MINUTES

Behavioral Health Advisory Panel
Wilsonville Training Center
Wilsonville, OR
September 16, 2015
9:00 am--11:00 ~~p~~am

Members Present: David Pollack, MD, Chair; Kathy Savicki, LCSW; Gary Cobb; Eric Davis, MSW, CADC III, PSS; Lynnea Lindsey-Pengelly, PhD, MSCP; Sheldon Levy, PhD; Mark Bradshaw, MD; Nimisha Gokaldas MD.

Members Absent: Roz Ringor-Carty, MSW

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Denise Taray.

Also Attending: Kim Wentz, MD, MPH, Laurie Theodorou, LCSW ~~(?)~~, and Lea Forsman (by phone), OHA; Molly Luoto, ~~from~~ Lindsay Hart LLC; Amy Brookhouse, Cascadia; Steve Stolzoff, GOBHI; Dan Reece, LCSW (by phone), ~~with the~~ Transformation Center.

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1. CALL TO ORDER

David Pollack called the meeting to order at 10:05 am. Members were introduced. Smits reviewed the agenda and briefly described the organizational structure of the HERC and its subcommittees. Coffman reviewed the purpose of the BHAP group in supporting HERC activities.

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2. ~~-~~PRIORITIZED LIST ISSUES

~~-~~Integration of physical and mental health care for child abuse and neglect

Discussion: Smits reviewed the staff summary document. The Advisory Panel agreed with consolidating the physical and mental health diagnoses and treatments onto the upper line for child abuse and neglect. There was a clarification that psychological abuse was also included on this line. The Panel also agreed that the related guideline was no longer needed.

Recommendations:

1) Combine medical and mental health treatments for child abuse and neglect into line 125 ABUSE AND NEGLECT
    a. Remove diagnosis codes for child abuse and neglect from line 177 POSTTRAUMATIC STRESS DISORDER
        i. ICD-9 995.52 (Child neglect (nutritional)), 995.53 (Child sexual abuse), 995.54 (Child physical abuse)
        ii. ICD-10 T74 series, T76 series (child neglect, child abuse, child sexual abuse)
        iii. All of these codes are already present on line 125
    b. Add certain mental health CPT codes to line 125
        i. CPT 90785 (Iinteractive complexity), 90832-90853 (pPsychotherapy, including family and group), 90882 (Environmental intervention for medical management purposes on a psychiatric patient's behalf with agencies, employers, or institutions), 90887 (Interpretation or explanation of results of psychiatric, other medical examinations and procedures), 96101 (psychological testing), 96127 (Brief emotional/behavioral assessment)
2) Delete Guideline Note 25

Mental Health Guidelines with Differential Treatment of Children by Age

Discussion: Smits introduced the summary staff recommendations. The first guideline discussed was GN20, ATTENTION DEFICIT/HYPERACTIVITY DISORDERS IN CHILDREN. The Panel felt that the list of required parent training was too restrictive. Other programs exist, or will likely be developed in the future. The group recommended replacing this list with "evidence-based, structured" parent-based training. The CCO/MCO representatives felt that their plans could develop a list of programs that were recommended. The other edits to this guideline were for clarity of wording.

The second guideline discussed was GUIDELINE NOTE 28, MOOD DISORDERS IN CHILDREN AGE EIGHTEEN AND UNDER. The panel disagreed with the staff recommendation and felt that there was no need for this guideline note and recommended deletion.

Next, GUIDELINE NOTE 42, DISRUPTIVE BEHAVIOR DISORDERS IN CHILDREN AGE FIVE AND UNDER was discussed and again the panel felt that this guideline did not add any value and should be deleted.

Lastly, GUIDELINE NOTE 45, ADJUSTMENT REACTIONS IN CHILDREN AGE FIVE AND UNDER was discussed. Generally, the panel felt that this guideline was not needed and should be deleted. It was pointed out that line 449 contains a coding specification which serves the function of the guideline note. It was brought to the attention of staff that the coding specification includes an

ICD-10 code (Z63.4 Disappearance and death of family member) that is not included on the actual line. Staff later noted that F43.8 (Other Specified Adjustment Reactions) is also including in line 449 coding specification but not actually on the line. Staff will add F43.8 and Z63.4 to line 449 as an errata. [or take as BHAP rec???]

The panel discussed having staff review the placement of the Z codes. Z codes are not always payable as primary billing codes; instead, they are often used as informational codes. Similar ICD-9 codes (the V code series) were used at times on the Prioritized List to allow for billing in certain situations. HERC staff will research the Z code placement issue further, and discuss with HSD staff and bring back to a future meeting.

Recommendations:

1) Modify GN20 as shown in Appendix A
2) Delete GN28, GN42, and GN45

Substance Intoxication and Withdrawal

Discussion: Smits reviewed the staff recommendations for this topic. The panel felt that the name of line 69 should be changed to reflect the inclusion of all the substance intoxication and withdrawal codes, and agreed with the recommended movement of ICD-9 codes. However, the group felt that the HCPCS substance abuse treatment codes recommended for removal from line 66 should stay there as there are diagnosis codes appropriate to pair with these procedures codes on that line.

Recommendations:

1) Rename line 69 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL
    a. Line includes all the substance intoxication and withdrawal ICD-10 codes
2) Remove drug intoxication ICD-9 codes from line 66 SUBSTANCE-INDUCED MOOD, ANXIETY, DELUSIONAL AND OBSESSIVE-COMPULSIVE and add to line 69
    i. 291.4 Idiosyncratic alcohol intoxication
    ii. 292.2 Pathological drug intoxication
    iii. 303.0x Acute alcoholic intoxication in alcoholism
    iv. Note: this change will be moot if the ICD-10 conversion occurs as scheduled on October 1, 2015

Statement of Intent 3, INTEGRATED CARE

Discussion: Smits reviewed the staff recommendation to delete SOI3. The panel felt that this was an excellent idea. There was some discussion about reviewing and allowing mental health diagnosis codes to pair with health education codes; however, this will fall under the new

workgroup that is convening to discuss ways to better integrate physical and mental health care at the state.

Recommendations:

1) Delete Statement of Intent 3

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3. CODING/REIMBURSEMENT ISSUES WITH INTEGRATED CARE

Taray and Dan Reece, LCSW with the Transformation Center reviewed a new workgroup that will be meeting, to assist the Health Systems Division and the health plans in integrating mental and physical health. This workgroup is tasked with clarifing existing rules to reduce confusion, and will work on coding and credentialing as core issues. BHAP will be updated on the work of this group, and will have the responsibility of applying workgroup recommendations to the Prioritized List (combine lines, aligning lines, adding codes to lines, etc.).

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4. ADJOURNMENT

The meeting was adjourned at 11:00am.

Appendix A
Recommended Guideline Revisions

GUIDELINE NOTE 20, ATTENTION DEFICIT/HYPERACTIVITY DISORDERS IN CHILDREN ~~AGE FIVE AND UNDER~~

Line 126

~~When using~~ Use of ~~ICD-9-CM 314.9/~~ICD-10-CM F90.9, Attention deficit/hyperactivity disorder, unspecified type, in children age 5 and under~~, it~~ is appropriate only when the following apply:

- Child does not meet the full criteria for the full diagnosis because of their age.
- For children age 3 and under, when the child exhibits functional impairment due to hyperactivity that is clearly in excess of the normal activity range for age (confirmed by the evaluating clinician's observation, not only the parent/caregiver report), and when the child is very limited in his/her ability to have the sustained periods of calm, focused activity which would be expected for the child's age.

For children age 5 and under diagnosed with disruptive behavior disorders, including those at risk for ADHD, ~~F~~first line therapy is evidence-based, structured "parent-behavior training." ~~(i.e. Triple P (Positive Parenting of Preschoolers) Program, Incredible Years Parenting Program, Parent-Child Interaction Therapy and New Forest Parenting Program). The term "parent" refers to the child's primary care givers, regardless of biologic or adoptive relationship.~~ Second line therapy is pharmacotherapy.

For children age 6 and over who are diagnosed with ADHD, pharmacotherapy alone or pharmacotherapy with psychosocial/behavioral treatment are included on this line for first line therapy.

~~Use of ICD-9-CM 314.9/ICD-10-CM F90.9 for children age five and younger is limited to pairings with the following procedure codes:~~

- ~~Assessment and Screening: 90791, 90792, H0002, H0031, H0032, T1023~~
- ~~Family interventions and supports: 90832-90838, 90846, 90847, 90849, 90887, H0038, H0045, H2021, H2022, H2027, S5151, S9125, T1005~~
- ~~Group therapy: 90785, 90832-90838, 90853, 99201-99215, H2032~~
- ~~Medication management: 90832-90838, 99201-99215~~
- ~~Case Management: 90882, T1016~~
- ~~Provider/teacher care coordination: 99366, 99367, 99368~~
- ~~Interpreter Service: T1013~~

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/herc/Pages/blog-treatment-adhd.aspx

Appendix B

Recommended Guideline Deletionsed Guidelines

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

Line 177

ICD-10-CM T76.02xA and T76.02xD (Child neglect or abandonment, suspected), (ICD-10-CM T74.02xA and T74.02xD (Child neglect or abandonment, confirmed), T74.22xA and T74.22xD (Child sexual abuse, confirmed), T76.22xA and T76.22xD (Child sexual abuse, suspected), T76.12xD (Child physical abuse, suspected, subsequent encounter) or T74.12xA and T74.12xD (Child physical abuse, confirmed) and corresponding ICD-9-CM codes 995.52, 995.53, 995,54 and – 995.59, may be used in any children when there is evidence or suspicion of abuse or neglect. These codes are to be used when the focus of treatment is on the alleged child victim. This can include findings by child welfare of abuse or neglect; or statements of abuse or neglect by the child, the perpetrator, or a caregiver or collateral report. Although these diagnoses can be used preventively, i.e. for children who are not yet showing symptoms, presence of symptoms should be demonstrated for interventions beyond evaluation or a short-term child or family intervention.

The codes T74.02xA, T74.02xD, T74.02XA, T74.02XD, T74.22xA, T74.22xD, T76.22xA, T76.22xD, T76.12xA, T76.12xD, 74.12xA or T74.12xD and corresponding ICD-9-CM codes 995.52, 995.53, 995,54 and – 995.59 may be used in children age five and younger and, in these instances only, is limited to pairings with the following procedure codes:

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

GUIDELINE NOTE 28, MOOD DISORDERS IN CHILDREN AGE EIGHTEEN AND UNDER

Line 207

The use of ICD-10-CM code F39 Unspecified Mood [Affective] Disorder/ICD-9-CM code 296.90, Unspecified Episodic Mood Disorder, is appropriate only for children 18 years old and under, who have functional impairment caused by significant difficulty with emotional regulation.

Use of ICD-10-CM F39/ICD-9-CM 296.90 is limited to pairings with the following procedure codes:

- · Assessment and Screening: 90791, 90792, H0002, H0031, H0032, T1023

- Family interventions and supports: 90832-90838, 90846, 90847, 90849, 90887, H0038, H0045, H2021, H2022, H2027, S5151, S9125, T1005
- Individual Counseling and Therapy: 90785, 90832-90838, 99201-99215, H0004
- Group therapy: 90785, 90832-90838, 90853, 99201-99215, H2032
- Medication management: 99201-99215
- Case Management: 90882, T1016
- Interpreter Service: T1013

GUIDELINE NOTE 42, DISRUPTIVE BEHAVIOR DISORDERS IN CHILDREN AGE FIVE AND UNDER

Line 425

The use of ICD-10-CM code F91.9 Conduct disorder, unspecified/ICD-9-CM 312.9, Unspecified Disturbance of Conduct), is appropriate only for children five years old and under, who display sustained patterns of disruptive behavior beyond what is developmentally appropriate. Interventions should prioritize parent skills training in effective behavior management strategies or focus on other relational issues.

Use of F91.9/312.9 is limited to pairings with the following procedure codes:

- Assessment and Screening: 90791, 90792, H0002, H0031, H0032, T1023
- Family interventions and supports: 90832-90838, 90846, 90847, 90849, 90887, H0038, H0045, H2021, H2022, H2027, S5151, S9125, T1005
- Individual Counseling and Therapy:90785, 90832-90838, 99201-99215, H0004
- Group therapy: 90785, 90832-90838, 90853, 99201-99215, H2032
- Case Management: 90882, T1016
- Interpreter Service: T1013
- Medication management is not indicated for these conditions in children age 5 and under.

GUIDELINE NOTE 45, ADJUSTMENT REACTIONS IN CHILDREN AGE FIVE AND UNDER

Line 449

ICD-10-CM code F43.2x/ICD-9-CM 309.89 can be used for individuals of any age. However, when using it for children five years of age or younger, who have experienced abuse or neglect, the following must apply:

The child must demonstrate some symptoms of PTSD (such as disruption of his or her usual sleeping or eating patterns, or more increased irritability/lower frustration tolerance) but does not meet the full criteria for PTSD or any other disorder.

A) F43.2x/309.89 is limited to pairings with the following procedure codes:

- Assessment and Screening: 90791, 90792, H0002, H0031, H0032, T1023
- Group Therapy: 90785, 90832-90838, 90853, 99201-99215, H2032
- Family Interventions and Supports: 90832-90838, 90846, 90847, 90849, 90887, H0038, H0045, H2021, H2022, H2027, S5151, S9125, T1005
- Case Management: 90882, T1016
- Interpreter Service: T1013

- Individual Counseling and Therapy: 90785, 90832-90838, 99201-99215
- Medication Management is not indicated for this condition in children five years of age or younger.

Note: Cessation of the traumatic exposure must be the first priority. Infants and toddlers may benefit from parental guidance regarding management of the child's symptoms, parental guidance around enhancing safety and stability in the child's environment, and therapeutic support for the parents.

