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, 2017
Next Review Date: September 2018

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

RELATED POLICIES:

CP# 12.01.01 Home uterine activity monitoring
CP# 12.01.04 Amniocentesis for diagnosis of fetal chromosomal abnormalities
CP# 12.01.05 Antepartum Fetal Surveillance
CP# 11.03.02 Fetal surgery in utero
CP# 02.01.01 Maternal genetic testing
CP# 13.01.02 Transvaginal and transabdominal ultrasound

ABOUT THIS POLICY: AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania’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 AmeriHealth Caritas Pennsylvania 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. AmeriHealth Caritas Pennsylvania’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania’s clinical policies are not guarantees of payment.

Coverage Policy

AmeriHealth Caritas Pennsylvania 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 ultrasound 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).
AmeriHealth Caritas Pennsylvania 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 increased from 1.5 examinations per pregnancy in the mid-1990s to 2.7 ultrasounds per pregnancy in the mid-2000s (Siddique 2009). 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:

<table>
<thead>
<tr>
<th>Screening for fetal anomalies</th>
<th>n.</th>
<th>Suspected ectopic pregnancy.</th>
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<tbody>
<tr>
<td>d. Evaluation of vaginal bleeding.</td>
<td>r.</td>
<td>Suspected amniotic fluid abnormalities.</td>
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<tr>
<td>e. Evaluation of abdominal or pelvic pain.</td>
<td>s.</td>
<td>Suspected placental abruption.</td>
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<tr>
<td>f. Evaluation of cervical insufficiency.</td>
<td>t.</td>
<td>Adjunct to external cephalic version.</td>
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<tr>
<td>g. Determination of fetal presentation.</td>
<td>u.</td>
<td>Evaluation of premature rupture of membranes and/or premature labor.</td>
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<tr>
<td>i. Adjunct to amniocentesis or other procedure.</td>
<td>w.</td>
<td>Follow-up evaluation of a fetal anomaly.</td>
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<tr>
<td>j. Evaluation of significant discrepancy between uterine size and clinical dates.</td>
<td>x.</td>
<td>Follow-up evaluation of placental location for suspected placenta previa.</td>
</tr>
<tr>
<td>k. Evaluation of pelvic mass.</td>
<td>y.</td>
<td>History of previous congenital anomaly.</td>
</tr>
<tr>
<td>m. Adjunct to cervical cerclage.</td>
<td>aa.</td>
<td>Assessment for findings that may increase the risk for aneuploidy.</td>
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</table>

According to a Cochrane review (Whitworth 2015) prenatal ultrasound is a useful adjunct to identify fetal abnormalities and multiple births. Such early diagnostic scanning does not appear to carry physical, emotional or neurodevelopmental risk. Moreover, early ultrasound may improve estimates of gestational age.

On the other hand, 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 (Abramowitz 2013).

**Searches**

AmeriHealth Caritas Pennsylvania 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 July 27, 2017 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**

Makhlouf (2013) in a narrative review 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.

Whitworth’s (2015) systematic review of ultrasound in early pregnancy examined 11 trials that enrolled 37,505 women. The authors found moderate evidence that use of routine use of ultrasound in women with low-risk pregnancies was associated with a lower rate of not identifying multiple births by 24 weeks gestation (risk ratio (RR) 0.07, 95% confidence interval (CI) 0.03 to 0.17) and an improvement in identification of major fetal abnormalities before 24 weeks gestation (RR 3.46, 95% CI 1.67 to 7.14). Use of routine scanning was associated with a reduction in induction of labor for presumed post-term pregnancy (RR 0.59, 95% CI 0.42 to 0.83), contributing to a reduction in overall labor induction rates due to any indication, and was not associated in adverse outcomes for infants or maternal or infant health services use. The authors encourage caution in interpreting these results due to variability in timing of the screening and in the number of scans received.

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.

Bricker et al.’s (2015) updated Cochrane review of ultrasound in late pregnancy included 13 trials (34,980 women) and repeated the main finding from their previous (2007) review, demonstrating that
routine late pregnancy ultrasound was not associated with a difference in perinatal or obstetric outcomes, and was neither a benefit to the mother nor to the infant. While the earlier (2007) analysis observed that there could be an association of routine late pregnancy ultrasound with an increase in cesarean section rates, the most recent (2015) systematic review found no association between ultrasound scans and cesarean delivery.

Policy updates:

A review of the literature produced seven additional references that have been added to this policy, four of which are included in the Summary of Clinical Evidence section.

