Obstetrical Ultrasound

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Instructions for Use

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Related Policies
None

Coverage Rationale

The use of prenatal or obstetrical ultrasound is proven and medically necessary during pregnancy when the following criteria are met:

- Up to three obstetrical ultrasounds are performed during routine pregnancy care which may include the following (see below for exception*):
  - One ultrasound during the first trimester for indications that include but are not limited to the following:
    - To confirm the presence of an intrauterine pregnancy
    - To estimate gestational age
  - One ultrasound during the second trimester (generally between 18-22 weeks) for indications that include but are not limited to the following:
    - To survey fetal anatomy
    - To determine an accurate estimation of gestational age
  - One ultrasound during the third trimester for indications that include but are not limited to the following:
    - To determine fetal presentation
    - To assess fetal growth
    - To evaluate fetal condition in late registrants for prenatal care
- Additional ultrasounds during the course of a High-Risk Pregnancy only when the treating provider will make therapeutic determinations based upon the results

Three-Dimensional (3-D) Prenatal Ultrasounds are unproven and not medically necessary due to insufficient evidence of efficacy.

The following are unproven and not medically necessary due to insufficient evidence of efficacy:

- More than one Detailed Fetal Anatomic Ultrasound Examination per pregnancy
- The use of prenatal or obstetrical ultrasound for the sole purpose of determination of sex of the fetus unless the determination of fetal sex is essential to the diagnosis of a condition

All other uses of prenatal obstetrical ultrasound are unproven and not medically necessary due to insufficient evidence of efficacy.

*Exception: The limit of three obstetrical ultrasounds per pregnancy does not apply to obstetrical ultrasound procedures rendered in the emergency room, during outpatient Observation Care, or inpatient hospital setting.

Definitions

Detailed Fetal Anatomic Ultrasound Examination: Ultrasound performed in the 2nd trimester when there is an increased risk of an anomaly based on the history, laboratory abnormalities, or the results of the limited or standard examination. Assessment focuses on the fetal anatomy to assess development. Measurement and assessment of major fetal organs and structures is performed (American College of Obstetricians and Gynecologists [ACOG], 2016).

High-Risk Pregnancy: A High-Risk Pregnancy is one in which some condition puts the mother, the developing fetus, or both at higher-than-normal risk for complications during or after the pregnancy and birth (Farlex Medical Dictionary, 2009).

Observation Care: A well-defined set of specific, clinically appropriate services, which include ongoing short-term treatment, assessment, and reassessment, that are furnished while a decision is being made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. Observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge.

Three-Dimensional (3-D) Prenatal Ultrasound: An advanced imaging technique which allows the volume of a target anatomic region to be calculated. The defined volume can then be displayed in three orthogonal two-dimensional planes representing the sagittal, transverse, and coronal planes of a referenced two-dimensional image within the volume (ACOG, 2016).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
Three-Dimensional (3-D) Prenatal Ultrasound	
76376	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation
76377	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation
Standard Ultrasound, Including Limited Ultrasound (76815 and 76816)	
76801	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester (< 14 weeks 0 days), transabdominal approach; single or first gestation
76802	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester (< 14 weeks 0 days), transabdominal approach; each additional gestation (List separately in addition to code for primary procedure)
76805	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (> or = 14 weeks 0 days), transabdominal approach; single or first gestation
76810	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (> or = 14 weeks 0 days), transabdominal approach; each additional gestation (List separately in addition to code for primary procedure)

CPT Code	Description
Standard Ultrasound, including Limited Ultrasound (76815 and 76816)	
76815	Ultrasound, pregnant uterus, real time with image documentation, limited (e.g., fetal heartbeat, placental location, fetal position and/or qualitative amniotic fluid volume), 1 or more fetuses
76816	Ultrasound, pregnant uterus, real time with image documentation, follow-up (e.g., re-evaluation of fetal size by measuring standard growth parameters and amniotic fluid volume, re-evaluation of organ system(s) suspected or confirmed to be abnormal on a previous scan), transabdominal approach, per fetus
Detailed Fetal Anatomic Examination	
76811	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach; single or first gestation
76812	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach; each additional gestation (List separately in addition to code for primary procedure)
Transvaginal Ultrasound	
76817	Ultrasound, pregnant uterus, real time with image documentation, transvaginal