ICD-10-CM codes Z62.82x (Parent-child conflict) and Z63.4 (Disappearance and death of family member), may only be used as secondary diagnoses to the primary diagnosis of F43.2x, and only for children five years of age or younger. Two ICD-9-CM codes, V61.20 (Counseling for Parent-Child Problem, Unspecified) and V62.82 (Bereavement, Uncomplicated), may only be used as secondary diagnoses to the primary diagnosis of 309.89 (Other specified adjustment reactions), and only for children five years of age or younger.

A) When using codes Z62.82x/V61.20, the following must apply:
   1) Service provision will have a clinically significant impact on the child.
   2) A rating of 40 or lower has been assessed on the PIR-GAS (Parent-Infant Relationship Global Assessment Scale).
   3) The same limitations in pairings to CPT and HCPCS codes as given for ICD-10-CM code F43.2x apply, with the only exception being that 90785 cannot be used.

B) When using ICD-10-CM Z63.4 (Disappearance and death of family member)/ICD-9-CM V62.82, the following must apply:
   1) The child exhibits a change in functioning subsequent to the loss of a primary caregiver;
   2) The child exhibits at least three of the following eight symptoms:
      a) Crying, calling and/or searching for the absent primary caregiver,
      b) Refusing attempts of others to provide comfort,
      c) Emotional withdrawal manifesting in lethargy, sad facial expression, and lack of interest in age-appropriate activities that do not meet mood disorder criteria,
      d) Disruptions in eating and sleeping that do not meet criteria for feeding and eating disorders of infancy or early childhood,
      e) Regression in or loss of previously achieved developmental milestones not attributable to other health or mental health conditions,
      f) Constricted range of affect not attributable to a mood disorder or PTSD,
      g) Detachment, seeming indifference toward, or selective "forgetting" of the lost caregiver and/or of reminders of the lost caregiver,
      h) Acute distress or extreme sensitivity in response to any reminder of the caregiver or to any change in a possession, activity, or place related to the lost caregiver;
   3) The symptoms in B(2) above are exhibited for most of the day and for more days than not, for at least 2 weeks.
   4) The same limitations in pairings to CPT and HCPCS codes as given for ICD-10-CM code F43.2x/ICD-9-CM code 309.89 apply.

~~Note: Intervention should include persons significantly involved in the child's care and include psychoeducation and developmentally-specific guidance.~~

~~STATEMENT OF INTENT 3: INTEGRATED CARE~~

~~Recognizing that many individuals with mental health disorders receive care predominantly from mental health care providers, and recognizing that integrating mental and physical health services for such individuals promotes patient-centered care, the Health Evidence Review Commission endorses the incorporation of chronic disease health management support within mental health service systems. Although such supports are not part of the mental health benefit package, mental health organizations (MHOs) that elect to provide these services may report them using psychiatric rehabilitation codes which pair with mental health diagnoses. If MHOs choose to provide tobacco cessation supports, they should report these services using 99407 for individual counseling and S9453 for classes.~~

MINUTES

Evidence-based Guidelines Subcommittee

Meridian Park Community Health Education Center, Room 117B&C
19300 SW 65th Avenue, Tualatin, OR
September 3, 2015
2:00-5:00pm

Members Present: Wiley Chan, MD, Chair; Vern Saboe, DC; Beth Westbrook, PsyD; George Waldmann, MD

Members Absent: Eric Stecker, MD, MPH, Vice-Chair; Bob Joondeph, JD

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

Also Attending: Adam Obley, MD, Val King MD, MPH and Aasta Thielke (OHSU Center for Evidence-based Policy); Judith Rooks; Sharron Fuchs; Joe Badolato (Family Care); Mellony Berdal (OHA Public Health); Kim Wentz, MD (OHA Health Systems Division); Carl Stevens (CareOregon).

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1. CALL TO ORDER

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

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2. MINUTES REVIEW

No changes were made to the June 4, 2015 minutes.
Minutes approved 4-0.

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3. STAFF REPORT

Coffman reported that Kathryn Leukin has resigned from the subcommittee as she took a different job. Alison Little, former CeBP staff member and now a medical director for PacificSource, has volunteered to join the subcommittee pending approval by HERC. If appointed by HERC, her first meeting would be in November.

Livingston reported about changes to the coverage guidance process, including a new format for the GRADE table. She asked for feedback after the meeting on the format and level of detail. There is more detail available in the appendices.

She also provided an update on the Coverage Guidance on Planned Out-of-Hospital Birth. The subcommittee had recommended that HIV and Hepatitis B status would need to be known to be

negative prior to a planned out-of-hospital birth, but there are a number of other indications where the subcommittee did not specify the need to rule them out prior to birth. Implementers want to have each risk factor addressed and ruled out for coverage.

There was an extensive discussion about whether it was the HERC versus implementers role to define how to rule in or out each of the criteria. It was clarified that documentation would be required, but clarity around whether each and every risk factor would have to be documented to rule out a risk condition was unclear. It was decided that discussing this with the ad hoc experts, to determine if every risk criteria was equal in requiring assessment and/or testing, was desireable and which tests may be required. . Plans and LDMs are both interested in clarity around what is required. Livingston asked whether EbGS had an expectation of whether each condition would need to be ruled out. Committee members agreed their discussion had not been this explicit except around specific issues such as whether to require a certain number of prenatal visits or testing for HIV and Hepatitis B. Livingston said that VbBS would discuss a staff proposal that every single condition would need to be addressed and ruled out. Wentz said she was working with an internal implementation committee to develop clear guidelines, and wanted to make sure only the key issues need to be addressed, and that no lower-priority items were included so that there would be no doubt about what was required. Waldmann expressed concern about requiring overly technical proof of something such as twin gestation, which he used to routinely detect before ultrasound was available. He said an experienced practitioner will recognize twins long before labor. After brief discussion, the subcommittee agreed that these concerns can be dealt with in the implementation process outside the coverage guidance process.

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4. REVIEW OF DRAFT COVERAGE GUIDANCE ON NITROUS OXIDE USE FOR LABOR PAIN MANAGEMENT

Livingston introduced Judith Rooks, who will serve as the ad hoc expert for this topic. Rooks is a certified nurse midwife and an epidemiologist. She also assisted with the development of the AHRQ report which served as the primary research source for this coverage guidance. Her only declared conflict of interest was nonfinancial; she has a long history of advocating the use of nitrous oxide for labor pain in the United States. King and Livingston provided an overview of the draft coverage guidance.

Livingston reviewed the GRADE table. Waldmann asked King whether any of the studies showed how often nitrous oxide administration is followed up with an epidural. King said she couldn't quote a number, but that in U.S. hospitals with limited anesthesia resources, there is often difficulty getting epidural anesthesia in a timely manner, so it may be of advantage for a woman to have nitrous oxide while waiting for an epidural. It was confirmed that studies also examined safety of nitrous oxide use in a home birth setting, but that many of the studies are non-U.S. studies, so standards for care in home birth are different than in the United States. Safety results were consistent across studies. There was general agreement that having a safe, effective alternative available to women in labor was valuable. The subcommittee briefly discussed the need for safe use of nitrous oxide (such as adequate ventilation and scavenging systems). These would need to be provided by the facilities in question, but these are regulatory issues, not coverage issues in the HERC's purview. Livingston invited public comment.

Sharron Fuchs offered comment. She noted that she was the one who suggested the topic for consideration by the HERC. She thanked the subcommittee for recommending a choice for women of an

additional effective, low cost treatment. She said her life would have been different if she had been provided with adequate pain relief in her first birth.

Chan commented that the values and preferences portion of the GRADE table in this case is different than is often the case. Where high variation in values and preferences generally leads to a weak recommendation, in this case because some women would want it and because the harms are low, it would argue for a statement that the values and preferences would strengthen the recommendation for coverage rather than weaken it. The same could happen under resource allocation; a high cost item could still be worthwhile. King noted that the values and preferences section may be influenced by public comment. Livingston asked whether there is an argument for a strong recommendation. After brief discussion the subcommittee made no change to the draft coverage guidance, as the underlying evidence is weak by normal standards.

The draft coverage guidance was referred for posting for public comment as presented, 4-0.

DRAFT HERC COVERAGE GUIDANCE

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

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5. TOPIC RESCAN—SCOPE REVIEW

Livingston explained that the topic rescan will now include an a priori scope statement, which will outline the search parameters and key questions for each topic prior to creating the literature search. For several topics (coronary artery calcium scoring, coronary CT angiography tomography and attention deficit/hyperactivity disorder), the HERC has already approved the scope statements, so the subcommittee can review the results of the literature scan based on the approved scope. For the remaining topics (neuroimaging for headache, cervical cancer screening, induction of labor and recurrent acute otitis media), HERC delegated the task of reviewing and approving the scope statements to EbGS.

Neuroimaging for Headache—Obley reviewed the draft scope document from the meeting packet. There was minimal discussion. Wentz asked about the outcome of harms from radiation—would it be reported by the amount of radiation or incidence of brain cancer. Obley said that the scan would retrieve both outcomes, but he suspects that most often it would be reported as the amount of radiation which could be cross-referenced with models to predict tumor incidence, though there is controversy in the literature about those models. After brief discussion the subcommittee changed the outcome to "harms from radiation exposure." Westbrook said her husband, who is a neurologist, believes imaging for headache tends to be overused but the harms are mostly the expense, or sometimes a delay in needed emergency care. Livingston said that during the previous review of the coverage guidance, the subcommittee asked which were the evidence-based indications for neuroimaging for headache, but the list was much shorter than any of the clinicians believed appropriate, so the current approved coverage guidance has a somewhat longer list based on trusted sources and evidence-based clinical guidelines. Because of this, key question 2 captures the red flag features, and that they will likely be based on evidence-based guidelines, not primary research.

Waldmann said he appreciated the inclusion of incidental findings. Chan suggested clarifying that the outcome should be "harms from incidental findings," as some incidental findings may be perceived as benefits; the subcommittee agreed to this change. It was clarified that comparative efficacy (such as between CT, PET, or MRI) would be identified by the search. After discussion the subcommittee made no additional changes to the scope document.

Cervical cancer screening—Livingston reviewed the recommendation to defer to the United States Preventive Services Task Force (USPSTF) on cervical cancer screening. Westbrook asked whether it would be reviewed in another two years. Livingston said the intent was to retire the coverage guidance and defer to the USPSTF going forward without any additional HERC review. Several concerns and issues were discussed, including the potential that a USPSTF recommendation may be out-of-date, differ from professional guidelines, or be out of line with the evidence in the future. There was also discussion about controversy regarding the impact of increased human papilloma virus vaccination on the need for screening. This question is currently under review by USPSTF. In addition the subcommittee heard about Federal requirements that most health plans must cover USPSTF "A" and "B" level services, and discussed whether services with an "I" (Insufficient evidence) rating might be appropriate coverage guidance topics. They agreed that taking on "I" recommendations may be appropriate, but not to take on "A" and "B" level recommendations with the intent that those recommendations would be followed. **The subcommittee voted 3-0, with Saboe abstaining, to recommend that HERC retire this coverage guidance.**

Induction of labor—Obley reviewed the scope document. Chan questioned the use of elective cesearean section as a comparator for induction of labor. After a brief discussion, including the lack of comparative trials, the fact that these are clinically not necessarily appropriate comparators, and the lack of current OHP coverage of elective cesarean, the group decided to remove elective cesarean as a comparator. It was also confirmed that elective induction with a favorable cervix after 39 weeks is a currently covered condition for OHP. **The subcommittee approved the revised scope document 4-0.**

Management of recurrent acute otitis media—Livingston drew the subcommittee's attention to a revised version which had been posted as a handout to the original meeting materials. Obley reviewed the draft and there was brief discussion. Wentz raised concerns about the harm of antibiotic resistance. There was a discussion about the potential lack of literature on this, but that it may be an important consideration that would sway coverage. They decided to have treatment related harms as an important outcome as this could change the recommendation. Wentz also raised the concern of age, as this problem occurs most often before the age of six, making the impact on school performance difficult to assess at the time a decision is made.

Carl Stevens, a medical director at CareOregon and professor of medicine at UCLA, provided public comment. He said that audiometry results are available during preauthorization conversations while speech delay can only be seen later. It would be a mistake to combine those. Wentz said that audiometry might not pick up intermittent hearing loss which may still lead to speech delay.

After additional discussion, the subcommittee edited the coverage guidance and settled on critical outcomes of severe infection (e.g. systemic infection, sepsis, meningitis, locally invasive infection), clinically significant hearing loss, and speech delay. Important outcomes were treatment-related harms and acute otitis media episodes. **The scope statement was approved as edited, 4-0.**

For the approved scope documents, see Appendix A.

6. TOPIC RESCAN—SCANNING RESULTS REVIEW

Livingston clarified that for these topics, HERC already set the scope parameters. The subcommittee's task was not to review the evidence at this meeting, but rather to determine whether an update to the existing coverage guidance is warranted based on the search which was conducted due to the rescan.

Coronary Artery Calcium Scoring—Obley reviewed the meeting materials. **After brief discussion, the subcommittee voted 4-0 to delay review of this topic until the AHRQ report is complete.** At that point the coverage guidance may or may not be re-opened depending on the results of that report. This could happen earlier than two years.

