

AGENDA
HEALTH EVIDENCE REVIEW COMMISSION
Wilsonville Training Center, Rooms 111-112
August 13, 2015
1:30-4:30 pm

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

#	Time	Item	Presenter	Action Item
1	1:30 PM	Call to Order	Som Saha	
2	1:35 PM	Approval of Minutes (5-7-2015)	Som Saha	X
3	1:40 PM	Director's Report	Darren Coffman	
4	1:45 PM	Planned out-of-hospital birth <ul style="list-style-type: none"> • HTAS coverage guidance recommendation • VbBS Prioritized List recommended changes 	Cat Livingston Valerie King	X
5	2:15 PM	Value-based Benefits Subcommittee Report	Ariel Smits Cat Livingston	X
6	3:05 PM	Coverage Guidance process redesign	Jason Gingerich	X
7	3:25 PM	Coverage guidance topic 2-year review <ul style="list-style-type: none"> • Review and approve scope documents 	Cat Livingston	
8	3:45 PM	Biomarker tests of cancer tissue for prognosis and potential response to treatment <ul style="list-style-type: none"> • HTAS coverage guidance recommendation • VbBS Prioritized List recommended changes 	Cat Livingston Robyn Liu	X
9	4:05 PM	Policies <ul style="list-style-type: none"> • Approve BHAP/OHAP membership changes • Discuss using SOI for best practices 	Darren Coffman Cat Livingston	X
10	4:15 PM	2016 Biennial Review <ul style="list-style-type: none"> • Formation of task force on obesity management 	Ariel Smits	
11	4:25 PM	Next Steps <ul style="list-style-type: none"> • Schedule next meetings (Wilsonville Training Center, Rooms 111-112) <ul style="list-style-type: none"> ○ October 8, 2015 (if needed) ○ November 12, 2015 	Som Saha	
12	4:30 PM	Adjournment	Som Saha	

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

AGENDA
VALUE-BASED BENEFITS SUBCOMMITTEE

August 13, 2015

8:00am - 1:00pm

Clackamas Community College

Wilsonville Training Center, Rooms 111-112

Wilsonville, Oregon

A working lunch will be served at approximately 12:00 PM

All times are approximate

- I. Call to Order, Roll Call, Approval of Minutes – Kevin Olson 8:00 AM**
- II. Staff report – Ariel Smits, Cat Livingston, Darren Coffman 8:05 AM**
 - A. Errata
- III. Straightforward/Consent Agenda – Ariel Smits 8:15 AM**
 - A. Straightforward table
 - B. Codes Without Line Placement for January 1, 2016
 - C. Straightforward guideline changes
 - D. Hypnotherapy
 - E. Abnormal vaginal pap smears
 - F. Wearable cardiac defibrillators
- IV. Previous Discussion Items – Ariel Smits 8:20 AM**
 - A. LVAD as destination therapy—with Dr. James Mudd
 - B. Gender dysphoria
 - A. Guideline modifications
 - B. Procedures
 - C. Age limitations
- V. New discussion items – Ariel Smits 10:00 AM**
 - A. Temporary prostatic stents
 - B. Vertebral fracture assessment
 - C. Optic neuritis
 - D. Trochanteric bursitis
 - E. Exhaled nitrous oxide testing for asthma
 - F. Nose repair
- VI. Guidelines – Ariel Smits, Cat Livingston 11:15 AM**
 - A. Coverage of perforations of the ear drum with hearing loss
 - B. Continuous glucose monitoring guideline
 - C. Acute peripheral nerve injury guideline
 - D. Botulinum toxin injections for migraine and bladder conditions

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| VII. Coverage Guidances for review | 12:00 PM |
| A. Biomarkers | |
| B. Out of hospital births— with Dr. Neilson | |
| VIII. Public comment | 1:25 PM |
| IX. Adjournment – Kevin Olson | 1:30 PM |

Coverage Guidance: Out-of-hospital birth

Question: How shall the Coverage Guidance on Out-of-hospital birth be applied to the Prioritized List?

Question source: Licensed Direct Entry Midwifery workgroup; Evidence-based Guidelines Subcommittee

Issue: The EbGS has approved a draft Coverage Guidance for when coverage is recommended for out of hospital birth. VbBS needs to evaluate application to the Prioritized List of Health Services.

Translating the coverage guidance box language to a List guideline raises a key implementation concern: whether or not each and every one of the risk criteria must be addressed in order to determine whether or not an out of hospital birth would be included in the funded region of the List. Therefore, there are two options to decide between.

Proposed List changes:

1) Adopt a new Guideline Note on Out-of-hospital Birth.

- a. Staff recommendations that have emerged after approval from EbGS are made in [blue](#) and ~~red~~, and reflect an attempt to remove duplication and add clarity

2) Decide between 2 options:

- a. **OPTION 1 (preferred)** – require an assessment of all risk factors in order to determine appropriate candidacy for out-of-hospital birth

The clinical and/or diagnostic assessment of each criterion is required for out-of-hospital birth to be included on these lines. Documentation of continuing risk assessment and routine prenatal care is required.

- b. **OPTION 2** – allow for some risk factors to be unknown because of maternal choice and/or provider choice
 - i. **If option 2 is chosen, review each of the green choices and determine if they are required or optional**
 - ii. Footnote 1. The presence or absence of these criteria may not be known if there has been no antepartum clinical evidence and diagnostic testing has not been done (e.g. a patient declines to have a prenatal ultrasound or bloodwork). If there is clinical concern for one of these conditions, the criterion must be assessed and managed to determine inclusion on these lines.