Diagnosis Codes
Obstetrical Ultrasound: High-Risk Diagnosis Code List

Description of Services

Ultrasound is energy in the form of sound waves. In an ultrasound exam, a transducer sends sound waves through the body. The sound waves come into contact with tissues, body fluids, and bones. The waves then bounce back, like echoes, from the structures they contact. The transducer receives these echoes, which are turned into images which can then be viewed as pictures on a computer monitor. In pregnancy, obstetricians and other health care providers use ultrasounds at a very low power level to check a fetus's health and development, monitor the pregnancy, and potentially detect congenital anomalies (ACOG, 2017).

Ultrasonography in pregnancy should be performed only when there is a valid medical indication. ACOG Practice Bulletin 175 (2016) states, "The use of two-dimensional or three-dimensional ultrasonography without a medical indication and only to view the fetus, obtain a "keepsake" picture, or determine the fetal sex is inappropriate and contrary to responsible medical practice." This Practice Bulletin further recommends that in the absence of specific indications, the optimal time for an obstetric (OB) ultrasound examination is between 18 - 22 weeks of gestation. During this time, anatomically complex organs, such as the fetal heart and brain, can be imaged with sufficient clarity to allow detection of many major malformations. This timing also allows for management options such as fetal monitoring and other treatments, and for those who may desire it, termination. Ultrasound waves can product bioeffects in tissues. Diagnostic ultrasound has been used in clinical practice for over a half century without reports of harmful effects in humans. However, in his 2013 review, Abramowitz recommends that diagnostic ultrasound only be used when medically indicated and exposure should be kept as low and as short in duration as possible.

ACOG uses the terms "standard", "limited," and "specialized" (also referred to as "detailed" or "targeted") to describe various types of ultrasound examinations performed during the second or third trimesters.

Standard Examination

A standard ultrasound includes an evaluation of fetal presentation, amniotic fluid volume, cardiac activity, placental position, fetal biometry, and fetal number, plus an anatomic survey. A standard examination of fetal anatomy includes the following essential elements:

- Abdomen (stomach, kidneys, bladder, umbilical cord insertion site into the fetal abdomen, umbilical cord vessel number)
- Chest (heart)
- Extremities (presence or absence of legs and arms)

- Head, face and neck (cerebellum, choroid plexus, cisterna magna, lateral cerebral ventricles, midline falx, cavum septi pellucidi, upper lip)
- Sex (medically indicated in low-risk pregnancies only for the evaluation of multiple gestations)
- Spine (cervical, thoracic, lumbar, and sacral spin)

Limited Examination

A limited examination does not replace a standard examination and is performed when a specific question requires investigation (e.g., to confirm fetal heart activity in a patient experiencing vaginal bleeding or to establish fetal presentation during labor). A limited examination may be performed during the first trimester to evaluate interval growth, estimate amniotic fluid volume, evaluate the cervix, and/or assess the presence of cardiac activity.

Specialized Examination

A detailed or targeted anatomic examination is performed when an anomaly is suspected on the basis of history, laboratory abnormalities, or the results of either the limited or standard examination. Other specialized examinations might include fetal Doppler ultrasonography, biophysical profile, amniotic fluid assessment, fetal echocardiography, or additional biometric measurements. Specialized examinations are performed by an operator with experience and expertise in such ultrasonography who determines that components of the examination on a case-by-case basis.