Coronary Computed Tomography Angiography—Obley reviewed the rescanning summary. Chan noted that there is new evidence on this topic, but there is also a pending AHRQ report. Stevens, an emergency doctor by training, said that the use of this technology for evaluation of possible angina versus for acute chest pain is different. The recent increase in use has been in the acute setting. **The motion to delay consideration until the release of the AHRQ report was approved 4-0.**

Attention Deficit/Hyperactivity Disorder—Obley reviewed the rescanning summary. For this topic there is an upcoming NICE report. The recommendation is to wait for the NICE report. The subcommittee discussed the changes in diagnostic criteria with DSM-5, the frequent comorbid conditions in the population with ADHD, and the exclusion of changes in diet. The subcommittee edited the key questions to include explicit consideration of mental health comorbidities to key questions 1 and 4. The issue of stimulant medication diversion was discussed, as this is an increasing problem. **After discussion, the subcommittee agreed to change the scope statement and to delay review pending the release of the NICE guideline, 4-0.** For the revised scope statement, see Appendix B

Chan asked a methodological question. If we are limiting the outcomes to 5, should we limit the interventions to five as well? For ADHD in particular there are a large number of interventions. Gingerich noted that limiting the number of interventions or subpopulations may be useful as well. Obley and King said that limiting the parameters simplifies the search and will help focus the discussion. The subcommittee also discussed that PICO and KQ need to be iterative throughout the process as unforeseen information can arise.

7. NEXT TOPICS

With none of the rescans resulting in an immediate review, the EbGS could take on an additional topic at its November meeting. Topics discussed included acupuncture, hysterectomy, management of chronic non-cancer pain, telepsychiatry, readmissions after hospitalizations for heart failure, bipolar disorder and smoking cessation in pregnancy and postpartum care. Any topics not already approved by HERC would need approval October 1. Livingston requested and received permission for staff to select a topic prior to the next meeting.

8. ADJOURNMENT

The meeting was adjourned at 5:00 pm. The next meeting is scheduled for November 5, 2015 in room 112 at the Wilsonville Training Center.

Appendix A

Neuroimaging for Headache

PICO & Key Questions for Updated Literature Search

Populations

Adults and children with non-traumatic, acute or chronic headache

Interventions

MRI or CT head/brain, with or without contrast enhancement

Comparators

Usual care, no neuroimaging

Outcomes

Critical: Morbidity from significant intracranial abnormalities

Important: Headache-free days, quality of life, harms from radiation exposure, harms from incidental findings

Outcomes considered but not selected for GRADE table:

Key Questions

KQ1: What is the comparative effectiveness of neuroimaging for headache in improving patient outcomes or detecting significant intracranial abnormalities?

a. Does the effectiveness of neuroimaging for headache vary based on acuity?

KQ2: What are evidence-supported red flag features which are indications for neuroimaging for headache?

a. Do the evidence-supported red-flag features which indicate neuroimaging vary based on acuity?

KQ3: What are the harms of neuroimaging for headache?

Cervical Cancer Screening

PICO & Key Questions for Updated Literature Search

Staff recommends retiring this coverage guidance and deferring to the United States Preventive Services Task Force (USPSTF).

The HERC Coverage Guidance, Routine Cervical Cancer Screening, approved in 2013, aligned with the USPSTF recommendations. Staff recommends retiring the coverage guidance because the USPSTF now defines use of preventive services for the Essential Health Benefits. The Essential Health Benefits provide minimum coverage standards on preventive services for most health plans in the United States.

Induction of Labor

PICO & Key Questions for Updated Literature Search

Populations

Pregnant adolescents and women

Interventions

IOL without medical or obstetrical indications

Comparator

Expectant management

Outcomes

Critical: Perinatal mortality, maternal mortality, neonatal morbidity

Important: Mode of birth (stratified by indication for operative delivery), maternal length of stay

Outcomes considered but not selected for GRADE table: iatrogenic prematurity, hemorrhage, epidural, patient satisfaction, neonatal length of stay

Key Questions

KQ1: What are the outcomes of IOL versus expectant management for women without medical or obstetrical indications for induction of labor?

KQ2: How do outcomes vary by cervical favorability, gestational age and parity?

Contextual Questions

CQ1: What are the evidence-based medical or obstetrical indications for induction of labor?

Recurrent Acute Otitis Media

PICO & Key Questions for Updated Literature Search

Population

Children with recurrent acute otitis media (AOM)

Interventions

Prophylactic or suppressive antibiotics, tympanostomy tubes (grommets), tonsillectomy and/or adenoidectomy (note that these interventions may be used alone, serially or in combination)

Comparators

Usual care, episodic treatment of AOM

Outcomes

Critical: Severe infection (e.g. systemic infection, sepsis, meningitis, locally invasive infection), clinically significant hearing loss, speech delay

Important: Treatment harms, acute otitis media episodes,

Outcomes considered but not selected for GRADE table: Missed school days, school performance/academic achievement.

Key Questions

KQ1: What is the comparative effectiveness of interventions (alone, serially, or in combination) for recurrent acute otitis media?

a. Are there subpopulations of children with recurrent acute otitis media who are more likely to benefit from prophylactic interventions?

KQ2: What are the harms of interventions for recurrent acute otitis media?

Appendix B

Treatment of ADHD in Children

PICO & Key Questions for Updated Literature Search

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?

MINUTES

Health Technology Assessment Subcommittee

Clackamas Community College Wilsonville Training Center

29353 SW Town Center Loop E

Wilsonville, OR 97070

September 10, 2015

1:00-4:00pm

Members Present: Som Saha, MD, MPH (Chair Pro Tempore); Jim MacKay, MD; Chris Labhart; Gerald Ahmann, MD; Leda Garside, RN, MBA; Mark Bradshaw, MD; Derrick Sorweide, MD;.

Members Absent: Tim Keenen, MD

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

Also Attending: Adam Obley, MD, Val King MD, MPH & Aasta Thielke (OHSU Center for Evidence-based Policy), Caroline Stephens (OHSU), Carl Rossi (Scripps), Michael Bolen (Medtronic), Renee Taylor (Dexcom), Bruce Wolfe (OHSU), Kristi Amerson (WVMC), Valerie Halpin (Legacy), Ramesh Rengan (Seattle Cancer Care Alliance).

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1. CALL TO ORDER

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

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2. MINUTES REVIEW

Minutes from the 6/11/2015 meeting were reviewed and approved 5-0.

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3. STAFF REPORT

Livingston reported that HERC approved some process changes to the Coverage Guidance process. There were concerns about lack of clarity of what the key research questions were as well as completeness of the literature search that required repeated literature review after a public comment period. Going forward there will be an a priori definition of the scope of the literature search, including definitions of the key questions, populations, interventions, comparators and outcomes of interest. This will be defined in the scope documents to be reviewed later in this meeting. In some cases the research literature won't address some of the items on the scope document, but at least this will be clearly acknowledged so that the subcommittee can make a decision based on the most relevant factors rather than just those with the largest evidence base. In addition, there will be a more comprehensive initial evidence search.

4. INDICATIONS FOR PROTON BEAM THERAPY—REVIEW OF PUBLIC COMMENT

Livington reviewed the remaining issues to be settled during this meeting. The subcommittee needs to review public comment on the three cancers not considered at the last meeting (lung cancer, prostate cancer and lymphoma) as well as some overall issues including coverage with evidence development, the age limit for pediatric cancers and how to address recurrent cancers. If the subcommittee completes its work, the draft coverage guidance would be referred to the VbBS and HERC.

She reviewed the issue of dosimetric studies. Previously the subcommittee had decided that comparative studies were possible for most cancers. But for some rare cancers it may be worth recommending coverage based on dosimetric studies without comparative evidence.

Saha invited public comment on this issue. Rossi explained dosimetric studies and how they are routinely used to compare radiation exposure (both for healthy and cancerous tissue) during treatment planning. Rengan detailed a process by which they use a comparative planning process with photon and proton models and decide which would be optimal based on maximum dose to the cancer tissue and minimal dose to surrounding tissue. For instance, tumors close to the spinal column and pediatric tumors are often best treated with protons, while photons can be preferable for rare geometries or mobile tumors. In other cases it's a coin toss. Cost and resources are also taken into account.

Livingston drew the subcommittee's attention to Table 1, where comparative data are available for many cancers. Is dosimetry enough to decide about a rare cancer for which there will likely be no evidence? MacKay asked what it is about a rare cancer that would make a proton preferable. Rossi said that it's typically the proximity of sensitive tissue to the tumor and the ability to give a higher dose to the tumor with less effect on surrounding tissue. He gave an example of a basal skull chordoma, where the spinal chord is nearby, and mesothelioma. Livingston noted that the draft guidance already recommends coverage for skull-based tumors.

Saha distinguished between the two arguments, of increasing radiation to the tumor and sparing surrounding tissue. For increasing dose to the tumor, the outcomes are known within two to five years, so research should be easier to do. The argument that research is difficult may be more compelling for sparing normal tissue because cancer resulting from the exposure of normal tissue to radiation may not appear for many years. Rengan agreed—for that reason outcomes are available for basal skull chordomas, where the rationale for proton beam therapy is improved local control due to the ability to safely deliver a higher radiation dose, and not for pediatric cancers, where secondary tumors are considered likely, but will not appear for many years after treatment. In addition, he said that newer proton beam technology can now target a smaller field, allowing treatment of additional sites, and that even for local control of these cancers comparative data is not yet available. After discussion the subcommittee decided to remain silent on rare cancers as they could be evaluated by medical directors through an exceptions process, noting that the same thing could happen with common cancers with rare circumstances. The subcommittee also affirmed the staff recommendation to remove the language recommending noncoverage for all other cancerous and noncancerous conditions.

Livingston brought up the question about recurrent cancers. Based on the discussion at the previous meeting, she believed the subcommittee's decision was not to put any specific limitations on proton beam therapy for recurrent cancers. There was little discussion.

The next issue was regarding the age limit for defining pediatric cancers. The subcommittee discussed that there is no evidence to guide this age cutoff. The staff proposal was to include patients up through age 21 in the pediatric group. Coffman noted that for the Oregon Health Plan in general, the limit for pediatric services is under age 21 (that is, through age 20). Lacking evidence to set a specific limit, the subcommittee decided to align with the age limits for other pediatric services in Medicaid.

Discussion turned to locally advanced non-small-cell lung cancer and medically inoperable non small-cell lung cancer. Livingston reviewed the public comments. The subcommittee and audience members with expertise in proton beam therapy discussed the alternative treatments available for these cancers and the evidence for these indications. Rossi and Rengan cited a study which reported positive results for this population. This study was included in the evidence base for the draft coverage guidance, but that subpopulation was not specifically addressed. Saha said that there will be individual circumstances where coverage is appropiate but that this subcommittee cannot itemize all of these. The subcommittee made no change to the recommendation for noncoverage based on this public comment.

Livingston brought up non-small cell lung cancer requiring re-irradiation. Rengan said there is no data comparing photons and protons for this population because they can't be safely retreated with photon-based therapy. Rengan said there is data showing a survival advantage over no retreatment with radiation for patients with a local (not systemic) relapse. The data were published by MD Anderson. After brief discussion, no change was made based on this comment.

For prostate cancer, Livingston reviewed the arguments for coverage made in the public comments. The studies referenced were already addressed by the evidence source and therefore staff recommended no change to the document. There was no discussion.

For lymphoma, Livingston reviewed the arguments for coverage from the public comments. Saha said lymphoma is a case where you might extend the age for coverage based on biology. It often affects people who are young or middle-aged. Ahmann said fewer patients are getting radiation for lymphomas, but Rossi said that what he is seeing instead is reduced dose and extent of radiation or combination chemotherapy and radiation; the majority still will receive radiation. Saha noted that we don't have evidence of short-term benefits, so the consideration is a theoretical long-term benefit based on reduced secondary malignancies years later, which is a significant issue in lymphoma, especially Hodgkin's disease. He asked whether secondary malignancies are still an issue with current lower radiation doses. Rengan said that preventing these is exactly why they are working to reduce the radiation dose. Rossi noticed there is also risk of pulmonary fibrosis and cardiac injury with radiation to normal tissue. Livingston said she sees a reason why this could be considered the preferred treatment, but that studies showing patient-oriented outcomes were possible.. Rengan said that without payers covering this, there will never be data showing the benefit as there is no stakeholder to fund the necessary studies. Saha acknowleged this but said it is a discussion for the full Commission, likely with input from the Oregon Health Authority, as this is experimental treatment.

Livingston then discussed ocular hemangiomas, which currently has a strong recommendation against coverage. She suggested changing the recommendation to weak because the strength of evidence is very low and the decision could change based on higher-quality evidence. After brief discussion, the subcommittee agreed to make that change and to list it with all the other conditions with a weak recommendation against coverage.

Saha thanked Drs. Rengan and Rossi for traveling to assist with the coverage guidance.

The subcommittee voted 5-0 to refer the draft coverage guidance to VbBS and HERC for review and application to the Prioritized List of Health Services.

DRAFT HERC Coverage Guidance

Proton beam therapy (PBT) is recommended for coverage for malignant ocular tumors (*strong recommendation*).

Proton beam therapy is recommended for coverage *(weak recommendation)* for:

- malignant brain, spinal, skull base, paranasal sinus, and juxtaspinal tumors
- pediatric malignant tumors (incident cancer under age 21)

Proton beam therapy is not recommended for coverage for cancer of the bone, breast, oropharynx, nasopharynx, esophagus, liver, lung, or prostate or for gynecologic or gastrointestinal cancers, lymphoma, sarcoma, thymoma, seminoma, arteriovenous malformation or ocular hemangiomas *(weak recommendation).*

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5. COVERAGE GUIDANCE MONITORING

Livingston explained that the subcommittee's next task is the review and approval of scope statements for the coverage guidance topics approved in 2013. The HERC had originally started on these but referred the task to the subcommittee. For each topic, Obley reviewed the meeting materials. There was no public comment except where mentioned below. The scope statements and rescan results appear in Appendix A as modified during this discussion.

Continuous glucose monitoring Obley reviewed the scope statement on continuous glucose monitoring. Bradshaw suggested the inclusion of subpopulations such as those with frequent hospitalizations for ketoacidosis. It may not be cost effective in the general population, but may be for this group. Obley said he didn't know if there were specific studies of this population, but that if ketoacidosis were reduced in a general population, it would be reasonable to conclude that it would help in this subgroup. After discussion the subcommittee added "patients with persistently poor glycemic control" as a subpoint under key question 3. The subcommittee discussed adding insulin dose reduction as an outcome but elected not to, as it would be included in the narrative if reported in the literature.