Guideline Note XXX OUT-OF-HOSPITAL BIRTH

Coverage Guidance: Out-of-hospital birth

Lines 1,2

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 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 is required for out-of-hospital birth to be included on these lines. Documentation of continuing risk assessment and routine prenatal care is required.**

High risk criteria

Complications in a previous pregnancy:

- Cesarean section or other hysterotomy
- Unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty
- Baby with neonatal encephalopathy
- HELLP syndrome
- Placental abruption with adverse outcome
- Pre-eclampsia requiring preterm birth
- Eclampsia
- Uterine rupture
- Retained placenta requiring surgical removal
- Fourth-degree laceration without satisfactory functional recovery

Complications of current pregnancy:

- Gestational age - preterm or postdates (defined as gestational age < 37 weeks + 0 days or > 41 weeks + 6 days)
- 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
- **Multiple gestation**
- Non-cephalic fetal presentation
- **Low lying placenta within 2 cm or less of cervical os at term; placenta previa, vasa previa¹**
- Eclampsia or pre-eclampsia
- Placental abruption/abnormal bleeding
- **Anemia – hemoglobin less than 8.5 g/dL¹**

Coverage Guidance: Out-of-hospital birth

- Induction of labor
- [Drug or alcohol use with high risk for adverse effects to fetal or maternal health](#)
- Recurrent antepartum hemorrhage
- IUGR (defined as fetal weight less than fifth percentile using ethnically-appropriate growth tables, or concerning reduced growth velocity on ultrasound)¹
- Abnormal fetal heart rate/Doppler/surveillance studies
- Oligohydramnios or polyhydramnios¹
- Blood group incompatibility with atypical antibodies, or Rh sensitization
- Prelabor rupture of membranes > 24 hours
- Life-threatening congenital anomalies¹
- Unknown 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
- Thrombosis/thromboembolism/ thrombocytopenia (platelets <100,000), or other maternal bleeding disorder¹
- Uteroplacental insufficiency
- Molar pregnancy
- Maternal mental illness requiring inpatient care
- Diabetes, type I or II, uncontrolled gestational diabetes, or gestational diabetes controlled with medication¹

Transfer criteria:

If out-of-hospital birth is planned, certain intrapartum and postpartum complications may necessitate transfer to a hospital to still be included on these lines. 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.

- Non-cephalic fetal presentation
- Eclampsia or pre-eclampsia
- Placental abruption/abnormal bleeding
- ~~• Anemia — hemoglobin less than 8.5 g/dL~~
- ~~• Current active infection of varicella at the time of labor~~

Coverage Guidance: Out-of-hospital birth

- ~~• Current active infection (outbreak) of genital herpes at the time of labor~~
- Repetitive or persistent abnormal fetal heart rate pattern
- Thick meconium staining of amniotic fluid
- ~~• Pregnancy induced hypertension with diastolic blood pressure greater than or equal to 90 mmHg or raised systolic blood pressure greater than or equal to 140 mmHg on two consecutive readings taken at least 30 minutes apart~~
- Chorioamnionitis or other serious infection (including toxoplasmosis, rubella, CMV, HIV, etc.)
- Failure to progress/failure of head to engage in active labor
- Prolapsed umbilical cord
- Uterine rupture, inversion or prolapse
- Hemorrhage (hypovolemia, shock, need for transfusion)
- Retained placenta > 60 minutes
- Temperature ≥ 38.0 C
- Laceration requiring hospital repair (e.g., extensive vaginal, cervical or third- or fourth-degree trauma)
- Enlarging hematoma
- Infection (endometritis, UTI, wound, breast)
- ~~• Thrombophlebitis/thromboembolism~~
- Bladder or rectal dysfunction

If the infant is delivered out-of-hospital, the following complications require transfer to a hospital for the out-of-hospital birth to be included on this linen:

- Low Apgar score (< 5 at 5 minutes, < 7 at 10 minutes)
- Temperature instability, fever, suspected infection or dehydration
- Hypotonia, tremors, seizures, hyperirritability
- Respiratory or cardiac irregularities, cyanosis, pallor
- Weight less than 5th percentile for gestational age (using ethnically-appropriate growth tables)
- Unexpected significant or life-threatening congenital anomalies
- Excessive bruising, enlarging cephalohematoma, significant birth trauma
- Hyperglycemia/hypoglycemia unresponsive to treatment
- Vomiting/diarrhea

Consultation criteria:

Coverage Guidance: Out-of-hospital birth

Certain high risk conditions require consultation (by a provider of maternity care who is credentialed to admit and manage pregnancies in a hospital) to be included on this line. These complications include (but are not limited to) patients with:

Complications in a previous pregnancy:

- More than three first trimester spontaneous abortions, or more than one second trimester spontaneous abortion
- Blood group incompatibility
- Pre-eclampsia, not requiring preterm birth
- More than one preterm birth, or preterm birth less than 34 weeks 0 days in most recent pregnancy
- Cervical insufficiency/prior cerclage
- 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)
- Third degree laceration; fourth-degree laceration with satisfactory functional recovery
- Child with congenital and/or hereditary disorder
- Baby > 4.5 kg or 9 lbs 14 oz
- ~~Perinatal death~~
- Unexplained stillbirth/neonatal death or previous death unrelated to intrapartum difficulty
- Shoulder dystocia, with or without fetal clavicular fracture
- Postpartum hemorrhage requiring additional pharmacologic treatment or blood transfusion
- Retained placenta requiring manual removal

Complications of current pregnancy:

- Fetal macrosomia (estimated weight >4.5 kg or 9 lbs 14 oz)
- Family history of genetic/heritable disorders
- History of maternal seizure disorder (excluding eclampsia)
- Laparotomy during pregnancy
- Cervical dysplasia requiring evaluation
- Gestational diabetes, diet-controlled¹
- Maternal mental illness under outpatient psychiatric care
- Maternal anemia with hemoglobin < 10.5 g/dL
- Third-degree laceration not requiring hospital repair

Coverage Guidance: Out-of-hospital birth

- Confirmed intrauterine death
- 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

1. The presence or absence of these criteria may not be known if there has been no antepartum clinical evidence and diagnostic testing has not been done (e.g. a patient declines to have a prenatal ultrasound or bloodwork). If there is clinical concern for one of these conditions, the criterion must be assessed and managed to determine inclusion on these lines.

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

Important: Measures of, impulsiveness, and global functioning, grade retention, academic achievement, 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?

