Clinical Policy Title: Prenatal Obstetrical Ultrasound

Clinical Policy Number: 12.01.02

Effective Date: January 1, 2016
Initial Review Date: September 16, 2015
Most Recent Review Date: September 21, 2016
Next Review Date: September 2017

Policy contains:
- Sonogram.
- Ultrasound, pregnancy.
- Fetal assessment.

RELATED POLICIES:

CP# 12.01.01 Home Uterine Monitoring
CP# 11.03.02 Fetal Surgery in Utero
CP# 02.01.01 Maternal Genetic Testing

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina's clinical policies are not guarantees of payment.

Coverage Policy

Select Health of South Carolina considers the use of prenatal or obstetrical ultrasound to be clinically proven and, therefore, medically necessary when the following criteria are met:

- Three obstetrical ultrasounds during a normal or low-risk pregnancy.
- Additional ultrasounds during the course of a high-risk pregnancy only when the treating provider will make therapeutic determinations based upon the results and seeks prior authorization for obstetrical ultrasounds beyond three studies by providing medical rationale (e.g., specialty society guidelines).

Select Health of South Carolina considers the use of prenatal or obstetrical ultrasound for determination of gender of the fetus, or three-dimensional (3-D) or four-dimensional (4-D) ultrasounds, to be investigational and therefore not medically necessary.

All other uses of prenatal obstetrical ultrasound are considered investigational, and therefore not medically necessary.
Alternative covered services:

Routine prenatal visits and laboratory studies.

Background

The use of low-power obstetrical ultrasound has proved useful to obstetricians to assess anatomic fetal development and growth, screen for evidence of aneuploidy or screen for other obstetrical abnormalities, such as amniotic fluid volume, and cervical or placental concerns. The number of ultrasounds in pregnancy has increased from 1.5 examinations per pregnancy in the mid-1990s to 2.7 ultrasounds per pregnancy in the mid-2000s. Although the prevalence of higher-risk pregnancies has increased in this time frame, this does not fully explain the higher use of ultrasound examinations.

The American College of Radiology (ACR)/American College of Obstetricians and Gynecologists (ACOG)/American Institute of Ultrasound in Medicine (AIUM)/Society of Radiologists in Ultrasound (SRU) practice guidelines (2014) recommend that “fetal ultrasound should be performed only when there is a valid medical reason, and the lowest possible ultrasonic exposure settings should be used to gain the necessary diagnostic information.” Ultrasound examinations are performed at different obstetrical trimesters for different conditions. The list of indications was developed on a consensus basis, and includes:

ACR/ACOG/AIUM/SRU Consensus — Based First Trimester Indications:

|a. Confirmation of intrauterine pregnancy. | h. Assessment of fetal anomalies, such as anencephaly, in high-risk patients. |
|b. Evaluation for possible ectopic pregnancy. | i. Evaluation of uterine masses or abnormalities. |
e. Enhanced estimation of gestational age. | l. Assessment of fetal cardiac activity. |
f. Evaluation of multiple gestations. | m. Assessment of fetal anomalies, such as anencephaly, in high-risk patients |
g. Assessment of fetal cardiac activity. |

ACR/ACOG/AIUM/SRU Consensus — Based Second and Third Trimester Indications:

|Screening for fetal anomalies | n. Suspected ectopic pregnancy. |
d. Evaluation of vaginal bleeding. | r. Suspected amniotic fluid abnormalities. |
e. Evaluation of abdominal or pelvic pain. | s. Suspected placental abruption. |
f. Evaluation of cervical insufficiency. | t. Adjunct to external cephalic version. |
g. Determination of fetal presentation. | u. Evaluation of premature rupture of membranes and/or premature labor. |
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<tr>
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<tbody>
<tr>
<td>i.</td>
<td>Adjunct to amniocentesis or other procedure.</td>
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<tr>
<td>j.</td>
<td>Evaluation of significant discrepancy between uterine size and clinical dates.</td>
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<tr>
<td>k.</td>
<td>Evaluation of pelvic mass.</td>
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<tr>
<td>l.</td>
<td>Evaluation of suspected hydatidiform mole.</td>
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<tr>
<td>m.</td>
<td>Adjunct to cervical cerclage.</td>
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<tr>
<td>w.</td>
<td>Follow-up evaluation of a fetal anomaly.</td>
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<tr>
<td>x.</td>
<td>Follow-up evaluation of placental location for suspected placenta previa.</td>
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<tr>
<td>y.</td>
<td>History of previous congenital anomaly.</td>
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<tr>
<td>z.</td>
<td>Evaluation of fetal condition in late registrants for prenatal care.</td>
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<tr>
<td>aa.</td>
<td>Assessment for findings that may increase the risk for aneuploidy.</td>
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Systematic studies of evidence found in the medical literature demonstrate the use of ultrasound in low-risk patients caused adjustment in the estimated date of delivery by more than 10 days in a significant percentage of pregnancies from clinical assessment alone. Based upon these studies, such an adjustment occurred in 11 percent to 24 percent of pregnancies. There is weak evidence to demonstrate at a population level the impact of obstetrical ultrasounds on perinatal morbidity and mortality or on mean birth weight. Differences in Apgar scores, neonatal intensive care unit (NICU) admissions or newborn mortality rates have been demonstrated on a population to be associated with ultrasound screening during pregnancy.

Nabhan and Faris (2010) performed a meta-analysis for the Cochrane Database and found insufficient evidence to support reducing maternal anxiety over the pregnancy outcomes by providing feedback from ultrasound examinations.

Ultrasound is an energy source that can induce thermal changes in tissues. Studies on the safety of ultrasound on the fetus have not found harmful effects despite concerns over the repeated application of this energy source during pregnancy.

**Searches**

Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

Searches were conducted on Sept. 1, 2016 using the terms “obstetrical ultrasound” and “prenatal sonogram.” Included were:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
• **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

The use of prenatal obstetrical ultrasound in low-risk pregnancies is primarily a screening tool. In population studies, it has not been found to have a significant impact except in better defining the expected date of delivery. But as with all screening tests, there may be incidental findings that suggest the patient or fetus is at risk. In higher-risk pregnancies, the tests require greater energy levels and may include more frequent ultrasonic examinations.

Makhlouf (2013) noted that first trimester ultrasound is now considered the standard of care, and that ultrasound use before 24 weeks improves detection of undiagnosed twins, reduces postdate inductions and allows detection of fetal anomalies before birth. However, wide variations exist in the sensitivity of ultrasound in detecting fetal anomalies which may be related to equipment, maternal body habitus or operator variances.

Bricker (2007) provided some counterpoint to analysis of the original Cochrane report of 2000 with inclusion of eight new trials included in a meta-analysis that involved 27,024 women. The authors concluded that “routine late pregnancy ultrasound in low-risk or unselected populations does not confer benefit on mother or baby. Placental grading in the third trimester may be valuable, but whether reported results are reproducible remains to be seen. Second- or third-trimester ultrasound may be associated with a small increase in caesarean section rates.”

Hayes (2010) suggests that the use of routine ultrasound examination in early pregnancy (< 24 weeks) for low-risk pregnant women with regard to safety and impact on health outcomes is at least comparable to standard treatment/testing. The body further opines the use of ultrasound examinations in early pregnancy is appropriately a “C” category recommendation for low-risk women. A “C” rating from Hayes is interpreted broadly as a diagnostic or therapeutic input of “potential but unproven benefit.”

**Policy updates:**

Åhman (2015) polled Swedish obstetricians to establish practice habits with regard to the use of prenatal obstetric ultrasound. Participants in the study cited prenatal obstetric ultrasound as an “essential” and “invaluable” examination in assuring the health of pregnant women; however, many struggled with decision-making when a conflict between maternal and fetal health emerged as a result of the study. The authors found that prenatal ultrasound is almost universally expected by pregnant women, and second-trimester evaluation of the fetus is regarded as a routine investigation.

**Summary of Clinical Evidence**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Åhman (2015)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Two sides of the same</td>
<td>• Cohort study of Swedish obstetricians’ experiences and views on the role of obstetric ultrasound</td>
</tr>
<tr>
<td>coin – an interview</td>
<td>• Obstetricians viewed the ultrasound as an essential tool in obstetric decision-</td>
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</table>
study of Swedish obstetricians’ experiences using ultrasound in pregnancy management.