Saha invited public testimony. Michael Bolen, director of government affairs for Medtronic testified, requesting consideration of an integrated system including an insulin pump and continuous glucose monitor, as this has now been approved by the Food and Drug Administration for patients with recurrent hypoglycemia (not high glucose levels). The device suspends insulin delivery for up to two hours when hypoglycemia is detected, allowing parents of children with Type 1 diabetes to sleep through the night without checking insulin.

After brief discussion, the subcommittee agreed to make a change to key question 3 to include consideration of this technology.

Self monitoring of blood glucose There was minimal discussion and concluded no changes to the draft document were necessary.

Diagnosis of sleep apnea in adults. The subcommittee discussed adding mental health outcomes such as depression, but after discussion decided that this would be included under quality of life. Obley said the narrative could include outcomes such as this if they appeared in the literature, though these would not be included in the GRADE table. The subcommittee made no changes.

Breast MRI after diagnosis of breast cancer The subcommittee deleted the contextual question about decisional conflict as it would be unlikely to influence a coverage decision.

PET scan for breast cancer The subcommittee discussed whether to include the population of patients with ductal carcinoma in situ (DCIS) or stage I breast cancer. Livingston said that if these populations weren't included the coverage guidance would need to remain silent on it. After discussion the subcommittee agreed to include this population so that a coverage recommendation could be made one way or the other. However, they decided to remove the contextual question about decisional conflict for the same reasons as for the MRI topic.

Vertebroplasty, kyphoplasty and sacroplasty The subcommittee discussed adding length of stay, but ultimately decided that this would be captured in functional improvement and added it as an outcome considered but not included.

Carotid endarterectomy For this topic, the HERC had completed the scope document, so for this topic, the subcommittee was charged with deciding whether a complete update of the coverage guidance was in order based on the preliminary literature search conducted by staff. The subcommittee discussed that there is no current coverage guidance on stenting, and that making coverage recommendations on which patients should receive stenting versus endarterectomy would be inappropriate for a coverage guidance. Obley said that the benefit of stenting may be primarily for the over 65 population. He said patients with a poor preoperative risk for endarterectomy have a slight mortality benefit from stenting, but at the expense of perioperative strokes. After brief discussion the subcommittee decided to recommend that HERC not authorize an update of this topic or request a review of stenting.

After discussion, the subcommittee voted 5-0 not to request an update for the coverage guidance on carotid endarterectomy and to approve the scope statements as modified above and shown in Appendix A.

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6. COVERAGE GUIDANCE ON BARIATRIC SURGERY

Coffman introduced Dr. Bruce Wolfe, who has been appointed as an ad hoc expert for this topic. Wolfe declared a conflict of interest in serving as an investigator on the Recharge trial of vagal blocking (an alternative obesity treatment) and notes funds received by OHSU from Enteromedics. Saha acknowledged his extensive involvement with the Health Services Commission's prior review of the topic several years ago.

Obley and Livingston reviewed the draft coverage guidance including the GRADE table. Coffman noted that the meeting was nearing its conclusion, but that most of the December meeting would be

dedicated to this coverage guidance. Wolfe mentioned written comments he submitted to staff, which contained some relatively minor concerns about the draft coverage guidance. The most significant is the omission of nonrandomized trials showing problems with gastric banding.

Saha provided some context for the topic. First, when the HERC previously reviewed the topic there was concern about high utilization of this procedure due to high rates of obesity in Oregon and specifically in the Medicaid population. There were also concerns about quality, which led to a restriction to surgeons who perform a high volume of bariatric surgery. In fact, this surgery has not become highly prevalent. He also reminded the subcommittee of the bias many people have that obesity is a behavioral problem which should not be treated surgically. This bias could easily result in an inappropriate reason to restrict coverage, a bias which might not affect judgments about a hypothetical surgery which could reduce diabetes by 75 percent in non-obese people. He encouraged the subcommittee to not let this sort of bias impact decisionmaking.

Livinston alerted the subcommittee to pending changes in the coverage recommendation. These will be made prior to the next meeting due to additional evidence that has been added since the recommendation portion was drafted. In addition, staff will include consideration of re-operation rates and outcomes for these surgeries. Discussion of this topic will continue at the next meeting.

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5. ADJOURNMENT

The meeting was adjourned at 4:00 pm. The next meeting is scheduled for December 10, 2015 from 1:00-4:00pm in Room 210 of the Wilsonville Training Center of Clackamas Community College.

Appendix A

Continuous Blood Glucose Monitoring

PICO & Key Questions for Updated Literature Search

Populations

Children, adolescents, and adults with type 1 or type 2 diabetes mellitus (DM) on insulin therapy, including pregnant women

Intervention

Continuous blood glucose monitoring (CBGM), either retrospective or real time

Comparators

Self-monitoring blood glucose (SMBG) and/or routine HbA1c monitoring

Outcomes

Critical: Severe morbidity (e.g. microvascular and macrovascular complications), severe hypoglycemia[1]

Important: Quality-of-life, change in HbA1c, ketoacidosis

Outcomes considered but not selected or GRADE table:
Myocardial infarction, cerebrovascular accident, amputations, neuropathy, retinopathy, nephropathy--we chose to generalize these into "severe morbidity" to simplify consideration; diabetes-related hospitalizations; and emergency department visits.

Key Questions

1. What is the evidence of effectiveness of CGM in improving outcomes in people with diabetes?
2. What are the indications for retrospective and for real time CGM?
3. Is there evidence of differential effectiveness of CGM based on:
    a. Type 1 vs Type 2 DM?
    b. Insulin pump (integrated with CGM or standalone) vs multiple daily insulin injections (MDII)?
    c. Frequency and duration of CGM?
    d. Patients with persistently poor glycemic control

[1] "An event requiring assistance of another person to actively administer carbohydrate, glucagons, or other resuscitative actions." (ADA Workgroup on Hypoglycemia, 2005)

Appendix A

Self-Monitoring of Blood Glucose

PICO & Key Questions for Updated Literature Search

Populations

Children, adolescents, and adults with type 2 diabetes mellitus who are not using multiple daily insulin injections (MDII)

Intervention

Self-monitoring of blood glucose (SMBG), with or without structured education and feedback programs.

Comparators

No routine monitoring using SMBG, periodic monitoring of HbA1c

Outcomes

Critical: Severe morbidity (e.g. microvascular and macrovascular complications, severe hypoglycemia[1]

Important: Quality-of-life, change in HbA1c, hyperosmolar hyperglycemic state (HHS)

Outcomes considered but not selected for GRADE table: Hospitalizations, emergency department visits.

Key Questions

1. What is the effectiveness of SMBG in improving outcomes in children, adolescents, and adults with type 2 diabetes mellitus who are not using multiple daily insulin injections (MDII)?
2. What is the evidence of harms associated with SMBG in this population?
3. Is there evidence of differential effectiveness of SMBG based on:
    a. Type of treatment (i.e. diet and exercise, oral antidiabetic agents, basal insulin, non-insulin injectables)
    b. Frequency of testing
    c. Degree of glycemic control at baseline
    d. Association with a structured education and feedback program
4. What are appropriate quantities of testing supplies for this population, and what factors should trigger allowances for additional supplies (e.g. infection, driving, new diagnosis, etc.)

[1] "An event requiring assistance of another person to actively administer carbohydrate, glucagons, or other resuscitative actions." (ADA Workgroup on Hypoglycemia, 2005)

Special considerations

1. We will not search the literature on people with Type I diabetes or Type II diabetes with multiple daily insulin injections, as these are well-established and had a strong recommendation in the last coverage guidance.

Diagnosis of Sleep Apnea in Adults

PICO & Key Questions for Updated Literature Search

Populations

Adults with clinical signs and symptoms of obstructive sleep apnea (OSA)

Intervention

Polysomnography; attended or unattended, sleep lab or at home

Comparators

Usual care

Outcomes

Critical: Major adverse cardiovascular events, fatigue-related accidents

Important: Improvement in HTN, measures of daytime fatigue, quality-of-life

Outcomes considered but not selected for GRADE table: Resolution of metabolic syndrome

Key Questions

KQ1: What is the effectiveness of polysomnography in improving outcomes for patients with suspected OSA?

a. What are the diagnostic cutoffs associated with improved outcomes?

KQ2: What is the differential effectiveness of polysomnography based on the type of device used or the setting in which testing is performed?

KQ3: What are the harms of polysomnography?

Contextual Questions

CQ1: Are there clinically validated tools (i.e. questionnaires and/or physical parameters) to assess the pretest probability of OSA?

a. If validated tools exist, at what levels of pretest probability should polysomnography not be recommended?

Breast MRI after Diagnosis of Breast Cancer

PICO & Key Questions for Updated Literature Search

Population

Adults with recently diagnosed breast cancer

Intervention

Breast MRI

Comparator

Usual care, including other imaging modalities

Outcomes

Critical: All-cause mortality, cancer-specific mortality

Important: Progression-free survival, false-positive test results, quality of life

Outcomes considered but not selected for GRADE table: change in surgical or non-surgical treatment plan

Key Questions

KQ1: What is the comparative effectiveness of breast MRI after the diagnosis of breast cancer for improving patient outcomes?

KQ2: What are the harms of breast MRI after the diagnosis of breast cancer?

Contextual Questions

CQ1: How often do the results of MRI after breast cancer diagnosis lead to changes in the surgical or non-surgical treatment plan?

PET CT for Breast Cancer Staging and Surveillance

PICO & Key Questions for Updated Literature Search

Populations

Adults with early stage breast cancer (DCIS, stage I, or stage II) or who have been treated for breast cancer with curative intent

Interventions

PET CT for initial staging, surveillance, or monitoring response to treatment

Comparators

Usual care (including axillary lymph node dissection [with or without sentinel lymph node biopsy], CT and radionucleide scintigraphy), MRI

Outcomes

Critical: All-cause mortality, cancer-specific mortality

Important: Progression-free survival, false positive tests, quality of life

Outcomes considered but not selected for GRADE table:

Key Questions

KQ1: What is the comparative effectiveness of PET CT in early stage breast cancer or breast cancer treated with curative intent in improving patient important outcomes for staging, monitoring response, or surveillance?

KQ2: What are the harms (including false positive tests, radiation exposure) of PET in early stage breast cancer or breast cancer treated with curative intent?

Contextual Questions

CQ1: How often do the results of PET CT after breast cancer diagnosis lead to changes in the surgical or non-surgical treatment plan?

Populations

Adults with acute or chronic vertebral compression or sacral insufficiency fractures

Interventions

Percutaneous vertebral and sacral procedures

Comparators

Open spinal surgical procedures, sham/placebo surgery, medical therapy (including non-pharmacologic interventions like physical therapy or acupuncture)

Outcomes

Critical: All-cause mortality, short- and long-term improvement in function

Important: Short- and long-term improvements in pain or quality of life, recurrent fracture, clinically significant embolization

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

Key Questions

KQ1: What is the comparative effectiveness of percutaneous interventions for vertebral compression or sacral insufficiency fractures?

KQ2: What are the harms of percutaneous interventions for vertebral compression or sacral insufficiency fractures?

Carotid Endarterectomy for Carotid Artery Stenosis – 2015 Rescanning Summary

Subcommittee : Health Technology Assessment Subcommittee (December 2013)

Bottom Line: There is new (but limited and contradictory) summary evidence and guidelines about the comparative effectiveness of CEA vs carotid stenting or optimal medical treatment.

Coverage Recommendation (Box Language)

Carotid endarterectomy is recommended for coverage for patients who are symptomatic (recent transient ischemic attack or ischemic stroke) and who have 70-99% carotid stenosis without near-occlusion (*strong recommendation*).

For patients with 50 – 69% carotid stenosis who are symptomatic despite optimal medical management, carotid endarterectomy is recommended for coverage (*weak recommendation*).

Carotid endarterectomy is not recommended for coverage for symptomatic patients with less than 50% carotid stenosis (*strong recommendation*).

Carotid endarterectomy is recommended for coverage for patients with asymptomatic carotid stenosis of at least 60% only for those who do not tolerate (or have contraindications to) best current medical therapy (*weak recommendation*).

Screening for asymptomatic carotid artery stenosis in the general primary care population is not recommended (*strong recommendation*).

Scope Statement

Population description	Adults with carotid stenosis with or without recent symptoms of cerebral ischemia *Population scoping notes:* None
Intervention(s)	Carotid endarterectomy *Intervention exclusions:* None
Comparator(s)	Optimal medical therapy, carotid stenting
Outcome(s) (up to five)	**Critical:** All-cause mortality, cerebrovascular accidents **Important:** Transient ischemic attacks, development/progression

	of vascular dementia, quality of life *Considered but not selected for GRADE table:* Need for reintervention
Key questions	1. What is the comparative effectiveness of carotid endarterectomy for treatment of symptomatic or asymptomatic carotid stenosis? 2. What degree of carotid stenosis predicts clinical utility of carotid endarterectomy? 3. What are the harms of carotid endarterectomy? 4. Under what circumstances should carotid endarterectomy be covered for asymptomatic patients (i.e. when stenosis is found as an incidental finding?)

Original Evidence Sources

Chambers B.R., & Donnan, G. (2005). Carotid endarterectomy for asymptomatic carotid stenosis. *Cochrane Database of Systematic Reviews*, Issue 4. Art. No.: CD001923. DOI: 10.1002/14651858.CD001923.pub2. Retrieved July 23, 2012 from http://summaries.cochrane.org/CD001923/carotid-endarterectomy-for-asymptomaticcarotid-stenosis

Publication status and date: Edited (no change to conclusions), published in Issue 4, 2008.