Clinical Evidence

Ultrasound in Pregnancy

In 2021 a Cochrane systematic review was conducted to assess the effect of routine ultrasound (US) examination performed before 24 weeks gestation as part of a screening program compared to selective or no ultrasound, on early diagnosis of abnormal pregnancy location, multiple pregnancy, termination for fetal congenital abnormality, maternal outcomes and later fetal compromise. The selection criteria of this review included 13 randomized controlled trials (RCTs) of 85,265 women from multiple countries with four comparisons. First trimester routine versus selective ultrasound included four studies, 1791 women from Australia, Canada, the UK and the US. These studies showed probable reduction in short-term anxiety about pregnancy but no information on whether the reduction was sustained. The evidence is uncertain about the effect on perinatal loss or induction of labor. There was no report of first trimester ultrasound effects on birth before 34 weeks or termination of pregnancy for fetal abnormality. Second trimester routine versus selection ultrasound included seven studies, 36,053 women from Finland, Norway, South Africa, Sweden and the US. The results showed little difference to perinatal loss or intrauterine fetal death with low certainty of evidence. Second trimester scans may presumptively be more accurate for dating therefore reducing induction of labor. Routine second trimester ultrasound may improve detection of multiple pregnancies, increase detection of major fetal abnormality before 24 weeks, and increase the number of women terminating pregnancy for major anomaly. The effect of routine second trimester ultrasound on birth before 34 weeks or maternal anxiety was not reported. Long term follow-up of physical or intellectual harm to child development was not indicated for those exposed to ultrasound scans prior to birth. One cluster-RCT of 47,431 women from Asia, Africa and Central America assessed standard care plus two ultrasounds and a referral for complications versus standard care including a community co-intervention (assessed separately). This study showed little to no difference in women with complications giving birth in a risk appropriate setting with facilities for caesarean section. The intervention made little to no difference to low birth weight or maternal mortality. Lastly, one study of 1095 UK women compared the revealed ultrasound results (communicated to both patient and doctor) versus concealed ultrasound results (blinded to both patient and doctor at any time before 24 weeks). The evidence reported uncertainty for all results related to revealed versus concealed scans. The authors concluded early scans may reduce maternal anxiety and later scans may reduce labor induction for post maturity. In addition, they may improve detection of major fetal abnormalities and increase the number of terminations for this reason. They may reduce the number of undetected twin pregnancies. Neither type of scan appears to alter other important maternal or fetal outcomes due to a possible underestimation of the effect in modern practice related to early development of the technology.

Al-Hafez et al. (2020) conducted a systematic review and meta-analysis of 7 RCTs with 23,643 participants (12,343 in ultrasound vs 11,300 in fundal height group) to determine whether routine third trimester ultrasounds in low-risk pregnancies decrease the rate of perinatal death compared with regular antenatal care with serial fundal height measurements. The authors analyzed perinatal death as the primary outcome and rates of fetal growth restriction, suspected large for gestational age, polyhydramnios, oligohydramnios, fetal anomalies, antenatal interventions, stillbirth, neonatal death, cesarean delivery,

induction of labor and other neonatal outcomes as the secondary outcome. The total rate of perinatal death was similar among the groups (41 of 11,322 [0.4%] vs 34 of 10,285 [0.3%]; relative risk, 1.14; 95% CI, 0.68-1.89). The rate of fetal growth restriction, the rate of suspected large for gestational age and polyhydramnios was higher in the ultrasound group than the fundal height group. The remainder of the secondary outcome rates were similar among the groups. In conclusion the authors determined routine third-trimester ultrasounds do not decrease the rate of perinatal death compared with serial fundal height in low-risk pregnancies.

In a multi-center, stepped-wedge cluster randomized trial, Henrichs et al. (2019) investigated the effectiveness of routine US in the third trimester in reducing adverse perinatal outcomes in low-risk pregnancies compared with usual care, and the effect on maternal outcomes and obstetric interventions (the IRIS study). Sixty midwifery practices in the Netherlands were evaluated, with a total of 13,520 women in mid-pregnancy (mean 22.8 weeks' gestation) enrolled and 13,046 women (intervention n = 7067, usual care n = 5979) ultimately included. A composite of severe adverse perinatal outcomes was the primary outcome measure. Secondary outcomes included two composite measures of severe maternal morbidity and spontaneous labor/delivery. Incidence of severe adverse perinatal outcomes was 1.8% (n = 106) for usual care, and 1.7% (n = 118) for the intervention group. The difference between the groups was not significant after adjustment of confounders. The intervention group showed a higher incidence of labor induction (1.16, 1.04 to 1.30) and a lower incidence of labor augmentation (0.78, 0.71 to 0.85). Maternal outcomes and obstetric interventions performed were not significantly different between the two groups. The incidence of detection of small for gestational age (SGA) at birth was significantly more often detected in the intervention group than in the usual care strategy group (179/556 or 32% vs. 78/407 or 19%). The researchers concluded that routine ultrasonography in the third trimester was associated with moderately increased detection of SGA and induction of labor. There was not, however, a reduction in the incidence of severe adverse perinatal outcomes in low risk-pregnancy compared with usual care (which includes clinically indicated ultrasonography). The authors further state that goals of future research will be to identify the most appropriate fetal growth and birth weight charts and continue developing more effective and sensitive methods for detection of fetal growth restriction, such as US markers of fetal compromise, maternal awareness of fetal well-being and maternal and placental biomarkers.

