

Minutes

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

Members Present: Som Saha, MD, MPH, Chair; Gary Allen, DMD; Beth Westbrook, PsyD; Wiley Chan, MD; Vern Saboe, DC; Mark Gibson; Leda Garside, RN, MBA; Susan Williams, MD; Gerald Ahmann, MD, PhD; Derrick Sorweide, DO; Mark Gibson; Chris Labhart; Holly Jo Hodges, MD.

Members Absent: Irene Crosswell, RPh

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

Also Attending: Kim Wentz, MD, MPH, Brian Nieuburt (Oregon Health Authority); Erica Pettigrew, MD, Karen Kovak (OHSU); Valerie King, MD MPH, Adam Obley, MD, MPH, Craig Mosbaek (OHSU Center for Evidence Based Policy); Silke Akerson (Oregon Midwifery Council); Sharron Fuchs; Duncan Neilson, MD (Legacy Health); Melissa Cheyney, PhD (OSU); Pam Keuneke (Providence); Laura Jenson (OHSU, American Council of Nurse Midwives).

Call to Order

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

Minutes Approval

MOTION: To approve the minutes of the 10-1-2015 meeting as presented. CARRIES 12-0.

Director's Report

Membership

Darren Coffman introduced Gary Allen, DMD, newly appointed dental representative. Dr. Allen is a native Oregonian who served in the military and is currently the dental director at Advantage Dental. He has been involved in many health policy commissions and taskforces over the last two decades and is interested in furthering oral health in Oregon.

At the end of December, some Commissioner's terms are expiring. Mark Gibson (consumer representative) and Dr. Derrick Sorweide (osteopathic physician) are on track to be reappointed directly. Replacement of Drs. Saboe (complementary and alternative medicine) and Ahmann (oncologist) is delayed; incumbents will continue to attend until replaced. Irene Crosswell (retail pharmacists) is leaving

the Commission after an employment change but will remain until another pharmacist can be recruited and appointed.

ICD-10-CM update

Staff have been publishing errata to the ICD-10 list implemented October 1, 2015 every 2 weeks since September. When the January 1, 2016 List is published, any errors that are not straightforward and can't be changed by errata may need to wait until the next interim modification date of October 1, 2016. Staff are working with OHA Health Systems to develop a plan to handle these types of issues. One option proposed is to have a March 1, 2016 List update. Another suggestion is to more liberally define what may be included in an errata.

Biennial review changes related to conditions of the back and spine

Implementation of these biennial changes approved by HERC in March are being delayed by OHA leadership to ensure that rate adjustments accurately reflect projected new costs and savings resulting from these changes in benefits. The January 1, 2016 List will reflect all the changes approved with the exception of these involving conditions of the back and spine, which will be notated clearly in a fashion still being developed by staff. Hodges asked that the new list represent only what it being implemented at that time to the degree possible.

Coverage Guidance Topic: Planned Out-of-hospital birth

[Meeting materials](#), pages 63-226

Dr. Cat Livingston gave a brief summation of the evidence presentation and discussion held at the October 1, 2015 meeting ([meeting materials](#) pages 168-173).

Minor changes were made to the box language at the same time the high risk coverage exclusion, transfer and consultation criteria were reorganized into categories according to whether they impact the mother, fetus or placenta.

Jason Gingerich introduced the appointed ad-hoc experts, Duncan Neilson, MD, and Melissa Cheyney, PhD, who assisted the subcommittee as they developed their recommendations, announced their stated conflicts of interest and outlined their role in the process.

Members discussed a mother's known strep Group B status at the time of birth. While very rare, an active infection can pass to the infant with sometimes devastating effects, with a near 50% mortality rate. Some mothers refuse the test and would reject the prophylactic IV antibiotics recommended during labor to prevent the passage of the infection. Cheyney added midwives are currently taking training to allow IV antibiotics used in home births as that has become part of their scope of practice.

Gibson noted the difficulty of demanding tests for Group B strep, stating if a mother wanted to have an out-of-hospital birth that the test should be completed as well as a risk assessment and informed consent about the pros and cons of the prophylaxis treatment. Only then should a mom be able to say no to antibiotics.