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Scanning Results (reviewed for applicability, methodologic quality not assessed)

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Summary

Citation 1 is a large meta-analysis of 44 studies (comprising nearly 600,000 patients) of CEA or carotid stenting. It provides new information on the comparative effectiveness of CEA vs carotid stenting and suggests that the best intervention may vary depending on the age of the patient.

Citation 2 is a systematic review of 50 studies reporting on indications for CEA or carotid stenting in patients with recurrent carotid stenosis after an initial CEA. It does not provide information that would change the coverage guidance.

Citation 3 is a systematic review and multidisciplinary evidence-based guideline from Germany and Austria. The recommendations generally comport with the existing HERC coverage guidance, although they do not require a trial of optimal medical therapy before considering CEA in asymptomatic individuals with >60% stenosis (while also acknowledging that controlled trials of various treatment options for asymptomatic

patients are needed). It also offers guidance on situations in which carotid stenting may be preferable to CEA.

Citation 4 is an AHRQ review of literature on cognitive outcomes after cardiovascular procedures in older adults. It concludes that CEA and endovascular interventions for carotid revascularization result in similar intermediate-term cognitive outcomes.

Citation 5 is a meta-analysis of individual-level patient data on CEA vs carotid stenting for treatment of ipsilateral restenosis after prior CEA. The short-term outcomes of stroke, death, and restenosis were similar between the two interventions.

Citation 6 is a systematic review and meta-analysis of RCTs comparing CEA and medical therapy in patients with symptomatic or asymptomatic carotid stenosis. It concludes that CEA is beneficial for symptomatic patients with >50% stenosis, but offers no benefit in asymptomatic patients. The latter conclusion is potentially at odds with the current HERC coverage guidance.

Citation 7 is a cost-effectiveness study of CEA in the Danish National Health Service. Any conclusions are probably too indirect to influence the HERC coverage guidance.

Citations 8, 9, and 11 comprise updated evidence and USPSTF guidelines regarding screening for carotid stenosis in asymptomatic individuals. They support the current HERC coverage guidance that does not recommend screening in asymptomatic individuals.

Citation 10 is an economic evaluation of carotid stenting with an embolic-prevention device vs CEA for patients at average surgical risk. Because stenting produces only marginally greater QALYs compared with CEA at greater cost, the ICER for stenting is >$200,000. It would provide new contextual information on resource use if the coverage guidance is updated.

Citation 12 is an updated systematic review and meta-analysis of RCTs comparing CEA and carotid stenting. Its overall conclusion is that stenting is inferior to CEA with respect to stroke or death, but because of a lower incidence of myocardial infarction, stenting may be preferable in selected patients.

Citations 13 and 20 summarize evidence on the appropriate use and timing of CEA after thrombolysis for acute ischemic stroke. Generally, these studies support the safety of CEA withing 14 days of an acute ischemic stroke treated with thrombolysis, though the quality of evidence is low.

Citation 14 is a systematic review of studies comparing cognitive function after CEA vs carotid stenting. Due to a high degree of heterogeneity among the included studies, meta-analysis was not performed and definite conclusions could not be drawn.

Citation 15 is a health technology assessment of carotid stenting performed for the Washington HTA. On the basis of these results, the Washington HTA has opted to cover carotid stenting for symptomatic patients with >50% stenosis or asymptomatic patients with >80% stenosis AND who are deemed to be at high operative risk for CEA. This information would potentially change HERC coverage guidance.

Citation 16 is a cost-effectiveness analysis of CEA vs carotid stenting based on a retrospective case series at a single institution. This study design is inadequate to inform HERC coverage guidance.

Citation 17 is a cost-effectiveness study of CEA for asymptomatic individuals in the British National Health Service. Any conclusions are probably too indirect to influence the HERC coverage guidance.

Citation 18 is an economic evaluation of carotid stenting vs CEA for patients at average surgical risk. It concludes that there are trivial differences in the long-term costs between the two interventions. It would provide new contextual information on resource use if the coverage guidance is updated.

Citation 19 is a meta-analysis of 8 trials comparing CEA vs carotid stenting in symptomatic patients. This appears to be a low-quality systematic review and would probably not be included for review in an update of the HERC coverage guidance.

Appendix A. Methods

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 "carotid endarterectomy" and "carotid stenosis." Searches of core sources were limited to citations published after 2011 (the last search date of original evidence sources).

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.
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

A MEDLINE® (Ovid) search was conducted to identify systematic reviews, meta-analyses, and technology assessments published after the search dates of original evidence sources. The search was limited to publications in English published after 2012 (last search dates of original evidence sources).

Searches for clinical practice guidelines were limited to those published since 2012 (last search date of coverage guidance). 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
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 assessment, or clinical practice guidelines.

MINUTES

Health Evidence Review Commission's
Oral Health Advisory Panel (OHAP)

Clackamas Community College
Wilsonville Training Center, Room 210
September 22, 2015
8:00-10:00 AM

Members Present: Bruce Austin, DMD, Chair Pro Tempore; Deborah Loy; Mike Shirtcliff, DMD (via phone); Gary Allen, DMD; Lynn Ironside; Lori Lambright; Mike Plunkett, DDS, MPH (at 8:20); Patricia Parker, DMD; Karen Nolan.

Members Absent: Benjamin Hoffman, MD; Eli Schwarz, DDS, MPH, PhD.

Staff Present: Darren Coffman; Ariel Smits, MD, MPH.

Also Attending: Dee Weston, Sarah Wetherson, Brian Nieubuurt, and Lori Johnson, OHA; Cathleen Olesitse, Care Oregon; Laura McKeane, All Care Health; Paul Bullinger and Ashlen Strong, Healthshare of Oregon; Caroline Larsen, WVCM; Dayna Steringer, DK Strategies LLC and Advantage Dental.

Roll Call/Minutes Approval/Staff Report

The meeting was called to order at 8:05 am and roll was called. Minutes from the October 15, 2014 OHP meeting were reviewed and approved.

Smits reviewed the charge of OHAP and the organizational structure within HERC.

- **Topic: 2016 CDT Code Review**

  Discussion: The proposed placement for the new 2016 CDT codes included in the meeting materials, reflecting input from the DCO Contractors, were reviewed. The code placements were accepted as proposed with minimal discussion except for the following:

  1) D5221-D5224 were placed as recommended on a non-covered line. OHAP clarified that immediate partial dentures are not a covered item because it is very difficult to correctly fit dentures until the mouth is healed from the extraction process. The delayed partial denture CDT codes are on a covered line.

  2) D9223 and D9243 (dental anesthesia codes) were recommended to be placed on the Exempt List rather than the Ancillary List, as the dental providers do not used

diagnosis codes and the Ancillary List therefore is not applicable. The other dental anesthesia codes are on the Exempt List, and there are dental rules in place regarding their use.

3) D1354 (interim caries arresting medicament application) was extensively discussed. This CDT code is mainly used for the application of silver diamine fluoride. This treatment provides tertiary prevention, to arrest caries already present. Therefore, this procedure is not appropriate for a prevention line, which contains only primary and secondary preventive services. It is most appropriate for the dental caries line (line 358). Plunkett asked that a guideline be added to define what a "medicament" is, as this term is very vague. Currently, it refers to silver diamine fluoride, but other existing compounds and compounds under development could fall into this category. HERC reviewed silver compounds including silver diamine fluoride in January, 2013 and determined that these compounds should not be covered and added a guideline to the Prioritized List (GN91) specifically calling out non-coverage. At that time, silver diamine fluoride was not FDA approved (it has subsequently been approved), and the majority of the research into its effectiveness was done outside of the US. The previous HERC discussion had also included silver nitrate, which OHAP does not feel should be covered. There was additional concern about the black staining of teeth with silver treatments.

The majority of OHAP felt that this treatment is effective for arresting caries and for treating the dental infectious process. The group felt that newer compounds currently being studied will prove to be equally or more effective. The group was unanimous in feeling that D1354 should be covered, and recommended adding a guideline limiting this code to represent only the use of silver diamine fluoride, with further limitation to 2 applications a year. The group felt that this guideline would be an interim guideline for the next year or two, while OHAP could further investigate the research and standards for use, and create a more comprehensive guideline note.

A representative from Delta Dental testified that Delta Dental was not going to cover this CDT code for 2016 due to concerns about defining medicament and for concerns about the experimental nature of the therapy.

Shirtcliff forwarded an in-press review by Horst in the California Dental Association Journal on silver diamine fluoride to the group, which he felt was an excellent summary of the technology and its recommended uses.

The decision was made to recommend placement of D1354 on line 358 DENTAL CONDITIONS (EG. CARIES, FRACTURED TOOTH), with a new guideline. GN91 was recommended for deletion. HERC staff was directed to 1) research the CDT committee minutes for additional information on why this code was approved, 2) review the recently published MED report on this topic, and 3) review the identified

review article on this topic. HERC staff will compile this material for the October 1, 2015 VBBS meeting for further discussion.

Actions:

1) See recommended 2016 CDT code placements in Appendix A
2) Delete GN91

~~**GUIDELINE NOTE 91, SILVER COMPOUNDS FOR DENTAL CARIES**~~

~~*Lines 57,347,348,473,599*~~

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

3) Add a new guideline for silver diamine fluoride as shown below

GUIDELINE XXX, CARIES ARRESTING MEDICAMENT APPLICATION

Line 358

D1354 is limited to silver diamine fluoride applications, with a maximum of two applications per year.

- **Topic: Placement of CDT Codes on the Prioritized List and on Another List**

Discussion: CDT codes which are currently located both on the Prioritized List and on another List (Diagnostic, Ancillary, etc.) were reviewed, along with the staff proposed placement. There was no discussion.

Actions:

1) The CDT codes appearing on two lists will all be removed from any other list other than the Prioritized List

- **Topic: Denture Coverage on the Prioritized List**

Discussion: Smits reviewed the current placement of CDT codes for dentures. There was no discussion.

Actions: This topic was informational only

- **Topic: Crowns**

  Discussion: Smits requested feedback from OHAP on whether the current OHA dental rules regarding crowns were sufficient or whether OHAP would like a guideline regarding crown coverage drafted for the Prioritized List. The group was in unanimous agreement that rules were preferable to a guideline.

  Actions: No action required

- **Topic: Dental Access Issues**

  Discussion: Austin reviewed an OHA survey on dental access. There was some discussion about dental metrics.

  Actions: This topic was informational/for discussion only

- **Topic: Restoration of Benefits for Adults**

  Discussion: The legislative decision to appropriate additional money to allow broader coverage of dentures, crowns, and scaling/planing was reviewed and information on possible additions to coverage was reviewed.

  Actions: This topic was informational only

- **Public Comment:**

  Caroline Larson testified about the importance of the work of OHAP and the importance of dental health for overall physical health and the ability of a person to function in society.

- **Issues for next meeting:**
  - Revisit caries arresting medicament guideline

- **Next meeting:**
  - TBD

Appendix A
2016 New CDT Codes

CDT Code	Code Description	Suggested Placement
D0251	extra-oral posterior dental radiographic image	Diagnostic List
D0422	collection and preparation of genetic sample material for laboratory analysis and report	Services Recommended for Non-Coverage Table
D0423	genetic test for susceptibility to diseases – specimen analysis	Services Recommended for Non-Coverage Table
D1354	interim caries arresting medicament application	**348** DENTAL CONDITIONS (EG. CARIES, FRACTURED TOOTH) *Note: With guideline limiting to silver diamine fluoride only, used up to twice per year*
D4283	autogenous connective tissue graft procedure (including donor and recipient surgical sites) – each additional contiguous tooth, implant or edentulous tooth position in same graft site	**496** DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D4285	non-autogenous connective tissue graft procedure (including recipient surgical site and donor material) – each additional contiguous tooth, implant or edentulous tooth position in same graft site	**496** DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D5221	immediate maxillary partial denture – resin base (including any conventional clasps, rests and teeth)	**594** DENTAL CONDITIONS (EG. CARIES, FRACTURED TOOTH)
D5222	immediate mandibular partial denture – resin base (including any conventional clasps, rests and teeth)	**594** DENTAL CONDITIONS (EG. CARIES, FRACTURED TOOTH)
D5223	immediate maxillary partial denture – cast metal framework with resin denture bases (including any conventional clasps, rests and teeth)	**594** DENTAL CONDITIONS (EG. CARIES, FRACTURED TOOTH)
D5224	immediate mandibular partial denture – cast metal framework with resin denture bases (including any conventional clasps, rests and teeth)	**594** DENTAL CONDITIONS (EG. CARIES, FRACTURED TOOTH)
D7881	occlusal orthotic device adjustment	**552** TMJ DISORDER
D8681	removable orthodontic retainer adjustment	**47** CLEFT PALATE WITH AIRWAY OBSTRUCTION **305** CLEFT PALATE AND/OR CLEFT LIP **621** DENTAL CONDITIONS (EG. MALOCCLUSION)
D9223	deep sedation/general anesthesia – each 15 minute increment	Exempt List
D9243	intravenous moderate (conscious) sedation/analgesia – each 15 minute increment	Exempt List
D9932	cleaning and inspection of removable complete denture, maxillary	Services Recommended for Non-Coverage Table
D9933	cleaning and inspection of removable complete denture, mandibular	Services Recommended for Non-Coverage Table

Appendix A
2016 New CDT Codes

CDT Code	Code Description	Suggested Placement
D9934	cleaning and inspection of removable partial denture, maxillary	Services Recommended for Non-Coverage Table
D9935	cleaning and inspection of removable partial denture, mandibular	Services Recommended for Non-Coverage Table
D9943	occlusal guard adjustment	**650** DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: NITROUS OXIDE FOR LABOR PAIN

DRAFT—as posted for public comment 9/4/2015 to 10/4/2015

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 Heath Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE 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 (N2O, 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

Citation	Total Studies Included	Included Studies Specifically Addressing Coverage Guidance Scope
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)	• 14 studies (5 RCTs; 8 prospective cohorts 1 case-series) for fetal/neonatal harms • 3 studies (2 prospective cohort studies, 1 cross-sectional study) for mode of delivery • 10 studies (7 RCTs; 2 prospective cohorts; 1 cross-sectional study) for maternal adverse effects • 2 studies (both cross-sectional studies) for use of neuraxial (e.g. epidural) anesthesia

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).