- Obstetricians described the obstetric ultrasound as an invaluable tool for surveillance and management.
- However, the responders identified risks to pregnant women when acting on the findings as a significant factor (i.e., dealing with conflicting health interests between the pregnant woman and the fetus).
- Ultrasound examination is no longer considered an optional study as many pregnant women already anticipate before their first visit that an ultrasound examination is done routinely in the second trimester.
- The diversity of fetal conditions which can be evaluated through ultrasound increases the maternal expectations of fetal health from both ultrasound operators and other antenatal health care professionals.

ACR/ACOG/AIUM/SRU Guidelines (2014) Key points:
- A consensus document originating with the American College of Radiology in collaboration with American Institute of Ultrasound in Medicine (AIUM), American College of Obstetricians and Gynecologists (ACOG), and the Society of Radiologists in Ultrasound (SRU).
- Recommendations are based upon diagnoses for which early identification may lead to change in clinical management.
- No evidence is offered to support the consensus guideline.

Makhlouf (2013) Should second trimester ultrasound be routine for all pregnancies?

Key points:
- First trimester ultrasound is now considered standard of care.
- Ultrasound use before 24 weeks improves detection of undiagnosed twins, reduces postdate inductions and allows detection of fetal anomalies before birth.
- Wide variations exist in the sensitivity of ultrasound in detecting fetal anomalies which may be related to equipment, maternal body habitus or operator variances.
- The benefits of routine first-trimester ultrasound in the diagnosis of structural fetal anomalies or of routine ultrasonography after 24 weeks are not proven.


Key points:
- Added to studies from the original Cochrane report of 2000; eight trials included in meta-analysis that involved 27,024 women.
- “Routine late pregnancy ultrasound in low-risk or unselected populations does not confer benefit on mother or baby.”
- “Placental grading in the third trimester may be valuable, but whether reported results are reproducible remains to be seen.”
- Second- or third-trimester ultrasound “may be associated with a small increase in caesarean section rates.”

Hayes (2010) Routine Ultrasound Examination in Low-Risk Pregnancy

Key points:
- “Overall evidence from the majority of randomized controlled trials and systematic reviews indicates that routine ultrasound is not associated with improved pregnancy management or improved clinical outcomes in most women with low-risk pregnancies.”
- Hayes rates the use of ultrasound examinations in early pregnancy a “C” for low-risk women.
**Glossary**

**High-risk pregnancies** — According to the Eunice Kennedy Shriver National Institute of Child Health and Human Development, “A high-risk pregnancy is one of greater risk to the mother or her fetus than an uncomplicated pregnancy”. Risk factors include but are not limited to:

- Maternal obesity.
- Teenage pregnancy or maternal age over 35 years.
- Medical conditions such as diabetes.
- Pregnancy related conditions such as gestational diabetes or pre-eclampsia.
- Multiple births such as twins or triplets.

**Medically Necessary** — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

**Normal or low-risk pregnancies** — A pregnancy with few if any risk factors where there is the expectation of an uncomplicated pregnancy with a healthy infant delivered at term.

**Ultrasound** — By using oscillating sound pressure waves at a level beyond human hearing, images of internal structures can be visualized. This includes the fetus and placental structures.

**References**

**Professional society guidelines/others:**


American Institute of Ultrasound in Medicine (AIUM); American College of Radiology (ACR); American College of Obstetricians and Gynecologists (ACOG); Society for Pediatric Radiology (SPR); Society of Radiologists in Ultrasound (SRU). AIUM practice guideline for the performance of ultrasound of the female pelvis. *J Ultrasound Med.* 2014;33(6):1122-30.


**Peer-reviewed references:**


**Clinical Trials**

Searched clinicaltrials.gov on August 31, 2016 using terms “prenatal obstetrical ultrasound” | Open Studies. 1 study found, 1 relevant.


**CMS National Coverage Determination (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<td>+76802</td>
<td>Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester, transabdominal approach; each additional gestation.</td>
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<td>76805</td>
<td>Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after the first trimester, transabdominal approach, single</td>
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or first gestation.

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<td>Z34.8x</td>
<td>Supervision of other normal pregnancy</td>
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<td>Z34.9x</td>
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<td>O09.00-O09.93</td>
<td>Supervision of high risk pregnancies</td>
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