In a 2017 Cochrane review, Alfirevic et al. examined the effects of Doppler US on obstetric care and fetal outcomes when used to assess fetal well-being in high-risk pregnancies. Selection criteria included randomized and quasi-randomized controlled trials of Doppler US for the investigation of umbilical and fetal vessel waveforms in high-risk pregnancies compared with no Doppler US. Nineteen clinical trials including 10,667 women were included in the analysis. After review of the evidence, the authors concluded that for high-risk pregnancies, the use of Doppler US on the umbilical artery reduces the risk of perinatal death and may also result in fewer obstetric interventions. None of the evidence related to the main outcomes was graded as high-quality, as some studies were missing information on trial methods and there was imprecision in risk estimates and heterogeneity. Additional high-quality studies with follow-up including neurological development are suggested.

In a 2015 Cochrane review, Alfirevic et al. assessed the effects of routine fetal and umbilical Doppler US in unselected low-risk pregnancy on obstetric practice and pregnancy outcome via a systematic review. Comparison was made between randomized and quasi-randomized controlled trials of Doppler US versus those with no Doppler US. Studies where uterine vessels were assessed along with fetal and umbilical vessels were included. The results included data from five trials with data analyzed for 14,185 women. None of the trials had adequate blinding of participants, but all trials had adequate allocation concealment and apart from lack of blinding, risk for bias was considered to be low. Overall, routine fetal and umbilical Doppler US did not result in higher antenatal, obstetric or neonatal interventions. There were no differences noted for the review's primary outcome of perinatal death and neonatal morbidity and no evidence of group differences for outcome of caesarean section, neonatal intensive care admissions or birth at less than 37 weeks. The authors concluded that existing evidence does not show conclusively that the use of routine Doppler US (either umbilical artery or combined umbilical and uterine artery) provides benefit for either mother or baby. Future studies should address small changes in perinatal outcomes and focus on preventable deaths.

Bricker et al., in a systematic Cochrane review (2015), examined the effects of routine US performed after 24 weeks' gestation (late pregnancy US) on obstetric practice and pregnancy outcome in women with either low-risk or unselected pregnancy. Thirteen trials enrolling 34,980 woman were included in this systematic review. The evidence for the primary outcomes of preterm birth less than 37 weeks, perinatal mortality, labor induction and caesarean section were deemed to be of moderate or high-quality using GRADE software. There was no association between US after 24 weeks and perinatal mortality (risk ratio (RR) 1.01, 95% confidence interval (CI) 0.67 to 1.54; participants = 30,675; studies = eight; I^2 = 29%), preterm birth less than 37 weeks (RR 0.96, 95% CI 0.85 to 1.08; participants = 17,151; studies = two; I^2 = 0%), labor induction (RR 0.93, 95% CI 0.81 to

1.07; participants = 22,663; studies = six; I^2 = 78%), or caesarean section (RR 1.03, 95% CI 0.92 to 1.15; participants = 27,461; studies = six; I^2 = 54%). The authors concluded that based on existing evidence, routine late pregnancy US does not benefit mother or baby in low-risk or unselected populations. Data were lacking for preterm birth less than 34 weeks, maternal psychological effects and neurodevelopment two years of age. Further research specific to these items was recommended.