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

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

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

Coronary Artery Calcium Scoring

PICO & Key Questions for Updated Literature Search

Populations

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

Intervention

Coronary artery calcium scoring (CACS)

Comparators

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

Outcomes

Critical: All-cause mortality, major adverse cardiovascular events

Important: Need for revascularization procedure; incidental findings, contrast induced nephropathy

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

Key Questions

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

KQ2: What is the cost-effectiveness of CACS?

KQ3: What are the harms of CACS?

Carotid Endarterectomy

PICO & Key Questions for Updated Literature Search

Populations

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

Intervention

Carotid endarterectomy

Comparators

Optimal medical therapy, carotid stenting

Outcomes

Critical: All-cause mortality, cerebrovascular accidents

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

Outcomes considered but not selected for GRADE table: Need for reintervention (to be discussed by HERC)

Key Questions

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

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

KQ2: What are the harms of carotid endarterectomy?

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

Coronary CT Angiography

PICO & Key Questions for Updated Literature Search

Population

Adults with acute chest pain or chronic stable chest pain

Intervention

Coronary CT angiography (CTA)

Comparators

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

Outcomes

Critical: All-cause mortality, myocardial infarction, stroke,

Important: Diagnostic accuracy, costs/cost-effectiveness,

Outcomes considered but not selected for GRADE table: avoidance of invasive testing; radiation exposure; need for revascularization procedure

Key Questions

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

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

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

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 USPSTF defines use of preventive services for the Essential Health Benefits which provide minimum coverage standards on preventive services for most health plans in the United States. Current coverage guidance aligns with USPSTF recommendations.

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: All-cause mortality, severe morbidity (e.g. microvascular and macrovascular complications)

Important: Quality-of-life, change in HbA1c, ketoacidosis, severe hypoglycemia¹

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.

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 vs multiple daily insulin injections (MDII)?
 - c. Frequency and duration of CGM?

Special Considerations

- CBGM devices are reported to have highly variable rates of adherence; should we exclude studies that aren't analyzed by intention-to-treat? *Decided to indicate which studies are done on intention to treat.*

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

Continuous Blood Glucose Monitoring

PICO & Key Questions for Updated Literature Search

- Include specific studies of people with “hypoglycemia unawareness”? *This is already captured in the indications.*

DRAFT

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: All-cause mortality, major adverse cardiovascular events

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

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?

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?

Induction of Labor

PICO & Key Questions for Updated Literature Search

Populations

Pregnant adolescents and women at term (≥ 37 weeks of gestation)

Interventions

Medically or obstetrically indicated induction of labor (IOL), elective IOL

Comparator

Expectant management

Outcomes

Critical: Perinatal mortality

Important: Mode of birth, maternal length of stay, neonatal length of stay, need for higher-level neonatal care

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

Key Questions

KQ1: What are the outcomes of IOL versus expectant management for women with medical or obstetrical indications for induction of labor?

KQ2: What are the evidence-based medical or obstetrical indications for induction of labor?

KQ3: How do outcomes vary by cervical favorability, gestational age and parity?

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?

CQ2: Does the information provided by MRI after breast cancer diagnosis change measurements of decisional conflict?

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: All-cause mortality, morbidity from significant intracranial abnormalities

Important: Headache-free days, quality of life, change in treatment plan

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?

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

KQ3: What are the harms (including incidental findings) of neuroimaging for headache?

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 radionuclide scintigraphy), MRI

Outcomes

Critical: All-cause mortality, cancer-specific mortality

Important: Progression-free survival, change in treatment plan, 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?

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

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)

Important: Hearing loss, school performance/academic achievement, treatment-specific harms

Outcomes considered but not selected for GRADE table: Missed school days

Key Questions

KQ1: What is the comparative effectiveness of interventions for recurrent acute otitis media?

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

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: All-cause mortality, severe morbidity (e.g. microvascular and macrovascular complications, hyperosmolar hyperglycemic state (HHS))

Important: Quality-of-life, change in HbA1c, severe hypoglycemia¹

Outcomes considered but not selected for GRADE table: Ketoacidosis, as this is not relevant to the target population.

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, etc.)

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

Self-Monitoring of Blood Glucose

PICO & Key Questions for Updated Literature Search

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.

Vertebroplasty, Kyphoplasty, and Sacroplasty

PICO & Key Questions for Updated Literature Search

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:

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?

Gender Dysphoria Guideline Amendments

Question:

- 1) Should the wording referring to mental health professionals be altered in the gender dysphoria guideline?
 - a. Should there be any requirements regarding the qualifications for providers who prescribe hormonal therapy
- 2) Should the requirement for mental health professionals to have experience with gender dysphoria be modified in the guideline?
- 3) Should the requirement for a thorough psychosocial assessment be changed to a mental health evaluation?
- 4) Should there be any specific qualification/training requirements for the mental health professional conducting the evaluation?

Question source: DMAP, Medicaid CCO's, Basic Rights Oregon

Issues:

1) The current gender dysphoria guideline has requirements for “qualified mental health professionals” to be involved in the care of transgendered persons. This wording was adopted from the international guideline on transgender health. However, this term has a specific meaning for Medicaid programs, referring to mental health providers without the traditional degree or licenses. The intent of the commission was to have mental health professionals with training/licenses/degrees (i.e. LCSW, psychologists, etc.). DMAP is suggesting that we change this phrase to “licensed mental health provider.”

Basic Rights Oregon has raised concerns that the current definition of mental health providers is confusing and inadequate. They agree with the proposed change to remove “qualified” and replace with “licensed.” In addition, they are requesting the addition of examples of providers the HERC feels meets the guideline definition. BRO suggests adding a full list of permissible practitioners (regular master’s level social worker, licenses professional counselor, licensed marriage and family therapist, occupational therapist, psychologist, physician, psychiatrist, physician assistant, naturopathic doctor, nurse practitioner, and/or psychiatric nurse). BRO feels that this clarification of providers will increase access to care.

Other insurers (**Cigna 2015** for example) require one mental health provider be a master’s level professional and the other provider be a psychiatrist or PhD level provider.