HERC has received multiple inquiries about bunions and flat feet being above the line as of October 1, 2015, as well as various patellar diagnoses such as chondromalacia patella. We've had a chance to look into this, and it is an error in the ICD-10 codes on the Prioritized List (an entire code series was added to a line when only some codes were meant to be added). This is an error, and we will publish an errata on our website (estimated date to publish is Monday, October 12, 2015) and correct the Prioritized List accordingly. Errors appeared on both lines 391 and line 362.

Errors on line 391 DEFORMITY/CLOSED DISLOCATION OF MINOR JOINT AND RECURRENT JOINT DISLOCATIONS

The entire range of ICD-10-CM codes M20.039-M21.769 was mistakenly added to line 391 DEFORMITY/CLOSED DISLOCATION OF MINOR JOINT AND RECURRENT JOINT DISLOCATIONS. This range of codes includes many codes which should *not* appear on line 391:

The codes that will be removed from line 391 as an error include:
M20.1x (hallux valgus, acquired)
M20.2x (hallux rigidus)
M20.3x (hallux varus, acquired)
M20.4x (hammer toes)
M20.5x (other deformities of toe)
M20.6x (acquired deformities of toe)
M21.0x (valgus deformity, various)
M21.1x (varus deformity, various)
M21.2x (flexion deformity, various)
M21.3x (wrist and foot drop)
M21.4x (flat foot)
M21.51x-M21.52 (acquired claw and club hand)
M21.54 (acquired club foot)
M21.6x (other acquired deformities of foot)
M21.70x-M21.73x (unequal arm length)

The correct list of M codes for line 391 (note that Q and S codes are omitted here) is: M20.021-M20.039,M21.531-M21.539,M21.751-M21.769,M24.074-M24.176,M24.30,M24.40,M24.411-M24.479

Errors on line 362 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS

On this line, the code range M22.00-M24.073 was mistakenly added in its entirety. Instead, from this range, only M22.0-M22.12 (recurrent subluxation and dislocation of patella) and M24.00-M24.073 (loose body in joint) should appear on line 362. M22.2x1-M23.92 (various knee conditions including chondromalacia patella) should not appear on this line.

The correct list of M codes for line 391 (note that Q, S and Z codes are omitted here) is: M22.00-M22.12,M24.00,M24.011-M24.073,M24.321-M24.376,M24.411-M24.443,M24.451-M24.476,M24.811-M24.812,M24.821-M24.822,M24.831-M24.832,M24.841-M24.842,M24.851-M24.852,M24.871-M24.872,M24.874-M24.875,M43.3-M43.4,M43.5x2-M43.5x9,M72.0,M92.40-M92.52,M99.16-M99.19

Let me know if you have any questions about this. We apologize for the mistake. Please let us know if you find other mistakes in the ICD-10 code placements.

Please pass this on to other medical directors and other interested parties.

Regards,
Ariel Smits

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Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on October 1, 2015

For specific coding recommendations and guideline wording, please see the text of the 10-1-2015 VbBS minutes.

RECOMMENDED CODE MOVEMENT (effective 1/1/16)

- Remove the procedure codes for temporary prostatic stents from 2 covered lines and place on the Services Recommended for Non-Coverage Table as investigational
- Add the 2016 CDT codes to various dental lines as recommended by the Oral Health Advisory Panel
- Add the procedure code for silver diamine fluoride application to the covered dental caries line
- Delete the procedure code for vertebral fracture assessment using DXA from the Diagnostic File and add to the Services Recommended for Non-Coverage Table as investigational
- Add several ophthalmology visit and evaluation codes to the Diagnostic File to allow for the evaluation of urgent eye conditions
- Add procedure codes to a covered line to allow trochanteric bursitis to be treated with steroid injections
- Clarify placement of various procedures and diagnoses relating to nose deformities. The repair of the tip of the nose not involved with cleft palate was moved to the Services Recommended for Non-Coverage Table.
- Add procedure codes for stem cell transplant to the covered line containing neuroblastoma with a new guideline limiting use to high-risk neuroblastoma
- Move all child abuse and neglect diagnosis codes to a single covered line, which had all mental health service procedure codes also added to it
- Add diagnosis and procedure codes for repair of ear drum perforations to the two covered hearing loss lines with a guideline
- Add and delete codes related to various straightforward changes
- Add procedure codes for breast augmentation to the covered gender dysphoria line; remove procedure codes for penile implants from this line

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- Optic neuritis did not have its prioritization changed from its current non-covered line

RECOMMENDED GUIDELINE CHANGES (effective 1/1/16)

- Add a new guideline governing the use of silver diamine fluoride for use only with dental caries up to twice a year
- Delete the existing guideline indicating lack of coverage for silver compounds for dental
- Add a new guideline outlining when ophthalmology codes are considered diagnostic

- Add a new guideline to clarify when trochanteric bursitis is included on a covered line (for steroid injections and physical therapy) and when it is included on a non-covered line (for surgical procedures)
- Modify the guideline for nose tip repair in cleft palate to clarify when this procedure is covered
- Delete the guideline regarding reconstruction of the nose
- Add new guidelines limiting the use of botulinum toxin injections for the treatment of migraines and bladder conditions.
- Modify the time period allowed for repair of peripheral nerve injuries from 8 weeks to 6 months in the nerve injury guideline
- Delete the statement of intent about behavioral and physical health integration
- Modify the gender dysphoria guideline to specify when breast augmentation is covered

MINUTES

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

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

Members Absent: none

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

Also Attending: Jesse Little, Kim Wentz, MD, MPH (by phone), Bruce Austin, DMD, and Brian Nieubuurt (Oregon Health Authority); Megan Bird, MD (Legacy Health); Karen Campbell and Jane Stephen (Allergan); Katie Noah (Willamette Dental); Jeanne Stagner (Klamath's Women's Center); Amy Rainbow (Birth Network National); Courtney Johnson (COHO); Karen Nolon (ODS); Neola Young and Emily McCan (Basic Rights Oregon); Amy Penkin, LSCW and Erica Pettigrew, MD (OHSU); Carl Stevens (Care Oregon); Pau Nielsen (Allermes); Sharron Fuchs; Carole Levana; Duncan Nielsen, MD; Pam Keuncke (PHS); Silke Akerson (Oregon Midwifery Council).

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

  The meeting was called to order at 8:45 am and roll was called. Minutes from the August, 2015 VbBS meeting were reviewed and approved.

  Staff reported that ICD-10-CM has been implemented as of today. All ICD-9 placement recommendations in the October VbBS packet are now informational only. HERC staff will keep ICD-9 codes available on and alternate version of the Prioritized List for the next few months for informational purposes as well. Staff are aware that there a likely errors in the ICD-10 codes on the Prioritized List and will be working diligently to correct these. Any errors found should be forwarded to staff.

  The 2016 CPT codes are now available and being reviewed by staff. Hodges asked that the straightforward codes be sent to committee members for review and comment prior to the meeting in November. Smits replied that she will send out a spreadsheet with the 2016 CPT codes with suggested placement once she has been able to do an initial review. This list may include all codes or just straightforward codes, depending on the complexity of the review.

The Oral Health Advisory Panel (OHAP) and Behavioral Health Advisory Panel (BHAP) met and their recommendations are included in the VbBS meeting materials. The obesity taskforce is being constituted with a first meeting planned for the winter.

Gary Allen, DMD, has been senate approved for membership on the HERC. The HERC will be asked to appoint him to the VbBS at their meeting later today, to replace James Tyack, DMD, as the dental expert on the subcommittee.

The errata document was reviewed and there was no discussion.

- **Topic: Straightforward/Consent Agenda**

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

  Recommended Actions:
  1. Add 43771 (Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only) to line 428 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
  2. Add 93740 to the Services Recommended for Non-Coverage (SRNC) Table
  3. Advise Health Services Division (HSD) to remove 93740 (Temperature gradient studies) from the Diagnostic Procedures File
  4. Advise HSD to move 76831 (Saline infusion sonohysterography (SIS), including color flow Doppler, when performed) from the Ancillary File to the Diagnostic Workup File
  5. Add 58321-58323 (Artificial insemination) to the SRNC
  6. Advise HSD to remove 58321-58323 from the Ancillary File

MOTION: To approve the recommendations stated in the consent agenda. CARRIES 7-0.

- **Topic: 2016 CDT codes and OHAP report**

  Discussion: Smits reviewed a spreadsheet with the OHAP recommendations for placement of the 2016 CDT codes, and a document reviewing placement recommendations for CDT codes appearing on both the Prioritized List and one of the HSD code files. There was no discussion about these documents.

  Silver diamine fluoride (SDF) was discussed in detail. Bruce Austen, DMD, the dental director for OHA, testified that silver diamine fluoride does turn caries black, but arrests the decay process. Dentists can do a second step to clear out the decay and add a more cosmetically acceptable filling. However, the SDF allows the dentist to avoid anesthetics

and drilling in young children and in the elderly. This makes caries arrest more readily available and more acceptable to the patient and less traumatic. He is in favor of SDF coverage and feels that medicaments are a new paradigm in the treatment of decay.

Smits noted that the medicaments must currently be applied by dental trained personnel. It is very easy to apply and may be done by non-trained personnel in the future, for example in the school.

Gibson asked for relative cost information vs. standard restoration. Austen responded that SDF is very cost effective, with a 100 dose bottle costing about $125. There is also no dental office time, anesthetic costs, etc.

Karen Nolan, who is an OHAP member, testified on behalf of her employer, ODS. ODS is not in favor of covering SDF. ODS dentists are concerned as it discolors teeth. Patients will need fillings eventually, so it will not save costs and will add cost for the exams and application twice a year on top of the usual filling costs. ODS feels that this treatment is experimental.

It was noted that Gary Allen, who is a member of OHAP and will be joining the HERC, has a conflict of interest regarding SDF as his company markets this product. Coffman noted that Dr. Allen had planned to recuse himself from any vote on this topic.

Recommended Actions:

1. Placement of 2016 CDT codes as shown in Appendix A
2. For CDT codes appearing on the Prioritized List and one of the HSD coding files, remove those codes from all other coding files and keep on their current line location on the Prioritized List
3. Add a new guideline for silver diamine fluoride as shown in Appendix B
4. Delete GN 91

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

- **Topic: 2016 CPT codes**

Discussion: This section was informational only. HERC staff will bring back these codes for official approval with the other 2016 CPT codes at the November 2015 VbBS meeting.

The group discussed fetal MRI. There was discussion about the proposed guideline note. The group felt that there should be a requirement for two physicians, one a fetal or pediatric radiologist, to agree on the medical necessity of the MRI. Hodges requested that a clause be added requiring >17 weeks of estimated fetal age. There were

questions about any specific requirements for the MRI machine, the training of the MRI tech or the reading radiologist. HERC staff were directed to reach out to radiologist and maternal-fetal medicine specialists to determine the best guideline wording.

High dose radionucleotide skin surface brachytherapy was briefly discussed. The subcommittee agreed with the staff recommendation to place on the Services Recommended for Non-Coverage Table.

Intravasular non-coronary ultrasound was discussed. There was a question about whether a guideline should be developed to limit the vessels in which this could be used. The thought was that this would be difficult to determine and the code should be suggested for the Diagnostic Procedures File.

Reflectance confocal microscopy for skin lesions was briefly discussed. The subcommittee agreed that this procedure was experimental and should be placed on the Services Recommended for Non-Coverage Table.

Intrastromal corneal ring segments was reviewed without substantive discussion. The subcommittee agreed that this procedure should be added to the line containing keratoconus with the proposed guideline.

Recommended Actions:
HERC staff will further research the 2016 CPT codes and bring recommendations for the entire set to the next VBBS meeting.

- **Topic: Temporary prostatic stents**

Discussion: Smits reviewed the summary document. There was minimal discussion.

Recommended Action:
Delete temporary prostatic stents (CPT 53855) from lines 332 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION and 334 CANCER OF PROSTATE GLAND and add to the Services Recommended for Non-Coverage Table as investigational.

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

- **Topic: Vertebral fracture assessment**

Discussion: Smits reviewed the summary document. There was minimal discussion.

Recommended Actions:

a. Place CPT 77086 (Vertebral fracture assessment via dual-energy X-ray absorptiometry (DXA)) on the Services Recommended for Non-coverage Table as experimental
2. Advise HSD to remove CPT 77086 from the Diagnostic Procedures File

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

- **Topic: Optic neuritis**

Discussion: Smits reviewed the summary document. Pollack requested that the ophthalmology codes proposed for the Diagnostic Procedures File be reviewed in a year to see if they are being abused.

Recommended Actions:

1. Do not change the current prioritization of optic neuritis on line 654 INTRACRANIAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
2. Advise HSD to add ophthalmology evaluation CPT codes to the Diagnostic Procedures File; also keep these codes on current lines on the Prioritized List as done with other evaluation and management codes
   a. 92002, 92004, 92012, 92014 (Ophthalmological services: medical examination and evaluation, new and established patients)
   b. 92081-92083 (Visual field examination)
   c. 92100 (Serial tonometry for intraocular pressure measurement)
   d. 92140 (Provocative tests for glaucoma)
   e. 92133-92134 (Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; optic nerve or retina)
3. Adopt a new diagnostic guideline for ophthalmology visits as shown in Appendix B

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

- **Topic: Trochanteric bursitis**

Discussion: Smits reviewed the summary document. There was minimal discussion.