Hodges shared, before 1996, every year 7,500 babies were born through the bacteria and would contract the disease, with half of the infants dying of sepsis.

Saha asked how the situation differed between hospital and an out-of-hospital birth. Duncan explained the baby gets the advantages of a neonatal team dedicate to its care 24/7 with at least a 48 hour stay. At home, midwives look in at 24 then 48 hours.

Dr. Val King mentioned that approximately 25% of the Medicaid population are Group B strep carriers.

Dr. Kim Wentz added that death or brain damage can occur in the few hours it takes to get IV antibiotics started in a home setting. She further stated surveillance at home cannot be the same as surveillance in the hospital. She also shared the many instances she's seen where true informed consent isn't documented or where patients did not understand the context of the risks.

MOTION: To approve the VbBS recommendation on the requirement of testing for Group B strep carrier status in order to receive coverage for a planned out-of-hospital birth in the guideline note. CARRIES: 11-1 (Opposed: Hodges)

MOTION: To approve the proposed planned out-of-hospital guideline note for the Prioritized List as recommended by VbBS. Carries 12-0.

MOTION: To include the the requirement of testing for Group B strep carrier status in order to receive coverage for a planned out-of-hospital birth in the coverage guidance. CARRIES: 12-0.

MOTION: To approve the proposed coverage guidance for planned out-of-hospital birth as presented, including the recommendations of EbGS and subsequent amendments. (Abstained: Hodges)

Sharron Fuchs offered testimony, thanking the Commission for taking these steps to help ensure newborn safety in an out-of-hospital setting.

Approved Coverage Guidance:

HERC COVERAGE GUIDANCE

Planned out-of-hospital (OOH) birth is recommended for coverage for women who do not have high-risk coverage exclusion criteria as outlined below (*weak recommendation*). This coverage recommendation is based on the performance of appropriate risk assessments¹ and the OOH birth attendant's compliance with the consultation and transfer criteria as outlined below.

Planned OOH birth is not recommended for coverage for women who have high risk coverage exclusion criteria as outlined below, or when appropriate risk assessments are not performed, or where the attendant does not comply with the consultation and transfer criteria as outlined below (*strong recommendation*).

High-risk coverage exclusion criteria:

Complications in a previous pregnancy:

Maternal surgical history

- Cesarean section or other hysterotomy

- Uterine rupture
- Retained placenta requiring surgical removal
- Fourth-degree laceration without satisfactory functional recovery

Maternal medical history

- Pre-eclampsia requiring preterm birth
- Eclampsia
- HELLP syndrome

Fetal

- Unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty
- Baby with neonatal encephalopathy
- Placental abruption with adverse outcome

Complications of current pregnancy:

Maternal

- Induction of labor
- Prelabor rupture of membranes > 24 hours
- Pre-existing chronic hypertension; Pregnancy-induced hypertension with diastolic blood pressure greater than or equal to 90 mmHg or systolic blood pressure greater than or equal to 140 mmHg on two consecutive readings taken at least 30 minutes apart
- Unknown group B strep carrier state
- Lack of informed consent on group B strep prophylaxis, if mother is Group B strep positive.
- Eclampsia or pre-eclampsia
- Anemia – hemoglobin less than 8.5 g/dL
- Thrombosis/thromboembolism/ thrombocytopenia (platelets <100,000), or other maternal bleeding disorder
- Drug or alcohol use with high risk for adverse effects to fetal or maternal health
- Maternal mental illness requiring inpatient care
- Unknown or positive HIV, syphilis or Hepatitis B status
- Current active infection of varicella at the time of labor; rubella infection anytime during pregnancy; active infection (outbreak) of genital herpes at the time of labor
- Refractory hyperemesis gravidarum
- Diabetes, type I or II, uncontrolled gestational diabetes, or gestational diabetes controlled with medication

Placental

- Low lying placenta within 2 cm or less of cervical os at term; placenta previa, vasa previa
- Placental abruption/abnormal bleeding
- Recurrent antepartum hemorrhage
- Uteroplacental insufficiency