The WPATH international guidelines require the following:

The training of mental health professionals competent to work with gender dysphoric adults rests upon basic general clinical competence in the assessment, diagnosis, and treatment of mental health concerns. Clinical training may occur within any discipline that prepares mental health professionals for clinical practice, such as psychology, psychiatry, social work, mental health counseling, marriage and family therapy, nursing, or family medicine with specific training in behavioral health and counseling. The following are recommended minimum credentials for mental health professionals who work with adults presenting with gender dysphoria:

1. Clinical training may occur within any discipline that prepares mental health professionals for clinical practice, such as psychology, psychiatry, social work, mental health counseling,

Gender Dysphoria Guideline Amendments

marriage and family therapy, nursing, or family medicine with specific training in behavioral health and counseling.

2. A master's degree or its equivalent in a clinical behavioral science field. This degree, or a more advanced one, should be granted by an institution accredited by the appropriate national or regional accrediting board. The mental health professional should have documented credentials from a relevant licensing board or equivalent for that country

MED 2015 lists Maryland Medicaid, New York Medicaid, Vermont Medicaid, city of San Francisco, some BCBS plans, Cigna, and GroupHealth, and as having the requirement that "One of the referring professionals must have a doctoral degree (PhD, MD, EdD, DSc, DSW, or PsyD) and be capable of adequately evaluating co-morbid psychiatric conditions" prior to gender reassignment surgery.

2) The guideline requires the mental health professional to have "experience in working with patients with gender dysphoria." DMAP and the CCOs are finding a significant shortage of mental health professionals with such experience. They are requesting that the requirement for experience be dropped to avoid having to pay for patient transportation out of their area to meet with a professional with this experience. In addition, Basic Rights Oregon has requested that "experience" be replaced with "knowledge about the assessment process and treatment of patients with gender dysphoria. The source of this knowledge could be academic coursework, continuing education class, residency exposure, mental health provider who is accessing supervision/consultation from an expert of specialist, etc."

WPATH lists the following requirement for mental health professionals who work with patients with gender dysphoria:

Knowledgeable about gender-nonconforming identities and expressions, and the assessment and treatment of gender dysphoria.

3) BRO is requesting that we change our current requirement for a "thorough psychosocial assessment" to "mental health evaluation." BRO feels that the term psychosocial assessment suggests a formal battery of objective measures, rather than a clinical interview. BRO considers a mental health evaluation sufficient to confirm a gender dysphoria diagnosis and provide results of a mental status exam. Requiring a psychosocial assessment is a high barrier and is difficult to obtain due to a shortage of qualified providers.

BRO is also requesting that HERC put in language clarifying that the mental health assessment does not have to provide a referral letter or other formal document prior to cross-sex hormone therapy initiation.

The WPATH guideline requires that a patient have an "evaluation of their psychosocial adjustment."

4) The CCOs have raised questions about whether there should be minimal requirements for the training and/or experience of providers who are prescribing pubertal suppression medications or cross-sex hormone therapy. Specifically, there have been questions raised about naturopaths, chiropractors, or other providers with prescribing privileges being allowed to prescribe these medications. Pharmacy and Therapeutics Committee has created a PA criteria for puberty suppression medications requiring that they be prescribed by a pediatric endocrinologist. Basic Rights Oregon has expressed concern about lack

Gender Dysphoria Guideline Amendments

of access to providers, particularly in more rural areas of the state. Currently, there are no requirements in the guideline for any specific training or experience for providers prescribing hormonal medications or cross sex hormone therapy. Generally, the HERC has avoided adding any qualifications or restrictions on provider types for prescribing medications. There are restrictions on the providers who can perform certain surgeries or other services on the Prioritized List.

The WPATH guidelines outline their recommendations for providers who prescribe hormone therapy.

With appropriate training, feminizing/masculinizing hormone therapy can be managed by a variety of providers, including nurse practitioners, physician assistants, and primary care physicians. Many of the screening tasks and management of comorbidities associated with long-term hormone use, such as cardiovascular risk factors and cancer screening, fall more uniformly within the scope of primary care rather than specialist care, particularly in locations where dedicated gender teams or specialized physicians are not available.

Given the multidisciplinary needs of transsexual, transgender, and gender-nonconforming people seeking hormone therapy, as well as the difficulties associated with fragmentation of care in general, WPATH strongly encourages the increased training and involvement of primary care providers in the area of feminizing/masculinizing hormone therapy. If hormones are prescribed by a specialist, there should be close communication with the patient's primary care provider. Conversely, an experienced hormone provider or endocrinologist should be involved if the primary care physician has no experience with this type of hormone therapy, or if the patient has a pre-existing metabolic or endocrine disorder that could be affected by endocrine therapy.

While formal training programs in transgender medicine do not yet exist, hormone providers have a responsibility to obtain appropriate knowledge and experience in this field. Clinicians can increase their experience and comfort in providing feminizing/masculinizing hormone therapy by co-managing care or consulting with a more experienced provider, or by providing more limited types of hormone therapy before progressing to initiation of hormone therapy. Because this field of medicine is evolving, clinicians should become familiar and keep current with the medical literature, and discuss emerging issues with colleagues.

Gender Dysphoria Guideline Amendments

HERC staff recommendations:

- 1) Modify GN127 as shown below
 - a. Change the term for the mental health providers required to evaluate patients from “qualified” to “licensed”
 - i. Add examples of providers meeting this definition per advocate request
 - ii. Consistent with WPATH definition of providers
 1. Consider whether to add requirement for a minimum of a master’s degree or equivalent to better conform with WPATH definition
 - iii. Addresses Medicaid problem with the “qualified” specification
 - b. Allow mental health providers to be “knowledgeable” rather than “experienced” with providing care for transgendered persons
 - i. Increases the pool of available providers for Oregon patients
 - ii. Conforms with WPATH guidelines
 - c. Change the requirement for the mental health visit to be a “thorough mental health evaluation” rather than “thorough psychosocial assessment”
 - i. Consider adding clarification that no formal referral letter needs to result from the mental health evaluation prior to cross-sex hormone therapy initiation.
 - d. Consider adding requirements for the training of the mental health professional(s) involved in the evaluation for cross-sex hormone therapy and the referral for gender reassignment surgery
 - i. For the evaluation for cross-sex hormone therapy, consider adding in wording regarding the need for a master’s degree level of training or the equivalent
 1. “a ~~qualified-licensed~~ mental health professional **with a master’s degree or its equivalent or higher in a clinical behavioral science field (including but not limited to: LCSW, psychologist, family therapist, psychiatric nurse practitioner, psychiatrist)** ~~with experience in knowledgeable about the assessment and treatment of~~ **working with** patients with gender dysphoria.
 2. Aligns with WPATH guidelines
 - ii. For the referrals for sex reassignment surgery, consider requiring a doctoral level professional being one of the two professionals
 1. “One of the referring professionals must have a doctoral degree (PhD, MD, DO, EdD, DSc, DSW, or PsyD) and be capable of adequately evaluating co-morbid psychiatric conditions.”
 2. Consider also mirroring the requirement for at least master’s level degree as above
 - iii. Brings Oregon into alignment with the majority of other private and public payers
 - e. Do not add qualifications for puberty suppression or cross-sex hormonal therapy providers
 - i. Not normally in the purview of the HERC
 - ii. Leave criteria to the Pharmacy and Therapeutics (P&T) Committee

Gender Dysphoria Guideline Amendments

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 thorough ~~psychosocial assessment~~ mental health evaluation by a ~~qualified licensed~~ mental health professional (including but not limited to: LCSW, psychologist, family therapist, psychiatric nurse practitioner, psychiatrist) ~~with experience in~~ knowledgeable about the assessment and treatment of ~~working with~~ patients with gender dysphoria.

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

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

Age Limitations for Gender Dysphoria Treatments

Question: Should any age restrictions be placed for surgical treatments for gender dysphoria?

Question source: multiple letters and email communication from members of the public, press reports/articles

Issue: The HERC has received multiple emails and phone calls regarding our coverage of surgery for adolescents after news stories were published/aired regarding this topic. Currently, gender-questioning children entering puberty can access puberty suppression medications. There is no age limit in the gender dysphoria guideline for initiating cross-sex hormone therapy or undergoing sex-reassignment procedures.

During the VBBS/HERC discussions regarding gender dysfunction in 2013 and 2014, there were multiple public meetings at which treatment of gender dysphoria in children and adolescents was discussed. Specific discussions and testimony occurred around puberty suppression medications, with the bulk of the evidence finding that this type of treatment was reversible and allowed pubertal children time to determine if they truly had gender dysphoria and, if so, desired any further treatment. There was a specific literature review and discussion regarding the possible harms of puberty suppression medications. The harms of not covering this type of therapy were thought to outweigh any harms from the therapy itself.

Additional discussions occurred regarding the access of adolescents to cross-sex hormone therapy. Testimony was heard that not allowing access to these types of therapies until the age of 18 could cause irreparable harm for some patients. The decision to allow persons younger than 18 to receive either cross-sex hormone therapy was not unanimous. The decision was made to allow coverage for persons younger than age 18, with various protections written into the guideline, including the requirement for one mental health evaluation prior to cross-sex hormone therapy.

The discussion around inclusion of sex reassignment surgery for adolescents was extensive and occurred at multiple meetings. Sex reassignment surgery is not reversible. There was considerable debate during Commission meetings regarding the ability to an adolescent to decide to undergo this type of surgery. The Commission heard testimony that surgery younger than age 18 is rare, but can be life saving for patients with severe depression or other mental health conditions arising from their gender dysphoria. The decision was made to cover with extensive guideline protections, including the requirement to have two separate mental health evaluations prior to irreversible procedures.

Recently, the Commission has received multiple letters and emails from citizens expressing concerns with allowing either cross-sex hormone therapy and/or gender reassignment procedures in persons younger than age 18 due to the developing nature of the adolescent brain and the inability of adolescents to make other life changing decisions such as voting or drinking alcohol.

The age of consent for medical procedures of any type in Oregon is age 15. This age is based on statute. Any Oregon citizen age 15 or older may consent for any type of surgical procedure without parental consent.

There is precedent for restricting surgical procedures based on age in the Prioritized List. Currently, bariatric surgery is limited to patients aged 18 and older.

Other state and private policies

Coverage for puberty suppression medications

MED 2015

- 1) New York Medicaid: no coverage. Cross sex hormone therapy limited to age 18 and older (MED 2015)
- 2) CA, MD, and VT Medicaid policies include coverage for medical therapy (i.e., hormone therapy) without specification if this is for cross-sex hormone therapy or puberty suppression medications (MED 2015)
- 3) Personal communication with MED staff, however, indicates that no other state Medicaid programs other than Oregon currently cover puberty suppression medications. MED is currently conducting a policy review for puberty suppression medications.

Age restrictions for gender reassignment surgeries

MED 2015

With the exception of Oregon and Vermont, all policies require an individual to be 18 years of age to receive hormone (where described) and gender reassignment surgery (Oregon does not specify an age requirement, and Vermont requires individuals be 21 years of age). These include all private payers surveyed.

Aetna (2015) and Cigna (2015) require a person to be 18 years of age for coverage of gender reassignment surgery.

Evidence for age for gender reassignment surgery:

1) deVries 2014

- a. N=55 young adults who had puberty suppression medications, cross sex hormone therapy and sex reassignment surgery
- b. Age at sex reassignment surgery: mean 19.2 yrs (SD 0.9), range 18.0–21.3 yrs
- c. Results: After gender reassignment, in young adulthood, the GD was alleviated and psychological functioning had steadily improved. Wellbeing was similar to or better than same-age young adults from the general population. Improvements in psychological functioning were positively correlated with postsurgical subjective well-being.

