Milano, Teresa Everson, Will Nettleton, MD and Julie Hanna, OHSU; Dr. Carter, private practice ND; Nico Quintana, Gig Cassel, Phoenix Singlet, Aaron Smith, Curtis Espinoza, Neola Young, Khalil Edwards, Abby Hoover, Nancy Haque, Basics Rights Oregon; Kazuaki Jindai, MD, VA/OHSU;; Bruce Croffy, FamilyCare; Megan Bird, MD, Legacy Health; Jess Guerriero, Lifeworks, NW; Adam Maxey, COHO; Karen L. Campbell, Jane Stephen and Chris Doyle, Allergan; Mellony Bernal, Jessie Little, Deborah Weston, Brian Nieubuurt, Kim Wentz, MD, Oregon Health Authority; Aiesha Moore, Acrocrine; Angela Carter, EQUI Institute; Ashlen Strong, Health Share; Rene Taylor, Dixun; Regina Eckles, WVP/WRICH.

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

The meeting was called to order at 8:10 am and roll was called. Minutes from the May, 2015 VbBS meeting were reviewed and approved.

Kim Wentz, MD, MPH was introduced as the new medical director for the Oregon Medicaid program. Smits reviewed the Errata document for changes to the Prioritized List which were done as corrections since the last meeting.

A new obesity task force is proposed for creation to review a variety of treatments, including medications and surgical interventions. Staff requested feedback on the type/specialty of providers to be invited to join this task force. There was no input.

Smits noted that the Oral Health Advisory Panel, Behavioral Health Advisory Panel, and Genetics Advisory Panel are all meeting in the next one to two months and asked for any topic suggestions for these groups. There were none.

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**Topic: Straightforward/Consent Agenda**

**Discussion:** There was no discussion about the consent agenda items. Staff clarified that code placements recommended in the document titled "Codes Without Line Placement for January 1, 2016" should take effect on October 1, 2015.

**Recommended Actions:**

- 1) Add CPT 55720 and 55725 (Prostatotomy, external drainage of prostatic abscess, any approach; simple and complicated ) to line 209 SUPERFICIAL ABSCESSSES AND CELLULITIS
  - o Advise Health Systems Division (HSD), formerly DMAP, to remove 55720 from the Ancillary File and 55725 from the Diagnostic File
- 2) Add ICD-10 Q54.4 (Congenital chordee), Q55.64 (Hidden penis), and Q55.69 (Other congenital malformation of penis) to line 667 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY and keep on line 438 HYPOSPADIAS AND EPISPADIAS
- 3) Add ICD-10 Q55.62 (Hypoplasia of penis) to line 438 HYPOSPADIAS AND EPISPADIAS and keep on line 667 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
- 4) Add G90.50 (Complex regional pain syndrome I, unspecified) to lines 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT and 381 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE
- 5) Remove G90.50 (Complex regional pain syndrome I, unspecified) from line 612 DISORDERS OF SOFT TISSUE
- 6) Advise HSD to add W94.31xx (Exposure to sudden change in air pressure in aircraft during descent) to the Informational Diagnosis File
- 7) Add S16.1xxA (Strain of muscle, fascia and tendon at neck level, initial encounter) to line 407 CONDITIONS OF THE BACK AND SPINE
- 8) Add 69710 (Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone) to the Services Recommended for Non-Coverage Table
- 9) Add 90378 (Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
- 10) Add 90460-90461 (Immunization administration through 18 years of age via any route of administration, first and subsequent) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
- 11) Add 90644 (Meningococcal conjugate vaccine, serogroups C & Y and Hemophilus influenza B vaccine (Hib-MenCY), 4 dose schedule, when administered to children 2-15 months of age), 90653 (Influenza vaccine, inactivated, subunit, adjuvanted), 90664-90668 (Influenza virus vaccine, pandemic formulation), 90672 (Influenza virus vaccine, quadrivalent, live, for intranasal use) and 90739