Fetal

- Gestational age - preterm or postdates (defined as gestational age < 37 weeks + 0 days or > 41 weeks + 6 days)
- Multiple gestation
- Non-cephalic fetal presentation
- IUGR (defined as fetal weight less than fifth percentile using ethnically-appropriate growth tables, or concerning reduced growth velocity on ultrasound)
- Abnormal fetal heart rate/Doppler/surveillance studies
- Oligohydramnios or polyhydramnios
- Blood group incompatibility with atypical antibodies, or Rh sensitization
- Molar pregnancy

Transfer criteria:

If out-of-hospital birth is planned, certain intrapartum and postpartum complications may necessitate transfer to a hospital to meet coverage criteria. For these indications, an attempt should be made to transfer the mother and/or her newborn; however, imminent fetal delivery may delay or preclude actual transfer prior to birth.

Maternal

- Temperature ≥ 38.0 C
- Maternal infection requiring hospital treatment (e.g. endometritis or wound infection)
- Hemorrhage (hypovolemia, shock, need for transfusion)
- Retained placenta > 60 minutes
- Laceration requiring hospital repair (e.g., extensive vaginal, cervical or third- or fourth-degree trauma)
- Enlarging hematoma
- Bladder or rectal dysfunction

Fetal and uteroplacental

- Repetitive or persistent abnormal fetal heart rate pattern
- Thick meconium staining of amniotic fluid
- Prolapsed umbilical cord
- Failure to progress/failure of head to engage in active labor
- Chorioamnionitis or other serious infection (including toxoplasmosis, rubella, CMV, HIV, etc.)
- Uterine rupture, inversion or prolapse

If the infant is delivered out-of-hospital, the following complications require transfer to a hospital for the out-of-hospital birth to meet coverage criteria:

- Low Apgar score (< 5 at 5 minutes, < 7 at 10 minutes)
- Weight less than 5th percentile for gestational age
- Unexpected significant or life-threatening congenital anomalies
- Respiratory or cardiac irregularities, cyanosis, pallor
- Temperature instability, fever, suspected infection or dehydration

- Hyperglycemia/hypoglycemia unresponsive to treatment
- Hypotonia, tremors, seizures, hyperirritability
- Excessive bruising, enlarging cephalohematoma, significant birth trauma
- Vomiting/diarrhea

Consultation criteria:

Certain high risk conditions require consultation (by a provider of maternity care who is credentialed to admit and manage pregnancies in a hospital) for coverage of a planned out-of-hospital birth to be recommended. These complications include (but are not limited to) patients with:

Complications in a previous pregnancy:

Maternal

- More than three first trimester spontaneous abortions, or more than one second trimester spontaneous abortion
- More than one preterm birth, or preterm birth less than 34 weeks 0 days in most recent pregnancy
- Pre-eclampsia, not requiring preterm birth
- Cervical insufficiency/prior cerclage
- Third degree laceration; fourth-degree laceration with satisfactory functional recovery
- Postpartum hemorrhage requiring additional pharmacologic treatment or blood transfusion
- Retained placenta requiring manual removal

Fetal

- Child with congenital and/or hereditary disorder
- Baby > 4.5 kg or 9 lbs 14 oz
- Shoulder dystocia, with or without fetal clavicular fracture
- Unexplained stillbirth/neonatal death or previous death unrelated to intrapartum difficulty
- Unresolved intrauterine growth restriction (IUGR) or small for gestational age (defined as fetal or birth weight less than fifth percentile using ethnically-appropriate growth tables)
- Blood group incompatibility, and/or Rh sensitization

Complications of current pregnancy:

Maternal

- Inadequate prenatal care (defined as less than five prenatal visits or care began in the third trimester)
- Body mass index at first prenatal visit of greater than 35 kg/m²
- History of maternal seizure disorder (excluding eclampsia)
- Gestational diabetes, diet-controlled
- Maternal mental illness under outpatient psychiatric care with suspicion for psychosis or potential harm to self or infant
- Maternal anemia with hemoglobin < 10.5 g/dL, unresponsive to treatment

- Third-degree laceration not requiring hospital repair
- Laparotomy during pregnancy

Fetal

- Fetal macrosomia (estimated weight >4.5 kg or 9 lbs 14 oz)
- Confirmed intrauterine death
- Life-threatening congenital anomalies (unless non resuscitation planned)
- Family history of genetic/heritable disorders that would impact labor, delivery or newborn care

¹Risk assessment should be done initially when planning the location of birth and updated throughout pregnancy, labor, and delivery to determine if out-of-hospital birth is still appropriate (*weak recommendation*).