HERC staff recommendations:

Discuss adding age restriction(s) for

- 1) Cross-sex hormone therapy to 18 yrs
 1. Staff does not recommend this change
- 2) Gender reassignment surgery to 18 yrs
 1. Pros:
 - a. Excellent outcomes noted in deVries study with this age limitation
 - b. Consistent with other state Medicaid and private payer “standard of care”
 2. Cons:
 - a. This would restrict this procedure unlike any other medical procedures in Oregon, where the age of consent for medical procedures is 15
 - i. Note: bariatric surgery is limited to age 18 on the Prioritized List
 - b. There may be potential harm to adolescents by delaying the procedure
 3. If an age limit is adopted, GN 127 would need be modified
 - a. “Sex reassignment surgery is included for patients 18 years of age and older who are sufficiently physically fit and meet eligibility criteria. “

Surgical Therapy for Gender Dysphoria

Questions:

- 1) Should the surgical procedures included on the gender dysphoria line be modified?
- 2) Should mastopexy (breast augmentation) be covered for gender dysphoria?
- 3) Should penile prosthesis for function be covered for gender dysphoria?
- 4) Should any restrictions be placed on who can provide surgical treatments for gender dysphoria?

Question Source: HERC staff, OHA, Medicaid CCO's

Issues:

The CCOs and DMAP have questions regarding the procedures included or omitted from the gender dysphoria line. The procedures included on the line were considered necessary for sex reassignment when this topic was discussed in 2014; a series of procedures were deliberately left off the line as they were considered cosmetic.

The specific questions raised by the CCOs and DMAP include

- a) Is there any evidence that one type of gender reassignment surgery or one subset of procedures is more effective than another at relieving gender dysphoria?
- b) Should breast augmentation be included for males transitioning to females? Is there evidence to support breast augmentation as being necessary for the treatment of gender dysphoria?
- c) Should tissue transplant and other procedures considered auxiliary to mastectomy be included on the line?
- d) Is there any guidance available on the type of provider or the qualifications for a provider to perform gender reassignment surgery?

As part of the research into these questions, HERC staff have identified multiple procedure codes on the line that need to be removed due to being inappropriate.

Surgical Therapy for Gender Dysphoria

Evidence:

HERC staff has been unable to identify any evidence for

- 1) Types of surgical procedures or groups of procedures with best outcomes for alleviating gender dysphoria or providing best mental health or functional outcomes
- 2) Particular surgical techniques to recommend. Specific techniques for various procedures have been studied or published, but no evidence was found that one technique is superior to another for resolution of gender dysphoria

Only 1 meta-analysis of surgical treatment for gender dysphoria was identified:

MED 2014

- 1) Hayes (2014c) reported that the evidence was insufficient to draw any conclusions regarding the comparative effectiveness of different types of sex reassignment surgery
- 2) Hayes (2014) rated ancillary procedures, such as facial surgeries, vocal cord procedures, and hair removal “D2”-- the intervention has no proven benefit and/or is not safe

Other Public and Private Payer Coverage

Based on the lack of published evidence, HERC staff undertook a review of current public and private payer coverage in an attempt to determine the current “standard of care” for gender dysphoria. Staff acknowledges that there is no actual widely accepted standard of care for surgical treatment of gender dysphoria and recognizes that other private and public payer policies are not evidence based. However, staff felt that it was desirable to align Oregon with other state and national policies when a majority of identified sources agree on a particular type or item of coverage.

General coverage policy information

MED 2015

Six state Medicaid programs and the District of Columbia have pending or current coverage criteria for the treatment of gender dysphoria (CA, MA, NY, OR, VT, WA), and two states (MD, WA) have recently initiated coverage for state employees. Of the 21 state Medicaid agencies reviewed, five explicitly do not provide coverage for gender reassignment services (AK, CT, MO, TN, WV). Note: Washington State Medicaid is not listed in the tables in this report as having coverage for gender dysphoria.

According to the Transgender Law Center, Illinois and Connecticut Medicaid also cover treatment for gender dysphoria [<http://transgenderlawcenter.org/equalitymap>]. Washington Medicaid is not listed as having specified coverage. Sixteen states listed as explicitly excluding Medicaid coverage for gender dysphoria.

Among states with coverage for hormone therapy and gender reassignment surgery, the requirements for these therapies (such as need for mental health evaluation, length of time living as the desired gender, etc.) generally agree with the current Prioritized List guideline requirements.

Surgical Therapy for Gender Dysphoria

Among states with Medicaid coverage for gender reassignment surgery, the procedures generally matched those included on the Prioritized List, with the exception of breast augmentation (covered by some but not Oregon) and penile prostheses (not covered by any except Oregon). The procedures listed as cosmetic in previous HERC discussions generally agree with the procedures listed as cosmetic by other public and private payers.

At least one private payer (Cigna 2015) requires that for sex reassignment surgery “the surgeon should have a demonstrated competency and extensive training in sexual reconstructive surgery.”

Coverage for mammoplasty

- **MED 2015:** breast augmentation coverage for gender dysphoria reported by 2 CMS regional coverage determinations, CA Medicaid, MD Medicaid, city of San Francisco, UnitedHealthcare.

- 1) California and Maryland Medicaid only cover when an appropriate trial of hormone therapy has not resulted in breast enlargement. Maryland specifies that 12 months of hormone therapy must have been tried and breast size continues to cause clinically significant distress in social, occupational, or other areas of functioning.

- Breast augmentation is not covered for treatment of gender dysphoria by NY Medicaid, VT Medicaid, Cigna, Aetna and most BCBS plans

- The British NHS (2014) covers breast augmentation with a guideline
 - a. “Breast augmentation should only be considered where there is a clear failure of breast growth in response to adequate hormone treatment. Review of breast development in anticipation of breast augmentation surgery should be made no earlier than after the completion of 18 months of adequate hormone treatment.”

Evidence

Bartolucci 2015 (only abstract available)

- 1) 67 male-to-female and 36 female-to-male gender-dysphoric adults consecutively attending a gender dysphoria treatment clinic
 - a. 30.1% had undergone breast augmentation or reduction.
- 2) RESULTS: Age, sex, having undergone some breast surgery, and personality factors were not associated with their perception [of sexual quality of life].