- (Hepatitis B vaccine, adult dosage (2 dose schedule), for intramuscular use) were line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
- 12) Modify Guideline Notes 31 and 39, and Diagnostic Guideline D17 as shown in Appendix A
  - 13) Modify the medical back pain guideline scheduled for inclusion on the January 1, 2016 Prioritized List as shown in Appendix B
  - 14) Add hypnotherapy (CPT 90880) to the Services Recommended for Non-Coverage List
    - Advise HSD to remove CPT 90880 from the Ancillary File
  - 15) Add diagnostic codes for abnormal vaginal pap smears (ICD-9 795.1x / ICD-10 R87.62x) to line 291 CANCER OF VAGINA, VULVA, AND OTHER FEMALE GENITAL ORGANS
    - Advise HSD to remove 795.1x/R87.62x from the Diagnostic Workup File.
  - 16) Add CPT 57420 (Colposcopy of the entire vagina, with cervix if present) and 57421 (with biopsy(s) of vagina/cervix) to line 291 CANCER OF VAGINA, VULVA, AND OTHER FEMALE GENITAL ORGANS
    - Advise HSD to remove 57420 and 57421 from the Ancillary File
  - 17) Modify the new guideline for wearable cardiac defibrillators as shown in Appendix A

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

➤ **Topic: Left Ventricular Assist Device (LVAD) as Destination Therapy**

**Discussion:** Smits introduced the summary of this topic and the staff recommendations. Dr. James Mudd from the OHSU Heart Failure Clinic gave a short presentation in favor of the staff recommendations and answered questions from the subcommittee members. He reported that patients receiving LVADs for cardiac transplant frequently do not receive a heart due to extreme limitations of organs available, and therefore LVADs are essentially serving as destination therapy for these patients. He argued that LVADs are a treatment for end stage heart failure, regardless of the choice of being placed on the transplant list. He reported that LVAD candidates undergo the same evaluation process as transplant patients in the OHSU program.

There was some discussion about whether the current guideline spoke to replacement of LVADs if a patient lived long enough to reach the device life limit. Dr. Mudd reported that current devices do not appear to have a life span which requires replacement in this extremely ill patient population with limited life expectancy. Some devices are replaced due to device failure. There was discussion about what happens when patients decide to elect hospice/palliative care. Dr. Mudd indicated that OHSU's program, as well as other programs that he is aware of, require a palliative care consult prior to LVAD

placement and an informed consent discussion with the patient about the option of hospice rather than LVAD. When and if a patient elects to choose hospice or is near the end of life, the LVAD can be turned off.

The decision was to cover LVAD for all indications, and adoption of the guideline modifications.

**Recommended Actions:**

- 1) Modify Guideline Note as shown in Appendix A

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

➤ **Topic: Gender dysphoria**

**Discussion:** The four separate staff recommendation documents were reviewed. Staff referred to the voluminous amount of written testimony which has been received on this topic and which is available on the HERC website.

The first item discussed regarded the mental health requirements in the guideline. Hodges read an extensive suggested change proposed by one of the plan mental health providers. The subcommittee discussed the staff proposed changes to the mental health provisions and had concern for the proposed change that a provider be “knowledgeable.” The term “knowledgeable” was considered difficult to define. Would providers need to submit documentation of training or credentials? There was discomfort with requiring anything that would be considered credentialing, as this is supposed to be the purview of the CCOs. There was additional discussion about whether the person doing the referral for surgery needed to be a mental health professional who is not the patient’s personal counselor or treating psychiatrist. Requiring an additional consult was considered to be a possible barrier due to the mental health provider shortage in the state. However, the subcommittee members wanted to ensure that the evaluation was as thorough and unbiased as possible. In regards to the type and extent of an evaluation, the subcommittee felt that partially reversible interventions such as cross-sex hormone therapy should have a lower bar than irreversible interventions such as surgery. In addition, the majority of the subcommittee felt that all surgical interventions should have two referral letters. *[Note: the number of referrals for chest/breast surgery was reduced from 2 to 1 by HERC that afternoon to align with WPATH guidelines]*

The next topic discussed was possible limitations to the providers who could prescribe puberty suppression medications and/or cross sex hormone therapy. There was a clarifying question about whether naturopaths could prescribe these medications (yes). There was general concern that the group of providers should be large enough to ensure access but should have limits placed if there was a need for improved quality.