Recommended Actions:

1. Remove CPT 27062 (Excision; trochanteric bursa or calcification) from line 431 ACUTE PERIPHERAL MOTOR AND DIGITAL NERVE INJURY
2. Add CPT 20611 (Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance) to line 381

DISRUPTIONS OF THE LIGAMENTS AND TENDONS OF THE ARMS AND LEGS, EXCLUDING THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT

3. Add trochanteric bursitis (ICD-10 M70.6x, M70.7x) to line 508 PERIPHERAL ENTHESOPATHIES Treatment: SURGICAL THERAPY
4. Adopt the new guideline regarding trochanteric bursitis as shown in Appendix B

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

- **Topic: Nose repair**

Discussion: Smits reviewed the summary document. There was minimal discussion.

Recommended Actions:

1. Guideline note 80 was modified as shown in Appendix C
2. Guideline note 81 was deleted as shown in Appendix D
3. ICD-10 Q30.1 (Agenesis and underdevelopment of nose), Q30.2 (Fissured, notched and cleft nose), and Q30.8 (Other congenital malformations of nose) were deleted from line 261 DEFORMITIES OF HEAD
4. ICD-10 Q30.2 was added to line 305 CLEFT PALATE AND/OR CLEFT LIP
5. ICD-10 Q30.8 was added to lines 509 NASAL POLYPS, OTHER DISORDERS OF NASAL CAVITY AND SINUSES and 578 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT
6. CPT 30430 (Rhinoplasty, secondary; minor revision (small amount of nasal tip work)) was removed from all lines and placed on the Services Recommended for Non-Coverage List
7. CPT 30460 (Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip only) and 30462 (Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip, septum, osteotomies) were removed from lines 469 CHRONIC SINUSITIS and 509 NASAL POLYPS, OTHER DISORDERS OF NASAL CAVITY AND SINUSES

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

- **Topic: Stem cell transplant for neuroblastoma**

Discussion: Smits reviewed the summary document. There was minimal discussion.
Note: The new guideline was amended to add the ICD-10 code.

Recommended Actions:

1. Add stem cell transplantation (CPT 38204-38215, 38230-38241; HCPCS S2150) to line 264 CANCER OF ENDOCRINE SYSTEM, EXCLUDING THYROID; CARCINOID SYNDROME
2. Adopt a new guideline for line 264 as shown in Appendix B

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

- **Topic: Integration of medical and mental health services for child abuse and neglect**

Discussion: Smits reviewed the summary document. There was minimal discussion.

Recommended Actions:

1. Delete diagnosis codes for child abuse and neglect from line 177 POSTTRAUMATIC STRESS DISORDER
   a. ICD-10 T74 series, T76 series (child neglect, child abuse, child sexual abuse)
2. Add mental health CPT codes to line 125 ABUSE AND NEGLECT
   a. CPT 90785 (interactive complexity)
   b. 90832-90853 (psychotherapy, including family and group)
   c. 90882 (Environmental intervention for medical management purposes on a psychiatric patient's behalf with agencies, employers, or institutions)
   d. 90887 (Interpretation or explanation of results of psychiatric, other medical examinations and procedures)
   e. 96101 (psychological testing)
   f. 96127 (Brief emotional/behavioral assessment)
3. Delete GN25 as shown in Appendix D

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

- **Topic: Acute substance intoxication and withdrawal**

Discussion: Smits reviewed the summary document. There was minimal discussion.

Recommended Action:

Rename line 69 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL

MOTION: To recommend the line title change as presented. CARRIES 7-0.

- **Topic: Botulinum toxin for migraines and bladder conditions**

Discussion: Smits reviewed the summary document. Gibson voiced concerns about the poor quality of the underlying studies cited in the botulinum toxin for migraine review. He was concerned about covering this treatment at all given its questionable efficacy. Williams agreed that there was little evidence to support the use of botulinum toxin for migraines. Gibson recommended increasing the proposed reduction in migraine frequency required for continued therapy from the proposed 6 to 8, to better reflect the study findings. Gibson also expressed concern about the use of urinary frequency reductions as a requirement for continuation for botulinum toxin for bladder indications as this symptom may just be a variant of normal. However, it was pointed out that earlier in the guideline, use is restricted to specific bladder indications and Gibson agreed that frequency reduction was acceptable as an outcome for those conditions.

Karen Campbell from Allergan testified that botulinum toxin for bladder indications is reserved for patients failing oral medications, and the only alternative to botulinum injections is nerve stimulation or bladder surgery. She noted that one injection may provide symptom relief for 6 months or longer.

Ms. Campbell further testified that migraine patients must also fail oral therapy prior to consideration for botulinum toxin. The other possible treatments for these patients include nerve block or neurostimulation, reflecting that few other options exist for this group of patients. She testified that many patients continue to improve the more injections they have. The treatment for migraines involve 31 injections during the session, and patients are only likely to endure this amount of injections if the treatment is actually helpful. She did not agree with requiring a reduction in headache days as a requirement for continuing therapy. She testified that patients improve in other ways, such as improvement in the level of pain on headache days or in quality of life measures. They may have shorter headaches, less intense headaches, have better response to their acute headache pain medications, less disability and improved ability to work. Chronic migraine patients have hypersensitivity to stimuli, and botulinum toxin injections can gradually help this. Clinical trials and practice show that botulinum toxin injection may require 2-3 injection cycles to improve hypersensitivity and headaches. She felt that the HERC should base coverage on symptomatic and functional improvement for these patients. She was concerned that the proposed guideline would mean that patients with reductions of 4 or 5 headache days would not qualify for further treatment and yet would have quality of life improvements. She suggested that the committee review utilization in Oregon to see if this treatment is overused or high.

Jane Stevens from Allergan testified that most private insurance plans require a reduction of 7 headache days per month or 100 headache hours per month for continued coverage of botulinum toxin injections for migraines.

The subcommittee debated whether to require a reduction of 6, 7 or 8 headache days per month for the migraine guideline. The reduction of 7 days was determined to be the best compromise.

The subcommittee debated about the number of incontinence incidents or episodes of urinary frequency required for the bladder conditions guideline. The group increased the reduction of frequency episodes to 8 and the incontinence episodes to 2 to better reflect the reductions seen with botulinum treatment in the clinical trials.

Recommended Actions:

1. Adopt a new guideline for line 414 as shown in Appendix B
2. Adopt a new guideline for line 331 as shown in Appendix B

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

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

Discussion: Smits reviewed the summary document. There was minimal discussion.

Recommended Actions:

1. Add diagnosis codes for ear drum perforations/open wounds to lines 316 HEARING LOSS - AGE 5 OR UNDER and 450 HEARING LOSS - OVER AGE OF FIVE and keep on line 479 CHRONIC OTITIS MEDIA, OPEN WOUND OF EAR DRUM
   a. ICD-10 H72.xx (perforation of tympanic membrane) and S09.2xx (Traumatic rupture of unspecified ear drum)
2. Add treatment CPT codes for perforations/open wounds to lines 316 and 450
   a. 69610 (Tympanic membrane repair, with or without site preparation of perforation for closure, with or without patch)
   b. 69620 (Myringoplasty)
   c. 69631-69646 (Tympanoplasty with or without mastoidectomy)
3. Change the treatment description of lines 316 and 450 to MEDICAL THERAPY INCLUDING HEARING AIDS, LIMITED SURGICAL THERAPY
4. Adopt a new guideline note for lines 316, 450 and 479 as shown in Appendix B

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

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

Discussion: Smits reviewed the summary document. The subcommittee discussed the fact that the neurosurgeon who brought up the issue recommended extending the limit to 6 months and recommended that the guideline was modified only to extend the

surgical period to 6 months, rather than the proposed 1 year. The exceptions process could be used for patients who are between 6 months and 1 year from injury.

Recommended Actions:

1. Modify GN133 as shown in Appendix C

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

- **Topic: Tobacco cessation coverage and prevention**

  Discussion: This topic was tabled to the November, 2015 VBBS meeting

- **Topic: Tobacco use and elective surgery**

  Discussion: This topic was tabled to the November, 2015 VBBS meeting

- **Topic: Acupuncture guideline referral requirement**

  Discussion: Smits reviewed the summary document. There was discussion about whether acupuncturists can generate diagnosis codes, which are required to determine if a condition is covered by this guideline. If acupuncturists cannot make the diagnoses, then coverage of acupuncture must continue to be done by referral from a provider who can make diagnoses. Hodges argued that acupuncture should be covered like physical therapy; PT requires an ICD9/10 code from a provider and a referral/order. Ocker indicated that acupuncturists are capable of making certain diagnoses, but not complex diagnoses.

  It was also noted that the staff proposed changed all acupuncture indications to have 12 covered acupuncture sessions. This is in conflict with the new back conditions guideline, which allows up to 30 visits. Staff was advised to rework this portion of the guideline.

  Livingston recommended that retaining the referral requirement for pelvic pain during pregnancy was appropriate, as this symptom can be caused by many conditions, and should be evaluated by a maternity care provider first. Ocker raised no objections to this.

  Staff was directed to work with the HSD clinical services unit to determine what acupuncturists can diagnosis and code and how referrals should work for acupuncture.

Recommended Actions:
HERC staff to research whether acupuncturists can make diagnoses and whether acupuncture services need a referral. This topic will be revisited at a future meeting.

- **Topic: Mental health guidelines for children**

  Discussion: This topic was tabled to the November, 2015 VBBS meeting

- **Topic: Statement of Intent 3 - Behavioral Health Integration**

  Discussion: Smits reviewed the summary document. There was minimal discussion.

  Recommended Actions:
  Delete SOI3 as shown in Appendix D

  MOTION: To recommend the statement of intent be deleted as presented. CARRIES 7-0.

- **Topic: Breast augmentation and penile implant coverage for gender dysphoria**

  Discussion: Smits reviewed the staff summary document. Gibson objected to adding coverage for breast augmentation, arguing that this service is not covered for other women with social functioning issues due to small breast size, and that this type of procedure is cosmetic. Hodges agreed that breast augmentation appears to be cosmetic and coverage for gender dysphoria is unfair to other women with breast size issues.

  Dr. Megan Bird from Legacy testified that the goal of breast augmentation for patients with gender dysphoria is to reduce the dysphoria, suicide rates, and other negative outcomes. Breasts are an overwhelming cue for a person to be recognized by others as a women. She argued that lack of coverage will increase the risk of violence and is therefore a safety issue.

  Gibson raised concerns that the presence of breasts is a defining aspect of being a women. Williams argued that the coverage for adolescents to receive early hormone treatment should lessen the need for breast reconstructions.

  Bird responded that access to hormones, specifically estrogen for breast development, is limited for many patients due to medical or other issues.

Olson noted breast reconstruction is covered for patients with breast cancer, and he was wondering whether gender dysphoria should be considered a biologic condition on par with breast cancer. He also noted that patients with gender dysphoria as a group have terrible outcomes with no treatment, which is not the case for other women with simple cosmetic breast concerns.

Bird argued that the improvement in outcomes reviewed in the studies by HERC included breast augmentation as a possible therapy. The reduction in suicide rates and other negative outcomes were based on access to a package of therapy which included breast augmentation.

Amy Penkin, LCSW, from OHSU testified that breast surgery actually treats the dysphoria, rather than just being for social passing. She argued that linking it to gender dysphoria sets it apart from the cosmetic use.

Gibson asked when breasts could be considered large enough to be adequate to address gender dysphoria. Bird responded that there are guidelines based on Tanner developmental stages. Stage 5 on the Tanner scale corresponds to adult female breasts. This is a structural assessment, rather than based on size.

Neola Young, from Basic Rights Oregon, testified that breast surgery is more important to many transgender women than other types of gender dysphoria surgery. It is an important service to offer to reduce self harm in this population.

The discussion on penile implants was short. Bird testified that the only entity covering this is the city of San Francisco and they require 2 physicians to agree that the procedure is necessary, a surgeon's note that the phallus is appropriate for the prostheses, and evidence that the patient has used and failed external support devices.

Recommended Actions:

1. Add coverage for breast augmentation for male to female patients
    a. CPT codes to add to line 413 GENDER DYSPHORIA
        i. 14000-14001 Adjacent tissue transfer or rearrangement, trunk
        ii. 15200-15201 Full thickness graft, free, including direct closure of donor site, trunk
        iii. 19316 Mastopexy
        iv. 19324-19325 Mammaplasty, augmentation
        v. 19340 Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
        vi. 19342 Delayed insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
    b. Modify GN127 as shown in Appendix C
2. Remove penile prostheses (CPT 54400-54417, 54660) from line 413

MOTION: To recommend the code and guideline note changes as presented (option B) for breast augmentation. CARRIES 4-3 (Opposed: Hodges, Williams, Gibson)

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

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

  Discussion: Livingston presented the process overview, evidence summary and core issues addressed by public comment. Dr. Duncan Neilson was introduced as an appointed expert. He is the Clinical Vice President of surgical services of Legacy health system and an obstetrician/gynecologist. Dr. Neilson reviewed the history of this effort beginning with a legislative mandate that involved licensing direct entry midwives as of January 2015 and an Oregon Health Authority Licensed Direct Entry Midwifery Workgroup that recommended that HERC evaluate the evidence and update the appropriate risk criteria to try to ensure safe and effective planned out-of-hospital births.

  The subcommittee discussed that these risk criteria are about coverage. A woman with risk criteria may choose to have a planned out-of-hospital birth, but this would not be covered by the Oregon Health Plan. There was an amendment made to the box language to clarify that the intent is about coverage.

  Livingston proceeded to discuss the options, being explicit about which criteria needed to be ruled out and also allowing for ambiguity when certain criteria may remain unknown if there were not clinical suspicion that would indicate a workup was appropriate. The example of ultrasound was discussed and the subcommittee agreed that it would be necessary to rule out certain risk criteria. Livingston highlighted some of the risk criteria that had received more public comment as well as some suggestions for clarifying language.