Whitworth et al. (2015) performed a systematic review of US in early pregnancy (prior to 24 weeks' gestation) focused on 11 trials including 37,505 women. The review includes multiple large, well-designed trials but lack of blinding was an issue common to all studies which may have an impact on some outcomes. The objective of this review was to evaluate whether routine US for fetal assessment (i.e., its use as a screening technique), before 24 weeks gestation, influences the diagnosis of multiple pregnancies, fetal malformations, rate of clinical interventions, and/or the occurrence of adverse fetal outcome when compared with the selective use of early pregnancy US (for specific indications). The authors found evidence that use of US in early pregnancy was associated with reduction of failure to identify multiple pregnancy before 24 weeks (RR 3.46, 95% CI 1.67 to 7.14; participants = 387; studies = 2, *moderate quality of evidence*), improved detection of major fetal abnormality before 24 weeks' gestation (RR 3.46, 95% CI 1.67 to 7.14; participants = 387; studies = 2, *moderate quality of evidence)* and improved gestational dating which can result in fewer inductions for post maturity (RR 0.59, 95% CI 0.42 to 0.83; participants = 25,516; studies = 8, low quality of evidence due to design limitation with presence of heterogeneity). Additionally, long-term follow-up of children who were exposed to US scanning in utero does not indicate that scans have a negative or harmful effect on children's development, either physical or cognitive.

Clinical Practice Guidelines

American Institute of Ultrasound in Medicine (AIUM)/American College of Radiology (ACR)/American College of Obstetricians and Gynecologists (ACOG)/Society for Maternal and Fetal Medicine (SMFM)/Society of Radiologists in Ultrasound (SRU)

The 2018 AIUM/ACR/ACOG/SMFM/SRU Practice Guidelines recommend that "obstetric ultrasound examinations 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."

Indications for first-trimester ultrasound examinations include (but are not limited to):

- Confirmation of intrauterine pregnancy
- Evaluation for possible ectopic pregnancy
- Evaluation of vaginal bleeding in pregnancy
- Assessment of pelvic pain
- Enhanced estimation of gestational age
- Diagnosis or evaluation of multiple gestations, including determination of chorionicity
- Assessment of fetal cardiac activity
- Evaluation of uterine masses or abnormalities
- Evaluation of suspected gestational trophoblastic disease
- Measurement of nuchal translucency as part of screening for fetal aneuploidy
- Assessment of fetal anomalies, such as anencephaly
- Imaging as an adjunct to chorionic villus sampling, embryo transfer and localization/removal of intrauterine device

Second and third trimester ultrasound examinations are commonly performed to assess fetal biometry and anatomy. Other Indications include (but are not limited to):

- Evaluation of fetal anatomy
- Estimation of gestational age
- Screening for fetal anomalies
- Evaluation of fetal growth
- Evaluation of vaginal bleeding
- Evaluation of abdominal or pelvic pain
- Evaluation of cervical length
- Determination of fetal presentation
- Evaluation of suspected multiple gestation
- Adjunct to amniocentesis or other procedure
- Evaluation of significant discrepancy between uterine size and clinical dates

- Evaluation of pelvic mass
- Suspected fetal death
- Suspected uterine abnormality
- Evaluation of fetal well-being
- Suspected amniotic fluid abnormalities
- Suspected placental abruption
- Evaluation of suspected gestational trophoblastic disease
- Adjunct to external cephalic version
- Evaluation of premature rupture of membranes and/or premature labor
- Follow-up evaluation of a fetal anomaly
- Follow-up evaluation of placental location for suspected placenta previa

Detailed Fetal Anatomic Ultrasound

In a Consensus Report on the Detailed Fetal Anatomic Ultrasound Exam (Wax et al., 2014), which was developed with the assistance of and reviewed by the American College of Obstetricians and Gynecologists (ACOG) and was reviewed and endorsed by the American College of Osteopathic Obstetricians and Gynecologists (ACOOG), American College of Radiology (ACR), American Institute of Ultrasound in Medicine (AIUM), Society of Diagnostic Medical Sonography (SDMS), Society for Maternal-Fetal Medicine (SMFM), and Society of Radiologists in Ultrasound (SRU), the authors state that fetal ultrasound with detailed anatomic examination (CPT 76811) is not intended to be a standard or routine ultrasound for all pregnancies. This scan is indication-drive and is used for a known or suspected fetal anatomic abnormality, genetic abnormality, known fetal growth disorder or increased risk for fetal abnormality. As such, the performance of this scan is expected to be rare outside of referral practices with special expertise in the identification of, and counseling about, fetal abnormalities. No more than one fetal ultrasound with detailed anatomic examination is medically necessary per pregnancy, per practice. Once this detailed fetal anatomical examination has been done, a second should not be performed unless there are extenuating circumstances. If one or more required structures are not adequately accessible during the detailed fetal anatomic ultrasound, the patient may require a focused assessment (CPT 76816.)