There was a general sense, however, that provider type for prescribing was an implementation question to be answered by HSD and the CCOs rather than by HERC.

Discussion then changed to the proposed surgical coding/guideline changes. Dr. Megan Bird from Legacy testified as an expert to assist with coding questions. Dr. Bird also testified that Washington Medicaid has recently changed their surgical coverage for gender dysphoria, and now cover mastopexy and penile implants. She suggested that HERC staff review this coverage. Dr. Bird also supplied 4 additional CPT codes for consideration that were not included in the meeting materials.

The last discussion item on this topic was regarding the possibility of age restrictions for various treatments for gender dysphoria. The subcommittee members were against adding any restrictions.

At this point, public testimony was heard. Dr. Christina Milano from OHSU testified that the current mental health requirements were limiting access to hormone therapy. She feels that an adequately trained PCP can prescribe cross sex hormone therapy if this provider is appropriately trained and competent in transgender health. She recommended following WPATH guidelines and considering carefully any deviations from WPATH. She also spoke to the issue of requiring providers to show documentation of being “knowledgeable,” testifying that it was difficult for providers to show adequate documentation.

Amy Penkin, LCSW from OHSU discussed who should be a “qualified mental health professional.” She felt that many providers are not yet licensed but are eligible. Many providers have the required degree, but are working on hours of patient care to qualify for licensure, and would be able to make these types of evaluations.

Dr. Megan Bird from OHSU testified that she encouraged alignment with WPATH, which is a conservative organization with appropriate care guidelines. She argued against age restriction. She feels that there are multiple safeguards for persons under 18 getting surgery—4 total evaluations (primary care, surgeon, 2 mental health) prior to surgery. She also testified about an ethics consult being available if needed. Hodges asked Bird about evidence that surgical outcomes being better or worse under age 18 (no evidence available).

Pollack voiced concern about possible poor care if there are not stringent requirements for the mental health evaluation. Milano replied that as a consultant, she finds most providers are very hesitant to prescribe rather than over-eager and felt that stringent requirements were not necessary. Olson asked about the number of providers available for these mental health services. Milano replied that there is no comprehensive registry, so the actual number of providers available and trained to do these evaluations is not known; however, there is lots of discussion amongst the various plans about who is trained and available. In her personal experience, she finds few providers outside the

Portland metro area. Bird noted that for surgical providers, the surgeon must show evidence of experience/training to obtain privileges to do a procedure at a hospital. There was discussion about the argument that PCPs provide care for other mental health issues other than gender dysphoria (depression, anxiety, PTSD, etc). Olson replied that there is a large body of evidence regarding best practices for these other mental health considerations, but standards are still being determined for gender dysphoria. Wentz noted that there was an access and implementation issue for HSD with the current guideline, with multiple complaints to the state about lack of access/providers.

Nico Quintana of Basic Rights Oregon testified that the lowest barriers possible for care should be adopted due to the marginalized nature of the transgender community, and their high risk of violence and suicide.

Kate Kauffman, a therapist, testified in opposition to age of consent changes. She feels that the current guideline ensures youth under 18 have a rigorous evaluation.

Dr. Carter, a naturopath active in transgender care, testified in favor of maintaining lower barriers to care. Many providers are competent to prescribe cross sex hormones and other therapy (like naturopaths).