Approved Changes for the Prioritized List of Health Services:

Guideline Note XXX, PLANNED OUT-OF-HOSPITAL BIRTH

Lines 1, 2

Planned out-of-hospital birth is included on these lines when appropriate risk assessments are performed, and the consultation and transfer criteria are followed, and no high risk coverage exclusion criteria exist. Risk assessment should be done initially when planning the location of birth, and updated throughout pregnancy, labor, and delivery to determine if out-of-hospital birth is still appropriate. The clinical and/or diagnostic assessment of each criterion, with the exception of those marked with an asterisk (*), is necessary for planned out-of-hospital birth to be included on these lines. (Criteria marked with an asterisks may not be known or not be pertinent if there is no clinical indication for concern and additional diagnostic testing is not indicated.) An ultrasound is required to rule out certain risk criteria (e.g. multiple gestation, placenta previa, and life threatening congenital anomalies). Certain risk criteria require serial measurements such as fundal height and blood pressure. If a woman refuses a required clinical or diagnostic assessment, then ascertainment of her risk status is unknowable and she does not meet criteria for coverage for an out-of-hospital birth. Documentation of continuing appropriate risk assessment and routine prenatal care is required.

High-risk coverage exclusion criteria:

Complications in a previous pregnancy:

Maternal surgical history

- Cesarean section or other hysterectomy
- Uterine rupture
- Retained placenta requiring surgical removal
- Fourth-degree laceration without satisfactory functional recovery

Maternal medical history

- Pre-eclampsia requiring preterm birth
- Eclampsia
- HELLP syndrome

Fetal and placental

- Unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty
- Baby with neonatal encephalopathy

- Placental abruption with adverse outcome

Complications of current pregnancy:

Maternal

- Induction of labor
- Prelabor rupture of membranes > 24 hours
- Pre-existing chronic hypertension; Pregnancy-induced hypertension with diastolic blood pressure greater than or equal to 90 mmHg or systolic blood pressure greater than or equal to 140 mmHg on two consecutive readings taken at least 30 minutes apart
- Unknown group B strep carrier state
- Lack of informed consent on group B strep prophylaxis, if mother is Group B strep positive.
- Eclampsia or pre-eclampsia
- Anemia – hemoglobin less than 8.5 g/dL
- Thrombocytopenia (platelets <100,000)
- Thrombosis/thromboembolism or other maternal bleeding disorder*
- Maternal mental illness requiring inpatient care*
- Drug or alcohol use with high risk for adverse effects to fetal or maternal health
- Unknown, or positive, syphilis, HIV, or Hepatitis B status
- Current active infection of varicella at the time of labor; rubella infection anytime during pregnancy; active infection (outbreak) of genital herpes at the time of labor*
- Refractory hyperemesis gravidarum*
- Diabetes, type I or II, uncontrolled gestational diabetes, or gestational diabetes controlled with medication

Placental

- Low lying placenta within 2 cm or less of cervical os at term; placenta previa, vasa previa
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- Gestational age - preterm or postdates (defined as gestational age < 37 weeks + 0 days or > 41 weeks + 6 days)
- Multiple gestation
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- IUGR (defined as fetal weight less than fifth percentile using ethnically-appropriate growth tables, or concerning reduced growth velocity on ultrasound)*
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- Temperature ≥ 38.0 C
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- Hemorrhage (hypovolemia, shock, need for transfusion)
- Retained placenta > 60 minutes
- Laceration requiring hospital repair (e.g., extensive vaginal, cervical or third- or fourth-degree trauma)
- Enlarging hematoma
- Bladder or rectal dysfunction