Indications for a detailed fetal anatomic examination include, but are not limited to, the following:

- Previous fetus or child with a congenital, genetic, or chromosomal abnormality
- Known or suspected fetal anomaly or known growth disorder in the current pregnancy
- Fetus at increased risk for a congenital anomaly, such as the following:
  - Maternal pregestational diabetes or gestational
  - Diabetes diagnosed before 24 weeks' gestation
  - Pregnancy conceived via assisted reproductive technology
  - High maternal body mass index (≥ 35 kg/m2)
  - Multiple gestation
  - Abnormal maternal serum analytes, includingα-fetoprotein level and unconjugated estriol
  - Teratogen exposure
  - First-trimester nuchal translucency measurement of 3.0 mm or greater
- Fetus at increased risk for a genetic or chromosomal abnormality, such as the following:
  - Parental carrier of a chromosomal or genetic abnormality
  - Maternal age of 35 or older years at delivery
  - Positive screening test results for aneuploidy, including noninvasive prenatal testing
  - Soft aneuploidy marker noted on an ultrasound examination
  - First-trimester nuchal translucency of 3.0 mm or greater
- Other conditions affecting the fetus, including the following:
  - Congenital infections
  - Maternal drug dependence
  - Isoimmunization
  - Oligohydramnios
  - Polyhydramnios

The same consensus report (Wax et al., 2014) lists the following fetal and maternal anatomical components for the detailed fetal anatomic ultrasound (CPT code 76811). Not all components are required. Components considered integral to the code are marked with an asterisk (*):

- Adrenal glands
- Amniotic Fluid Index*
- Anatomy and position of feet*
- Anatomy and position of hands*
- Appearance of ribs
- Ascites*
- Bowel*
- Cardiac location and axis*
- Cavum septum pellucidum
- Cerebellum*, integrity of lobes*, vermis*
- Cisterna magna measurement*
- Ear position, size
- Evaluation of amniotic fluid
- Evaluation of genitalia
- Evaluation of intracranial, facial and spinal anatomy
- Evaluation of limbs
- Evaluation of the abdomen
- Evaluation of the cervix (Not required)
- Evaluation of the chest
- Evaluation of the heart
- Evaluation of the maternal adnexa when feasible*
- Evaluation of the neck (e.g., for masses)
- Evaluation of the placenta and cord
- Examination of brain parenchyma, (e.g., for calcifications)
- Face
- Facial profile*
- Gallbladder
- Integrity and shape of cranial vault
- Integrity of both sides of the diaphragm*
- Lateral ventricles*, third and fourth ventricles
- Liver
- Masses
- Nuchal thickness measurement (16-20 weeks)*
- Number, size, and architecture*
- Outflow tracts*
- Palate*
- Placental cord insertion site*
- Placental masses*
- Pleural effusion*
- Presence of masses*
- Sex (whether or not parents wish to know sex of child)
- Spleen
- Umbilical-cord (number of arteries)
- Upper lip integrity*

Clinical Practice Guidelines

American Institute of Ultrasound in Medicine (AIUM)/American College of Radiology (ACR)/American College of Obstetricians and Gynecologists (ACOG)/American College of Osteopathic Obstetricians and Gynecologists (ACOOG)/Perinatal Quality Foundation (PQF)/Society of Diagnostic Medical Sonography (SDMS)/Society for Maternal-Fetal Medicine (SMFM)/Society of Radiologists in Ultrasound (SRU)

AIUM published a Practice Parameter for the Performance of Detailed Second- and Third-Trimester Diagnostic Obstetric Ultrasound Examinations in 2019, in collaboration with the ACR, ACOG, ACOOG, PQF, SDMS, SMFM and SRU. The document reinforces the indication-driven requirement for known or suspected fetal anatomic abnormality, known fetal growth disorder, genetic abnormality or increased risk for fetal anatomic or genetic abnormality, or placenta accreta spectrum. Indications align with those listed above from the 2014 Wax et. al Consensus Report. Only one such medically indicated detailed fetal anatomic ultrasound should be performed per pregnancy, per practice and should be performed by a practitioner with special expertise and training.