At this point, the subcommittee resumed discussion of the four sets of staff recommendations. The first discussion was about the mental health requirements. For the specific question of changing "qualified" to "licensed," the subcommittee reviewed the testimony that pre-licensed providers may be able to perform these evaluations, and that physical health providers could, with training, perform them as well. There was discussion about the ability of pre-licensed providers to do these evaluations well, as they by definition have less experience. The response was that in many cases, a pre-licensed provider might have more training and/or experience than their supervising provider in the specifics of trans-gender evaluation and care. King read out selections from the current WPATH guideline section on mental health providers to show the extent of the description on who should provide mental health care. The subcommittee members felt that the WPATH guidelines were more extensive and comprehensive than any guideline HERC could write, and the decision was made to simply require a mental health evaluation provided in accordance to WPATH version 7 guidelines.

There was minimal additional discussion on limiting provider types. The subcommittee decided to not specify any type or training for a provider of puberty suppression medications or cross sex hormone therapy.

Staff suggested that rather than extensively discuss the surgical suggestions, that the proposed CPT code changes which had been vetted by experts be accepted (other than the mastopexy code). Additionally, the electrolysis code was added with the proposed guideline wording changes. Further discussion of mastopexy/breast augmentation and

penile implants was tabled until the next meeting and staff was directed to find Washington state coverage and guidelines on surgery. Bird will also provide staff with other surgical guidelines for breast surgery.

There was minimal further discussion on possible age limitations. Williams reminded the group that there was a lot of public sentiment in opposition to surgery prior to age 18 in addition to the unanimous support for it from those giving testimony today. The decision was to add no age limits.

**Recommended Actions:**

- 1) Modify Guideline Note 127 as shown in Appendix A
  - No changes recommended to the guideline to specify provider type or training for prescribing any type of medications used in gender dysphoria
- 2) Remove CPT 19301 (Lumpectomy) and 19302 (Mastectomy, partial; with axillary dissection) from line 413 GENDER DYSPHORIA
- 3) Add the following CPT codes to line 413 GENDER DYSPHORIA
  - 19318 (Reduction mammoplasty)
  - 19350 (Nipple/areola reconstruction)
  - 53415-53430 (Urethroplasty)
  - 54120 (Amputation of penis, partial)
  - 55150 (Resection of scrotum)
  - 55866 (Laparoscopy, surgical prostatectomy)
  - 56620 (Vulvoplasty, simple, partial)
  - 57295-57296 (Revision (including removal) of prosthetic vaginal graft)
  - 57426 (Revision (including removal) of prosthetic vaginal graft)
  - 58152 (Total abdominal hysterectomy)
  - 58660-58661(Laparoscopic oophorectomy)
  - 58940 (Oophorectomy, partial or total, unilateral or bilateral)
- 4) Add electrolysis (CPT 17380) to line 413 GENDER DYSPHORIA with guideline note modifications restricting use to surgical site preparation
- 5) Discussion of coverage of mastopexy/breast augmentation, penile implants, and scrotal implants was tabled to the next VbBS meeting
- 6) Discussion of any requirements for qualifications of surgeons was tabled to a future discussion
- 7) No age restrictions for any service were adopted

**MOTION: To recommend the code and guideline note changes as discussed. CARRIES 5-0.**

➤ **Topic: Temporary prostatic stents**

**Discussion:** Tabled until the next VbBS meeting

➤ **Topic: Vertebral fracture assessment**

**Discussion:** Tabled until the next VbBS meeting

➤ **Topic: Optic neuritis**

**Discussion:** Tabled until the next VbBS meeting

➤ **Topic: Trochanteric bursitis**

**Discussion:** Tabled until the next VbBS meeting

➤ **Topic: Exhaled nitric oxide testing for asthma**

**Discussion:** Smits introduced the summary document and staff recommendation for continuation of non-coverage. There was some discussion about the lack of requests from providers for coverage and the lack of claims received for this service. The subcommittee members felt that there was a community consensus to not use this test in the management or diagnosis of asthma.