Summary of Clinical Evidence

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfirevic (2017)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Fetal and umbilical</td>
<td>• Cochrane review included 19 (10,667 women) randomized controlled trials (RCTs) and quasi-randomized trials.</td>
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<tr>
<td>Doppler ultrasound in</td>
<td>• Also assessed effects of Doppler ultrasound on the umbilical artery in high risk pregnancies on both obstetric care and fetal outcome.</td>
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<tr>
<td>high-risk pregnancies</td>
<td>• The authors noted that because the overall quality of evidence was moderate to low due to incomplete information on study methods, imprecise risk estimates, and heterogeneity, these results “should be interpreted with caution.”</td>
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<td></td>
<td>• Moderate evidence was found that use of Doppler of umbilical artery in high risk pregnancy was associated with reduced perinatal mortality (Risk Ratio (RR) 0.71, CI 0.52 0.98); 10,225 infants 1.2% mortality compared to 1.7%, number needed to treat (NNT) = 203; 95% CI 103 – 4352).</td>
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<td>• Stillbirth rate was consistent with overall perinatal mortality rate; evidence for this was low.</td>
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<td>• Moderate evidence for reduced levels of induction (RR 0.89, CI 0.80 – 0.99; 10 studies including 5,633 women) and of cesarean section (RR 0.90, CI 0.84 – 0.97; 14 studies including 7,918 women).</td>
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<td>• Improvement found in long-term neurological outcomes in the cohort of infants in whom the indication for delivery was either late changes in ductus venosus or abnormal cardiococgraphy (CTG) monitoring.</td>
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<td></td>
<td>• No differences found in operative vaginal births, or in APGAR scores &lt; 7 at 5 minutes.</td>
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<td></td>
<td>• Data for serious neonatal morbidity was not analyzed as there was high heterogeneity between the 3 studies that included it.</td>
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<tr>
<td>Höglund Carlsson (2016)</td>
<td>Key points:</td>
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<tr>
<td>Prenatal ultrasound and</td>
<td>• RCT found no difference in the autism spectrum disorder rate in a comparison of prenatal ultrasound at 12 or 18 weeks among a Swedish cohort of approximately 30,000 children born from 1999-2003. Rate was 1.2% in each group (181 of 14,726 at 12 weeks and 176 of 14,596 at 18 weeks).</td>
</tr>
<tr>
<td>autism</td>
<td>• During the study period, ultrasound scans were less frequent and used a lower intensity than that used at the date of publication.</td>
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<td></td>
<td>• The authors opined that this analysis should be repeated with more recent data.</td>
</tr>
<tr>
<td>Author (Year)</td>
<td>Key points:</td>
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<td>-------------------------------------------------</td>
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</tbody>
</table>
| Ahman (2015)                                    | - Cohort study of Swedish obstetricians’ experiences and views on the role of obstetric ultrasound  
- Obstetricians viewed the ultrasound as an essential tool in obstetric decision-making  
- 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. |
| Bricker (2015)                                  | - Cochrane review included 13 trials (34,980 women).  
- No differences were found in perinatal or obstetric outcomes or morbidity between screened and non-screened groups.  
- The authors indicated that “routine late pregnancy ultrasound was not associated with improvements in overall perinatal mortality” and that it does not confer benefit on the mother nor on the infant.  
- The evidence was graded as moderate or high quality.  
- Little information on other long-term outcomes including neurodevelopment; lack of data on psychological effects on women. |
| Whitworth (2015)                                | - Cochrane review included 11 trials (37,505 women) inclusive of RCTs and quasi-randomized studies comparing outcomes in women who had prenatal ultrasound at < 24 weeks gestation  
- The authors found moderate evidence showing that use of ultrasound lowers nondetection of multiple births (Risk Ratio (RR) 0.07, 95% CI 0.03 – 0.17) and improves detection of major fetal abnormalities (RR 3.46, CI 1.67 – 7.14).  
- While there was some evidence for lowering of labor induction (RR 0.59, CI 0.42 – 0.83), the evidence was of low quality due to study design limitations with a relatively high presence of heterogeneity among the included studies ($I^2 = 0.68$).  
- No evidence for impact of ultrasound on perinatal death, decrease in adverse outcomes, healthcare utilization by mothers or infants, or long-term physical or cognitive development assessed at as late as 8-9 or 15-16 years. |
| ACR/ACOG/AIUM/SRU Guidelines (2014)             | - 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)                                 | - Narrative review notes that first trimester ultrasound is now considered standard of care for prenatal care. |
Should second trimester ultrasound be routine for all pregnancies?

- 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.

**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:**


**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.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>76801</td>
<td>Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester, transabdominal approach; single or first</td>
<td></td>
</tr>
</tbody>
</table>
Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester, transabdominal approach; each additional gestation.

Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after the first trimester, transabdominal approach, single or first gestation.

Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach, single or first gestation.

Ultrasound, pregnant uterus, real time with image documentation, first trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach, single or first gestation.

Ultrasound, pregnant uterus, real time with image documentation, after the first trimester, transabdominal approach; each additional gestation.

Ultrasound, pregnant uterus, real time with image documentation, first trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach, per fetus.

Ultrasound, pregnant uterus, real time with image documentation, limited (e.g., fetal heart beat, placental location, fetal position and/or qualitative amniotic fluid volume, 1 or more fetuses.

Ultrasound, pregnant uterus, real time with image documentation, follow-up (e.g., reevaluation of fetal size by measuring standard growth parameters and amniotic fluid volume, reevaluation of organ system(s) suspected or confirmed to be abnormal on a previous scan), transabdominal approach, per fetus.

ICD-10 Code | Description | Comment
--- | --- | ---
Z34.0x | Supervision of normal first pregnancy | Add 5th digit for trimester
Z34.8x | Supervision of other normal pregnancy | Add 5th digit for trimester
Z34.9x | Supervision of normal pregnancy, unspecified | Add 5th digit for trimester
O09.00-O09.93 | Supervision of high risk pregnancies | 

HCPCS Level II | Description | Comment
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N/A | | 