Fetal and uterine

- Repetitive or persistent abnormal fetal heart rate pattern
- Thick meconium staining of amniotic fluid
- Prolapsed umbilical cord
- Failure to progress (as defined by the American Congress of Obstetricians and Gynecologists, March 2014, found at <http://www.acog.org/Resources-And-Publications/Obstetric-Care-Consensus-Series/Safe-Prevention-of-the-Primary-Cesarean-Delivery/>)/failure of head to engage in active labor
- Chorioamnionitis or other serious infection (including toxoplasmosis, rubella, CMV, HIV, etc.)
- Uterine rupture, inversion or prolapse

If the infant is delivered out-of-hospital, the following complications require transfer to a hospital for the out-of-hospital birth to meet coverage criteria:

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- Shoulder dystocia, with or without fetal clavicular fracture
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- History of maternal seizure disorder (excluding eclampsia)
- Gestational diabetes, diet-controlled
- Maternal mental illness with suspicion for psychosis or potential harm to self or infant under outpatient psychiatric care
- Maternal anemia with hemoglobin < 10.5 g/dL, unresponsive to treatment
- Third-degree laceration not requiring hospital repair
- Laparotomy during pregnancy

Fetal

- Fetal macrosomia (estimated weight >4.5 kg or 9 lbs 14 oz)
- Confirmed intrauterine death
- Family history of genetic/heritable disorders that would impact labor, delivery or newborn care

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

[Meeting materials](#), pages 228-329

Ariel Smits, reported that the VbBS met earlier in the day, 11-12-2015. The recommendations are mostly about coding changes.

RECOMMENDED CODE MOVEMENT (effective 1/1/16)

- Add or delete various codes related to straightforward changes
- Add the 2016 CPT and HCPCS codes to various lines/Health Systems Division files
- Add various diagnosis codes to a covered line for conditions which might affect young children placed on foster care or who have otherwise had early childhood trauma
- Add the diagnosis code for Buerger's disease to a covered line and remain on an uncovered line with a new guideline specifying that it is only on the covered line for treatment of ulcers and/or gangrene and does not pair with revascularization procedures

RECOMMENDED GUIDELINE CHANGES (effective 1/1/16)

- Modify the nerve block ancillary guideline to add new 2016 nerve block CPT codes
- Modify the non-prenatal genetic testing guideline to incorporate the current figure D1 (which will be removed), to update NCCN references, to add new BRCA testing CPT codes, to add a section recommending genetic counseling and indicated testing of cancer survivors, to add back a deleted section regarding a cystic fibrosis (CF) testing code, to limit CF testing to once per lifetime, and to move a requirement for the least costly/broad testing which would give the required information
- Modify the prenatal genetic testing guideline to allow panel testing for Ashkenazi Jewish patients, to limit CF testing to the 2 CPT codes most commonly used for this, and to add CPT

codes to the chorionic villus sampling (CVS)/amniocentesis entry to better capture the range of codes intended for coverage

- Modify the hyperbaric oxygen guideline to include all the appropriate ICD-10 codes for diabetic ulcers and gangrene
- Add new guidelines to limit use of 2016 CPT codes, including sclerotherapy, fetal MRI, and genetic testing for cardiac transplant rejection
- Add a new guideline to limit the use of a non-specific conduct disorder diagnosis to children 5 and younger
- Modify the acupuncture guideline to remove the requirement for referrals for non-pregnancy related indications, standardize the number of visits for various conditions to 12 (6 for breach fetal presentation), and correct ICD-10 codes for various conditions
- Modify the tobacco cessation guideline to clarify alignment of the recommended services for coverage with ACA requirements
- Add a new multisector intervention statement regarding tobacco cessation practices
- Tobacco cessation and elective surgery
 - Consider requirement of intensive intervention prior to surgery
 - This will come back later for further consideration

MOTION: To accept the VbBS recommendations on Prioritized List changes not related to coverage guidances, as stated. See the VbBS minutes of 11-12-2015 for a full description. Carries: 12-0.

Coverage Guidance Topic: Proton beam therapy

[Meeting materials](#), pages 330-445

Topic tabled until the January 14, 2016 meeting.

Adjournment

Meeting adjourned at 4:15 pm. Next meeting will be from 1:30-4:30 pm on Thursday, January 14, 2016 at Clackamas Community College Wilsonville Training Center, Rooms 111-112, Wilsonville, Oregon.