**Recommended Actions:**

- 1) No change in current non-coverage of exhaled nitric oxide testing

➤ **Topic: Nose repair**

**Discussion:** Tabled until the next VbBS meeting

➤ **Topic: Coverage of perforations of the ear drum with hearing loss**

**Discussion:** Tabled until the next VbBS meeting

➤ **Topic: Continuous glucose monitoring guideline**

**Discussion:** Smits introduced the summary document and staff recommendations for modifications to this guideline. Rene Taylor, a registered dietician representing Dexcom (a device manufacturer), testified about studies showing the poor prognostic

implications of having had hypoglycemia in the prior 6 months. She reviewed literature showing serious impact of hypoglycemia on risk of hospitalization or future episodes of hypoglycemia.

There was discussion regarding how to define recurrent hypoglycemia. The subcommittee decided that recurrent was 3 or more events. The time for these events was debated and it was determined that these events should have occurred in the prior 6 months.

There was also discussion about the suggested modification to require reassessment at 6 month intervals. The criteria that needed to be met for reauthorization of the continuous glucose monitor were debated. It was decided to not adopt wording regarding reassessment and to direct HTAS to specifically address the criteria for continuing use during their review of the continuous glucose monitoring devices scheduled for this fall. If HTAS does not provide clarification on criteria for how frequently to review and criteria for continuing use, then VbBS will take up this topic again to determine these.

**Recommended Actions:**

- 1) Modify Guideline Note 108 as shown in Appendix A

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

➤ **Topic: Acute peripheral nerve injury guideline**

**Discussion:** Tabled until the next VnBS meeting

➤ **Topic: Botulinum toxin injections for migraine and bladder conditions**

**Discussion:** Smits outlined the need for guidelines for migraine and bladder indications for botulinum toxin injections. Karen Campbell from Allergan offered to answer subcommittee questions.

The main discussion centered on what is the definition of “positive response” for these therapies. The Center for Evidence-based Policy has reviewed botulinum toxin and has a definition in their report on what was considered “improvement,” which Valerie King volunteered to research. The P&T Committee may also have specific criteria for what they consider “positive response.” HERC staff will work with CEbP and P&T, and review literature to help determine what the best definition of improvement should be.

**Recommended Actions:**

- 1) Staff will contact P&T and CEbP staff and determine what criteria were used for “positive response” in the PA criteria and studies of CGM and bring back this topic to a future meeting

➤ **Topic: Coverage Guidance—Biomarkers**

**Discussion:** Dr. Robyn Liu reviewed the evidence and public comment for the Draft Coverage Guidance Biomarker Tests of Cancer Tissue for Prognosis and Potential Response to Treatment. Livingston reviewed the GRADE table and box language and the proposed changes to the Prioritized List. There was a brief discussion on the rapidity of evolution of these diagnostic tests. The proposed coding changes and new guideline note were accepted.

**Recommended Actions:**

- 1) Add S3854 (Gene expression profiling panel for use in the management of breast cancer treatment) to Line 195 (breast cancer)
  - i. Advise the Health Systems Division to remove S3854 from the Ancillary File
- 2) Place 81275 (KRAS) on Line 161 (colon cancer)
  - i. Advise the Health Systems Division to remove 81275 from the Diagnostic File
- 3) Place 81210 (BRAF) on Line 233 (malignant melanoma)
  - i. Advise the Health Systems Division to remove 81210 from Diagnostic Procedures File
- 4) Add the following to the Services Recommended for Non-coverage Table (all represented by nonspecific CPT codes unless specified)
  - i. Mammaprint
  - ii. ImmunoHistoChemistry 4 (IHC4)
  - iii. Mammostrat
  - iv. Microsatellite instability (MSI)
  - v. Urovysion
  - vi. Prolaris
  - vii. Multiple molecular testing (81504)
- 5) Adopt a new Guideline Note as shown in Appendix C

**MOTION: To approve the recommended changes to the Prioritized List based on the draft biomarkers coverage guidance scheduled for review by HERC at their August 13, 2015 meeting. CARRIES 5-0.**

➤ **Topic: Coverage Guidance—Planned Out-of-hospital births**

**Discussion:** Dr. Valerie King presented the evidence review and summarized the changes as a result of the public comment period. There were a series of clarifying questions about the evidence and the changes made, as well as the Oregon public health records data and the mortality rate among OOH births in Oregon. It was clarified that 6 out of the 8 deaths reported in that data would not meet current nor draft coverage guidance criteria for coverage. Livingston reviewed the GRADE table and the box language and raised the concern of needing to clarify what exactly is required for coverage to be recommended, if each high risk criteria needs to be ruled out. Further discussion was curtailed due to the ending of the meeting.