  There was a discussion as to whether lethal congenital anomalies with planned nonrescucitation would be appropriate for coverage in an out-of-hospital birth setting. Kim Wentz stated that there are times when the prenatal diagnosis is wrong or the parents change their mind when the baby is born. Neilson stated that there are some lethal congenital anomalies that are more black and white and others that are gray. Also, in some cases it may be more explicit that nonresuscitation is clearly appropriate and changes in diagnosis or management plans are highly unlikely. There was a discussion about preserving the autonomy of the mother if the fetus doesn't require treatment. Anencephaly was given as an example. After discussion the subcommittee decided to move the revised language including "nonresuscitation planned" to be a criterion requiring consultation.

There was a discussion of a series of criteria that may not be known if there was no clinical suspicion, but also needing to define what those clinical factors may be. In a discussion about intrauterine growth reduction (IUGR), initially there was a proposal to define concerning clinical signs such as fundal height <3 cm from estimated gestational age over two measurements; however, Neilson suggested that other factors besides fundal height may be important and the estimation of fetal weight is multimodal. The language was changed to state that serial fundal measurements are required, but not to define what exactly suspicion for IUGR would entail. It was concluded that both serial blood pressure measurements and serial fundal heights would be required in order to verify the absence or presence of this high risk criteria.

There was a discussion of the unknown syphilis, HIV, or Hepatitis B status and a proposal to add "positive" status to the coverage exclusion criteria. Members discussed whether appropriate care could be given to a positive mother in a home setting and they decided that given the potential risk to the fetus/infant and the potential for intervention, that these would be risk criteria that would exclude a woman from coverage. Syphilis was added based on a staff recommendation as a result of recent public health data showing an increase in syphilis in Oregon.

Pollack commented and others agreed that readability of the box language would be improved with categorizing of the risk conditions.

Public comment:

Jeannie Stagner, CNM, of Klamath Falls. She stated she has been a midwife for 33 years, starting as direct entry midwife and later serving as a consultant to the Arizona State Department of Health Services. She stated she does not have hospital privileges and has a licensed birth center. She expressed concerns that inadequate stakeholder representation was involved in the process, and that guidelines are attempting to change midwifery statutes. She stated that 100% of her patients would have been found ineligible according to consultation guidelines, specifically raising concerns about VBAC and women receiving outpatient mental health care. She also raised concerns about the availability of consultants, especially in rural communities.

Neilson reviewed the history of this process starting with the legislation, the development of the licensed direct entry midwifery workgroup, including involvement of stakeholders with midwifery representation, and how the HERC work results from those processes.

The subcommittee discussed revising the language around maternal mental illness. Pollack suggested requiring consultation in cases where there is suspicion for psychosis or self-harm. The subcommittee ran out of further discussion time.

There was a discussion about the word "compliance" and the feeling it invokes. It was clarified that this will serve as the basis for rules and compliance would be an appropriate choice of words.

Summary of changes agreed to prior to the end of the meeting:

- Clarify further that these high risk criteria relate to coverage
- Move life-threatening congenital anomalies (unless fatal anomalies with nonresuscitation planned) to consultation criteria
- Add that serial fundal height measurements and serial blood pressure measurements are required
- Add unknown, or positive, syphilis, HIV, or hepatitis B status to high risk coverage exclusion criteria
- Categorize risk conditions in box language to improve readability
- Discuss further modifying the language on maternal mental illness requiring outpatient psychiatric care

Discussion to continue at the November 12, 2015 VbBS/HERC meetings.

- **Topic: Coverage Guidance—Indications for proton beam therapy**

  Discussion: This topic was tabled until the November 2015 VbBS meeting

- **Public Comment:**

  No additional public comment was received.

- **Issues for next meeting:**

  -2016 CPT code placement
  -Tobacco cessation for procedures guideline
  -Tobacco cessation coverage and prevention guideline
  -Acupuncture guideline
  -Mental health guidelines for children
  -Coverage guidances for proton beam therapy and planned out-of-hospital birth
  -Posterior tibialis tendonopathy
  -Adjustment disorder coding specification
  -Feeding tube code placement review

- **Next meeting:**

  November 12, 2015 at Clackamas Community College, Wilsonville Training Center, Rooms 111-112, Wilsonville, Oregon, Rooms.

- **Adjournment:**

  The meeting adjourned at 1:15 PM.

Appendix A
Recommended Placement of 2016 CDT Codes

CDT Code	Code Description	Suggested Placement
D0251	extra-oral posterior dental radiographic image	Diagnostic List
D0422	collection and preparation of genetic sample material for laboratory analysis and report	Services Recommended for Non-Coverage Table
D0423	genetic test for susceptibility to diseases – specimen analysis	Services Recommended for Non-Coverage Table
D1354	interim caries arresting medicament application	**348** DENTAL CONDITIONS (EG. CARIES, FRACTURED TOOTH) *Note: With guideline limiting to silver diamine fluoride only, used up to twice per year*
D4283	autogenous connective tissue graft procedure (including donor and recipient surgical sites) – each additional contiguous tooth, implant or edentulous tooth position in same graft site	**496** DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D4285	non-autogenous connective tissue graft procedure (including recipient surgical site and donor material) – each additional contiguous tooth, implant or edentulous tooth position in same graft site	**496** DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D5221	immediate maxillary partial denture – resin base (including any conventional clasps, rests and teeth)	**594** DENTAL CONDITIONS (EG. CARIES, FRACTURED TOOTH)
D5222	immediate mandibular partial denture – resin base (including any conventional clasps, rests and teeth)	**594** DENTAL CONDITIONS (EG. CARIES, FRACTURED TOOTH)
D5223	immediate maxillary partial denture – cast metal framework with resin denture bases (including any conventional clasps, rests and teeth)	**594** DENTAL CONDITIONS (EG. CARIES, FRACTURED TOOTH)
D5224	immediate mandibular partial denture – cast metal framework with resin denture bases (including any conventional clasps, rests and teeth)	**594** DENTAL CONDITIONS (EG. CARIES, FRACTURED TOOTH)
D7881	occlusal orthotic device adjustment	**552** TMJ DISORDER
D8681	removable orthodontic retainer adjustment	**47** CLEFT PALATE WITH AIRWAY OBSTRUCTION **305** CLEFT PALATE AND/OR CLEFT LIP **621** DENTAL CONDITIONS (EG. MALOCCLUSION)
D9223	deep sedation/general anesthesia – each 15 minute increment	Exempt List
D9243	intravenous moderate (conscious) sedation/analgesia – each 15 minute increment	Exempt List
D9932	cleaning and inspection of removable complete denture, maxillary	Services Recommended for Non-Coverage Table
D9933	cleaning and inspection of removable complete denture, mandibular	Services Recommended for Non-Coverage Table

Appendix A
Recommended Placement of 2016 CDT Codes

CDT Code	Code Description	Suggested Placement
D9934	cleaning and inspection of removable partial denture, maxillary	Services Recommended for Non-Coverage Table
D9935	cleaning and inspection of removable partial denture, mandibular	Services Recommended for Non-Coverage Table
D9943	occlusal guard adjustment	**650** DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT

Appendix B

New Guideline Notes

DIAGNOSTIC GUIDELINE DXX, OPHTHALMOLOGY DIAGNOSTIC VISITS

Ophthalmology diagnostic visits (CPT 92002, 92004, 92012, 92014, 92081-92083, 92100, 92140, 92133, 92134) are covered for the evaluation of serious eye symptoms such as sudden vision loss or eye pain.

GUIDELINE XXX, CARIES ARRESTING MEDICAMENT APPLICATION

Line 348

D1354 is limited to silver diamine fluoride applications, with a maximum of two applications per year.

GUIDELINE NOTE XXX, TROCHANTERIC BURSITIS

Lines 381, 508

Trochanteric bursitis (enthesopathy of the hip, ICD-9 726.5/ ICD-10 M70.6x, M70.7x) is included on line 381 for pairing with physical therapy and steroid joint injections. Trochanteric bursitis is included on line 508 for pairing with surgical interventions (i.e. CPT 27062).

GUIDELINE NOTE XXX, STEM CELL TRANSPLANTATION FOR NEUROBLASTOMA

Line 264

Stem cell transplantation (CPT 38204-38215, 38230-38241) is only included on this line for treatment of high risk neuroblastoma (ICD-9 194.0/ICD-10 C74.xx).

GUIDELINE NOTE XXX, CHEMODENERVATION FOR CHRONIC MIGRAINE

Line 414

Chemodenervation for treatment of chronic migraine (CPT 64615) is included on this line for prophylactic treatment of adults who meet all of the following criteria:

1) have chronic migraine defined as headaches on at least 15 days per month of which at least 8 days are with migraine
2) has not responded to or have contraindications to at least three prior pharmacological prophylaxis therapies (beta-blocker, calcium channel blocker, anticonvulsant or tricyclic antidepressant)
3) treatment is administered in consultation with a neurologist or headache specialist.

Appendix B

Treatment is limited to two treatments given 3 months apart. Additional treatment requires documented positive response to therapy. Positive response to therapy is defined as a reduction of at least 7 headache days per month compared to baseline headache frequency.

GUIDELINE NOTE XXX, CHEMODENERVATION OF THE BLADDER

Line 331

Chemodenervation of the bladder (CPT 52287) is included on this line only for treatment of idiopathic detrusor over-activity or neurogenic detrusor over-activity (ICD-9 596.5x/ICD-10-CM N32.81) in patients who have not responded to or been unable to tolerate at least two urinary incontinence antimuscarinic therapies (e.g. fesoterodine, oxybutynin, solifenacin, darifenacin, tolterodine, trospium). Treatment is limited to 90 days, with additional treatment only if the patient shows documented positive response. Positive response to therapy is defined as a reduction of urinary frequency of 8 episodes per day or urinary incontinence of 2 episodes per day compared to baseline frequency.

GUIDELINE NOTE XXX, EAR DRUM REPAIR

Lines 316,450,479

Repair of open wounds or perforations of the ear drum (ICD-9 384.2x, 389.02, 872.61, 872.71/ICD-10 H72.xx, S09.2xx) are only included on lines 316 and 450 when there is documented conductive hearing loss greater than or equal to 25dB persistent for more than three months. Otherwise, such repairs are included on line 479.

Appendix C

Modified Guidelines

GUIDELINE NOTE 80, REPAIR OF NOSE TIP

Line 305

Nose tip repair (CPT 30460) is included on this line only to be used in conjunction with codes 40700, 40701, 40702, or 40720~~or~~ . If not done in the context of a larger cleft palate/lip surgery, then nose tip repair is only included on this line if required for ~~subsequent~~ correction of physical functioning.

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).

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.

Mammoplasty (CPT 19316, 19324-19325, 19340, 19342, 19350, 19357-19380) is only included on this line when 12 continuous months of hormonal (estrogen) therapy has failed to result in breast tissue growth of Tanner Stage 5 on the puberty scale OR there is a medical contraindication to hormonal therapy.

GUIDELINE NOTE 133, ACUTE PERIPHERAL MOTOR AND DIGITAL NERVE INJURY

Lines 430,491,515,522,541

Repair of acute (< ~~8 weeks~~ 6 months) peripheral nerve injuries are included on Line 430. Non-surgical medical care of these injuries are included on Line 491. Chronic nerve injuries are included on Lines 515, 522 and 541.

Appendix C

Deleted Guidelines

~~STATEMENT OF INTENT 3: INTEGRATED CARE~~

~~Recognizing that many individuals with mental health disorders receive care predominantly from mental health care providers, and recognizing that integrating mental and physical health services for such individuals promotes patient-centered care, the Health Evidence Review Commission endorses the incorporation of chronic disease health management support within mental health service systems. Although such supports are not part of the mental health benefit package, mental health organizations (MHOs) that elect to provide these services may report them using psychiatric rehabilitation codes which pair with mental health diagnoses. If MHOs choose to provide tobacco cessation supports, they should report these services using 99407 for individual counseling and S9453 for classes.~~

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

~~Line 177~~

~~ICD-10-CM T76.02xA and T76.02xD (Child neglect or abandonment, suspected), (ICD-10-CM T74.02xA and T74.02xD (Child neglect or abandonment, confirmed), T74.22xA and T74.22xD (Child sexual abuse, confirmed), T76.22xA and T76.22xD (Child sexual abuse, suspected), T76.12xD (Child physical abuse, suspected, subsequent encounter) or T74.12xA and T74.12xD (Child physical abuse, confirmed) and corresponding ICD-9-CM codes 995.52, 995.53, 995,54 and – 995.59, may be used in any children when there is evidence or suspicion of abuse or neglect. These codes are to be used when the focus of treatment is on the alleged child victim. This can include findings by child welfare of abuse or neglect; or statements of abuse or neglect by the child, the perpetrator, or a caregiver or collateral report. Although these diagnoses can be used preventively, i.e. for children who are not yet showing symptoms, presence of symptoms should be demonstrated for interventions beyond evaluation or a short-term child or family intervention.~~

~~The codes T74.02xA, T74.02xD, T74.02XA, T74.02XD, T74.22xA, T74.22xD, T76.22xA, T76.22xD, T76.12xA, T76.12xD, 74.12xA or T74.12xD and corresponding ICD-9-CM codes 995.52, 995.53, 995,54 and – 995.59 may be used in children age five and younger and, in these instances only, is limited to pairings with the following procedure codes:~~

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

Appendix C

~~GUIDELINE NOTE 81, RECONSTRUCTION OF THE NOSE~~

~~Lines 261,648~~

~~ICD-10-CM codes Q30.1, Q30.2 and Q30.8/ICD-9-CM code 748.1 are on this line only for reconstruction of absence of the nose and other severe nasal anomalies which significantly impair physical functioning.~~

~~GUIDELINE NOTE 91, SILVER COMPOUNDS FOR DENTAL CARIES~~

~~Lines 57,347,348,473,599~~

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