Weigert 2013

- 1) N=35 patients receiving breast augmentation
- 2) Results: BREAST-Q subscale median scores (satisfaction with breasts, +59 points; sexual well-being, +34 points; and psychosocial well-being, +48 points) improved significantly ($p < 0.05$) at 4 months postoperatively and later. No significant change was observed in physical well-being.
- 3) Conclusions: In this prospective, noncomparative, cohort study, the current results suggest that the gains in breast satisfaction, psychosocial well-being, and sexual well-being after male-to-female transsexual patients undergo breast augmentation are

Surgical Therapy for Gender Dysphoria

statistically significant and clinically meaningful to the patient at 4 months after surgery and in the long term.

Coverage for penile prostheses

- **MED 2015:** penile prostheses are only covered by Aetna and OR Medicaid. All other Medicaid programs and private insurers surveyed did not cover.

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Testimony from Dr. Megan Bird regarding requested CPT code additions

Here would be what we are using or what I know to be used. I know it is a long list. I have bolded the codes that are not in the current structure.

Chest reconstruction for trans men:

19301 - 19304 Mastectomy

19316 Mastopexy - request addition

19318 Reduction mammoplasty - request addition

19350 Nipple/areola reconstruction - request addition

** the reason there are more than just one is that larger breasts require a different technique, including moving the nipple to make a male appearing chest, smaller breasts have different needs.*

Chest reconstruction for trans women:

19316 Mastopexy

19324 Mammoplasty, without prosthetics

19325 Mammoplasty, with prosthetics

19350 Nipple/areola reconstruction

19357 - 19380 Breast reconstruction

**I know this is controversial. In some patients this is a safety issue for passing as female. I think there can be clear guidelines on mammoplasty being available if patients don't reach Tanner IV after a period of time on estrogen or if estrogen is contra-indicated. Those are the requirements in use in Wash D.C and California which cover.*

Genital surgery for trans men:

53415 -53430 Urethroplasty; one and two stage - add 53415 - (encompasses all possible codes)

55175-55180 Scrotoplasty; simple and complex

56620 - 56625 Vulvectomy - add 56620 - (encompasses all possible codes)

56800 - 56810 Perineoplasty

57106-57111 Vaginectomy - add 57106 - (all possible codes)

58150 - 58180 Abdominal hysterectomy - large and small uterus, with and without salpingo-oophorectomy - adds all possible codes

58620 - 58294 Vaginal hysterectomy - large and small uterus, with and without salpingo-oophorectomy

adds all possible codes

58541 - 58544 Supracervical hysterectomy - large and small uterus, with and without salpingo-oophorectomy

58550 - 58554 Laparoscopic assisted hysterectomy - large and small uterus, with and without salpingo-oophorectomy

58570-**58574** Laparoscopic hysterectomy - large and small uterus, with and without salpingo-oophorectomy

adds all possible codes

58661 Laparoscopic salpingo-oophorectomy

58720 Open Salpingo-oophorectomy

58940 Open oophorectomy

55899 Unlisted procedure: phalloplasty and metoidioplasty

55980 Intersex surgery: female to male

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**intersex surgery code is often the most appropriate code to explain what was done even if the patient is not intersex.*

Genital surgery for trans women:

17380 -17999 Electrolysis and laser hair removal; pre-requisite for vaginoplasty

53415 - 53430 Urethroplasty

adds all possible codes

54120 - 54125 Amputation of penis

adds all possible codes

54520 Orchiectomy

54690 Laparoscopic orchiectomy

55866 Laparoscopic prostatectomy

55150 Resection of scrotum

55970 Intersex surgery, male to female

56800 -56810 Plastic repair of perineum

57291 - **57296** Vaginoplasty with possible revision

adds all possible codes

57335 Vaginoplasty for intersex state

57426 Vaginal apex repair, laparoscopic

Surgical site electrolysis is required for some surgeries for both trans men and women. Specifically phalloplasty/metoidioplasty for trans men and gender affirming surgeries of all types for women

Surgical Therapy for Gender Dysphoria

Current included CPT codes for sex reassignment surgery

CPT code	Code description	Comments
19301-19304	Mastectomy	Need to remove 19301 as this is a lumpectomy Need to remove 19302 as this code includes axillary node dissection
53430	Urethroplasty, reconstruction of female urethra	
54125	Amputation of penis; complete	
54400-54417	Insertion/repair/removal of penile prosthesis	Consider non-coverage
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach	
54660	Insertion of testicular prosthesis (separate procedure)	Consider non-coverage
54690	Laparoscopy, surgical; orchiectomy	
55175-55180	Scrotoplasty	
55970	Intersex surgery; male to female	Add to line 474 GONADAL DYSFUNCTION, MENOPAUSAL MANAGEMENT
55980	Intersex surgery; female to male	Add to line 474
56625	Vulvectomy simple; complete	
56800	Plastic repair of introitus	
56805	Clitoroplasty for intersex state	
56810	Perineoplasty, repair of perineum, nonobstetrical	
57106-57107	Vaginectomy, partial removal of vaginal wall;	
57110-57111	Vaginectomy, complete removal of vaginal wall	Need to remove 57111 as used for cancer resection
57291-57292	Construction of artificial vagina	
57335	Vaginoplasty for intersex state	
58150, 58180, 58260-58262, 58275-58291, 58541-58544, 58550-58554, 58570-58573	Hysterectomy	
58661	Laparoscopy, surgical; with removal of adnexal structures	
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral	

Note: Rhinoplasty, face-lifting, lip enhancement, facial bone reduction, blepharoplasty, liposuction of the waist (body contouring), reduction thyroid chondroplasty, hair removal, voice modification surgery (laryngoplasty or shortening of the vocal cords), and skin resurfacing, which have been used in feminization, are considered cosmetic. Similarly, chin implants, nose implants, and lip reduction, which have been used to assist masculinization, are considered cosmetic. Breast augmentation is currently considered cosmetic.