**Recommended Actions:**

This topic will be readdressed at the October 2015 VbBS meeting.

➤ **Public Comment:**

No additional public comment was received.

➤ **Issues for next meeting:**

- Coverage of breast augmentation and penile implants for gender dysphoria
- Botulinum toxin injections for migraine and bladder conditions
- Vertebral fracture assessment
- Trochanteric bursitis
- Nose repair
- Optic neuritis
- Temporary ureteral stents
- Coverage of repair of eardrum perforations in cases of hearing loss
- Acute peripheral nerve injury guideline
- Stem cell transplant for neuroblastoma
- Dysfunction line review
- Tobacco cessation coverage
- Tobacco use and elective surgery
- Craniofacial anomalies and obstructive sleep apnea

➤ **Next meeting:**

After a brief poll of those present, most could attend October 1, 2015, rather than the previously scheduled October 8, at location to be determined.

➤ **Adjournment:**

The meeting adjourned at 1:30 PM.

## Appendix A

### Revised Guideline Notes Effective October 1, 2015

#### DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING

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

1. Genetic counseling (CPT 96040, HPCPS S0265) for high risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, or elevated risk of neural tube defect.
2. Genetic counseling (CPT 96040, HPCPS S0265) prior to consideration of chorionic villus sampling (CVS), amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening
3. Validated questionnaire to assess genetic risk in all pregnant women
4. Screening high risk ethnic groups for hemoglobinopathies (CPT 83020, 83021)
5. Screening for aneuploidy with any of five screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, and contingency] (CPT 76813, 76814, 81508-81511)
6. Cell free fetal DNA testing (CPT [81420](#), 81507) for evaluation of aneuploidy in women who have an elevated risk of a fetus with aneuploidy (maternal age >34, family history or elevated risk based on screening).
7. Ultrasound for structural anomalies between 18 and 20 weeks gestation (CPT 76811, 76812)
8. CVS or amniocentesis (CPT 59000, 59015, 76945, 76946, 88235, 88267, 88280, 88291) for a positive aneuploidy screen, maternal age >34, fetal structural anomalies, family history of inheritable chromosomal disorder or elevated risk of neural tube defect.
9. Array CGH (CPT 81228, 81229) when major fetal congenital anomalies are apparent on imaging, or with normal imaging when array CGH would replace karyotyping performed with CVS or amniocentesis as in #8 above
10. FISH testing (CPT 88271, 88275) only if karyotyping is not possible due a need for rapid turnaround for reasons of reproductive decision-making (i.e. at 22w4d gestation or beyond)
11. Screening for Tay-Sachs carrier status (CPT 81255) in high risk populations. First step is hex A, and then additional DNA analysis in individuals with ambiguous Hex A test results, suspected variant form of TSD or suspected pseudodeficiency of Hex A
12. Screening for cystic fibrosis carrier status once in a lifetime (CPT 81220-81224)
13. Screening for fragile X status (CPT 81243, 81244) in patients with a personal or family history of
  - a. fragile X tremor/ataxia syndrome
  - b. premature ovarian failure
  - c. unexplained early onset intellectual disability
  - d. fragile X intellectual disability
  - e. unexplained autism through the pregnant woman's maternal line
14. Screening for spinal muscular atrophy (CPT 81401) once in a lifetime
15. Screening those with Ashkenazi Jewish heritage for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255)
16. Expanded carrier screening only for those genetic conditions identified above

The following genetic screening tests are not covered:

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

# Appendix A

## Revised Guideline Notes Effective October 1, 2015

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

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

Lines 86,102,267

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

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

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

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

When used as destination therapy, patients must

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

### **GUIDELINE NOTE 31, COCHLEAR IMPLANTATION**

Line 331

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

## Appendix A

### Revised Guideline Notes [Effective October 1, 2015](#)

- A) [Severe to p](#)rofound sensorineural hearing loss in both ears (defined as 71dB hearing loss or greater at 500, 1000 and 2000 Hz)
- B) Receive limited useful benefit from appropriately fitted hearing aids, defined as a speech discrimination score of <30% on age appropriate testing for children and as scores of 40% or less on sentence recognition test in the best-aided listening condition for adults
- C) No medical contraindications
- D) High motivation and appropriate expectations (both patient and family, when appropriate)

Bilateral cochlear implants are included on this line. Simultaneous implantation appears to be more cost-effective than sequential implantation.

#### **GUIDELINE NOTE 39, ENDOMETRIOSIS AND ADENOMYOSIS**

*Line 400*

- A) Hysterectomy, with or without adnexectomy, for endometriosis may be appropriate when all of the following are documented (1-4):
  - 1) Patient history of (a and b):
    - a) Prior detailed operative description or histologic diagnosis of endometriosis
    - b) Presence of pain for more than 6 months with negative effect on patient's quality of life
  - 2) Failure of a 3-month therapeutic trial with both of the following (a and b), unless there are contraindications to use:
    - a) Hormonal therapy (i or ii):
      - i) Oral contraceptive pills or patches, progesterone-containing IUDs, injectable hormone therapy, or similar
      - ii) Agents for inducing amenorrhea (e.g., GnRH analogs or danazol)
    - b) Nonsteroidal anti-inflammatory drugs
  - 3) Nonmalignant cervical cytology, if cervix is present
  - 4) Negative preoperative pregnancy test result unless patient is postmenopausal or has been previously sterilized
- B) Hysterectomy, with or without adnexectomy, for adenomyosis may be appropriate when all of the following are documented (1-~~6~~ 5):
  - 1) Patient history of dysmenorrhea, pelvic pain or abnormal uterine bleeding for more than six months with a negative effect on her quality of life.
  - 2) Failure of a six-month therapeutic trial with both of the following (a and b), unless there are contraindications to use:
    - a) Hormonal therapy (i or ii):
      - i) Oral contraceptive pills or patches, progesterone containing IUDs, injectable hormone therapy, or similar
      - ii) Agents for inducing amenorrhea (e.g., GnRH analogs or danazol)
    - b) Nonsteroidal anti-inflammatory drugs
  - 3) One of the following (a or b):
    - a) Endovaginal ultrasound suspicious for adenomyosis (presence of abnormal hypoechoic myometrial echogenicity or presence of small myometrial cysts)
    - b) MRI showing thickening of the junctional zone > 12mm
  - 4) Nonmalignant cervical cytology, if cervix is present

## Appendix A

### Revised Guideline Notes Effective October 1, 2015

- 5) Negative preoperative pregnancy test unless patient is postmenopausal or has been previously sterilized

#### **GUIDELINE NOTE 108, CONTINUOUS BLOOD GLUCOSE MONITORING**

*Line 8*

Services related to real-time continuous blood glucose monitoring (for long-term use) or retrospective glucose monitoring (for short-term use) are included on Line 8 only when insulin pump management is being considered, initiated, or utilized and only when the patient has at least one of the following despite compliance with treatment:

- HbA1c levels greater than 8.0% (~~despite compliance with treatment~~), or
- ~~a history of~~ recurrent hypoglycemia with at least three events in the past six months.

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

#### **GUIDELINE NOTE 127, GENDER DYSPHORIA**

*Line 413*

[*Note: The changes shown in **boldface italics** were approved by HERC later in the day to align with WPATH guidelines*]

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

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

1. have persistent, well-documented gender dysphoria
2. have the capacity to make a fully informed decision and to give consent for treatment
3. have any significant medical or mental health concerns reasonably well controlled
4. have a comprehensive mental health evaluation provided in accordance with Version 7 of the World Professional Association for Transgender Health (WPATH) Standards of Care ([www.wpath.org](http://www.wpath.org)). ~~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

## Appendix A

### Revised Guideline Notes Effective October 1, 2015

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. for breast/chest surgeries, have one referral from a mental health professional provided in accordance with version 7 of the WPATH Standards of Care.
7. for genital surgeries, 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)~~ provided in accordance with the version 7 WPATH Standards of Care.

Electrolysis (CPT 17380) is only included on this line for surgical site electrolysis as part of pre-surgical preparation for chest or genital surgical procedures also included on this line. It is not included on this line for facial or other cosmetic procedures or as pre-surgical preparation for a procedure not included on this line.

#### **GUIDELINE NOTE 49, WEARABLE CARDIAC DEFIBRILLATORS**

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

Wearable cardiac defibrillators (WCDs; CPT 93745, HCPCS E0617, K0606-K0609) are included on these lines for patients at high risk for sudden cardiac death who meet the medical necessity criteria for an implantable cardioverter defibrillator (ICD) as defined by the CMS 2005 National Coverage Determination but are unable to have an ICD implanted due to medical condition (e.g. ICD explanted due to infection with waiting period before ICD reinsertion or current medical condition contraindicates surgery). WCDs are not included on these lines for use during the waiting period for ICD implantation after myocardial infarction, coronary bypass surgery, or coronary artery stenting.

## Appendix B

### ~~Modified- Revised~~ gGuideline ~~n~~Notes ~~e~~Effective January 1, 2016

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

*Line 407*

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

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

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

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

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

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

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

## Appendix B

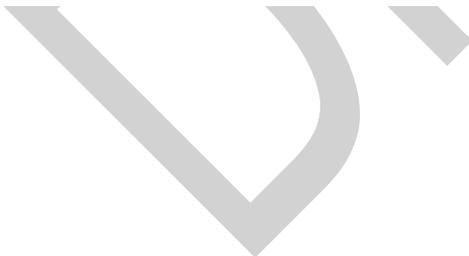
~~Modified- Revised~~ gGuideline ~~n~~Notes ~~e~~Effective January 1, 2016

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

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

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

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



## Appendix C

### New Guideline Notes Effective October 1, 2015

#### **GUIDELINE NOTE ~~XXX-148~~, BIOMARKER TESTS OF CANCER TISSUE**

*Lines 161, 188, 195, 233, 266, 274, 333*

The use of multiple molecular testing to select targeted cancer therapy (CPT 81504) is included on the Services recommended for non-coverage table.

For breast cancer, Oncotype Dx testing (CPT 81519, HCPCS S3854) is included on line 195 only for early stage breast cancer when used to guide adjuvant chemotherapy treatment decisions for women who are lymph node negative. Oncotype Dx is not included on this line for lymph node-positive breast cancer. Mammaprint, ImmunoHistoChemistry 4 (IHC4), and Mammostrat for breast cancer are included on the Services recommended for noncoverage table.

For melanoma, BRAF gene mutation testing (CPT 81210) is included on line 233.

For lung cancer, epidermal growth factor receptor (EGFR) gene mutation testing (CPT 81235) is included on line 266 only for non-small cell lung cancer. KRAS gene mutation testing (CPT 81275) is not included on this line.

For colorectal cancer, KRAS gene mutation testing (CPT 81275) is included on line 161. BRAF (CPT 81210) and Oncotype DX are not included on this line. Microsatellite instability (MSI) is included on the Services recommended for noncoverage table.

For bladder cancer, Urovysion testing is included on Services recommended for noncoverage table.

For prostate cancer, Oncotype DX is not included on line 333 and Prolaris is included on the Services recommended for noncoverage table.

The development of this guideline note was informed by a HERC coverage guidance. See [website](#).