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CPT code	Code description	Comments	Add?
14000-14001	Adjacent tissue transfer or rearrangement, trunk	Suggested for addition. On current breast cancer line but not on breast anomalies line. Unclear if used for reconstruction after mastectomy or for augmentation. Has been requested by surgeon as part of augmentation	
15200-15201	Full thickness graft, free, including direct closure of donor site, trunk	See 14000-14001 above	
17380	Electrolysis epilation		
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue		
19316	Mastopexy	Alternate to mastectomy. May also be used for breast augmentation	√
19318	Reduction mammoplasty	Alternate to mastectomy	√
19324	Mammoplasty, augmentation; without prosthetic implant		?
19325	Mammoplasty, augmentation; with prosthetic implant		?
19340	Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction		?
19342	Delayed insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction		?
19324-19325	Mammoplasty, augmentation		?
19350	Nipple/areola reconstruction	Used in mastectomy reconstruction and in augmentation	√
19357-19380	Breast reconstruction		√
53415-53430	Urethroplasty		√

Surgical Therapy for Gender Dysphoria

CPT code	Code description	Comments	Add?
54120	Amputation of penis, partial		√
55150	Resection of scrotum		√
55866	Laparoscopy, surgical prostatectomy		√
55899	Unlisted procedure, male genital system		
56620	Vulvoplasty, simple, partial	Used more commonly than the included 56625	√
57109	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy) with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy)		
57295-57296	Revision (including removal) of prosthetic vaginal graft		√
57426	Revision (including removal) of prosthetic vaginal graft		√
58152	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s); with colpo-urethrocystopexy (eg, Marshall-Marchetti-Krantz, Burch)		√
58660-58661	Laparoscopic oophorectomy		√
58940	Oophorectomy, partial or total, unilateral or bilateral		√

Surgical Therapy for Gender Dysphoria

HERC staff recommendations:

- 1) Remove the following from line 413 GENDER DYSPHORIA as not appropriate as part of gender reassignment surgery
 - a. 19301 (Lumpectomy)
 - b. 19302 (Mastectomy, partial; with axillary dissection) – cancer treatment
 - c. 57111 (Radical vaginectomy) – cancer treatment
- 2) Add the following to line 413 as these represent additional codes utilized in previously adopted procedures
 - a. 19316 (Mastopexy)
 - b. 19318 (Reduction mammoplasty)
 - c. 19359 (Nipple/areola reconstruction)
 - d. 53415-53430 (Urethroplasty)
 - e. 54120 (Amputation of penis, partial)
 - f. 55150 (Resection of scrotum)
 - g. 55866 (Laparoscopy, surgical prostatectomy)
 - h. 56620 (Vulvoplasty, simple, partial)
 - i. 57295-57296 (Revision (including removal) of prosthetic vaginal graft)
 - j. 57426 (Revision (including removal) of prosthetic vaginal graft)
 - k. 58152 (Total abdominal hysterectomy)
 - l. 58660-58661(Laparoscopic oophorectomy)
 - m. 58940 (Oophorectomy, partial or total, unilateral or bilateral)
- 3) Add the following to line 474 GONADAL DYSFUNCTION, MENOPAUSAL MANAGEMENT and keep on line 413
 - a. 55970 Intersex surgery; male to female
 - b. 55980 Intersex surgery; female to male
 - c. Pairs with ICD-9 578.6 Gonadal dysgenesis
- 4) Change current surgical procedure coverage to agree with other state Medicaid and private coverage
 - a. Consider adding mammoplasty (CPT 19316, 19324-19325, 19340, 19342, 19350, 19357-19380) to line 413 with guideline note changes as in #5 below
 - i. About half of public and private payers cover
 - ii. Limited literature finds mixed evidence of benefit
 - iii. Generally has been considered a cosmetic procedure by HERC other than for most-mastectomy reconstruction
 - iv. If coverage is added, modify guideline as in #5b below
 - b. Remove penile prostheses (CPT 54400-54417, 54660) from line 413
 - i. Vast majority of public and private payers do not cover
 - ii. Currently on a non-covered line for sexual dysfunction on the Prioritized List
 - c. Consider removing testicular prostheses (CPT 54660)
 - i. Not covered by many public and private plans
 - ii. Not included on list of current procedure codes
- 5) Modify GN127 as shown below
 - a. Previous suggested changes noted in **green** from separate guideline document
 - b. If mammoplasty is added in #3 above, add restrictions for breast augmentation [**purple** wording] following NICE/NHS guidelines as well as California and Maryland Medicaid guidelines

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- c. Add provisions regarding the training/experience of the surgeon to address CCO concerns
- d. Do not add any recommendations for type of procedure/method/etc. to the guideline as no evidence was found that any particular procedure or group of procedures has better outcomes

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 thorough ~~psychosocial assessment~~ mental health evaluation by a qualified licensed mental health professional (including but not limited to: LCSW, psychologist, family therapist, psychiatric nurse practitioner, psychiatrist) ~~with experience in knowledgeable about the assessment and treatment of~~ working with patients with gender dysphoria

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

1. have persistent, well documented gender dysphoria
2. have completed twelve months of continuous hormone therapy as appropriate to the member's gender goals unless hormones are not clinically indicated for the individual
3. have completed twelve months of living in a gender role that is congruent with their gender identity unless a medical and a mental health professional both determine that this requirement is not safe for the patient
4. have the capacity to make a fully informed decision and to give consent for treatment
5. have any significant medical or mental health concerns reasonably well controlled
6. have two referrals from qualified licensed mental health professional (including but not limited to: LCSW, psychologist, family therapist, psychiatric nurse practitioner, psychiatrist) ~~with experience in knowledgeable about the assessment and treatment of~~ working with patients with gender dysphoria who have independently assessed the

Surgical Therapy for Gender Dysphoria

patient. Such an assessment should include the clinical rationale supporting the patient's request for surgery, as well as the rationale for the procedure(s).

Additional surgical requirements include:

- 1) Mammoplasty should only be considered where there is a clear failure of breast growth in response to adequate hormone treatment. Review of breast development in anticipation of breast augmentation surgery should be made no earlier than after the completion of 12 months of adequate hormone treatment. Breast size must continue to cause clinically significant distress in social, occupational, or other areas of functioning.
- 2) The surgeon for all sex reassignment genital procedures should have a demonstrated competency and extensive training in sexual reconstructive surgery.