Three-Dimensional (3D) Ultrasound

There is no evidence that 3D ultrasound improves clinical outcomes compared to standard two-dimensional (2D) ultrasound. Additional research is needed to determine the role of 3D ultrasound in prenatal diagnosis.

Kurjak et al. (2007) reviewed the published literature on the use of perinatal three-dimensional ultrasound (3DUS) and four-dimensional ultrasound (4DUS). A total of 438 articles were deemed relevant to this review. After review of the applicable literature, the authors concluded that 3DUS and 4DUS provided additional information regarding potential diagnosis of evaluation of neural tube defects, facial anomalies and skeletal malformations, however additional research is needed to determine the clinical utility of 3DUS and 4DUS for diagnoses of congenital heart disease, central nervous system anomalies and detection of fetal neurodevelopmental impairment.

Benacerraf et al. determined that standard fetal anatomic survey with 3D volume can be performed more quickly than standard 2DUS in their 2006 comparative study. In this study, fifty women undergoing fetal anatomic survey at 17-21 weeks gestation

made up the cohort. A designated sonographer first performed 2DUS, then the same sonographer obtained five 3DUS volumes to encompass the entirety of fetal anatomy. Three physicians interpreted the scans and independently evaluated the scans for completeness of examination and time required to read the scans (comparing 2DUS method with 3D volume reconstruction technique). Specifically, comparison was done on biparietal diameter (BPD), femur length and performance times between the two measurements. Differences were deemed significant when $P < .05$. Mean time to perform 2D ultrasound was 19.6 minutes per examination and mean to time perform complete 3D volume acquisition was 1.8 minutes. Mean time to interpret the 3D images and measure BPD and femur were 5.34, 4.79 and 5.53 minutes for the three physicians. When compared to 2D ultrasound, fetal landmarks were identified > 94% of time when doing 3DUS. Overall, 74% of 3D BPD measurements and 64% of 3D femur measurements were within 1 mm of the 2D measurements. This study did not evaluate clinical utility.

In a 2005 systematic review of the published literature, Goncalves et al. evaluated whether three-dimensional ultrasound (3DUS) and four-dimensional ultrasound (4DUS) in obstetrics added diagnostic information to what is provided by two-dimensional ultrasound (2DUS). Five hundred twenty-five articles were identified as related to this evaluation. Articles included described technical developments, provided reviews and editorials and documented clinical studies, and studies on fetal behavior or maternal-fetal bonding. Based on the evidence in the articles, the authors concluded that 3DUS provides additional diagnostic information for the diagnosis of facial anomalies, including facial clefts. Some benefit was identified for use of 3DUS in the evaluation of fetuses with neural tube defects and malformations in the skeletal system as well. However, large studies comparing diagnostic performance of 3DUS with 2DUS have not resulted in definitive recommendations. The researchers believe that additional research is needed, focusing on the role of both 3DUS and 4DUS in improvement of diagnosing congenital heart disease and central nervous system anomalies, including whether the information contained in the volume dataset by itself is sufficient to assess fetal biometric measurements and diagnose congenital anomalies.

Clinical Practice Guidelines

The American College of Obstetricians and Gynecologists (ACOG)

ACOG Practice Bulletin 175 (2016) comments on the technical advantages of 3DUS, including its ability to acquire and manipulate a large number of planes and to display planes that were inaccessible with 2DUS. However, the bulletin also states that despite the technical advantages, there is a lack of proof of any clinical advantage of 3DUS in prenatal diagnosis. In addition, ACOG points out that the use of 2D or 3D ultrasound without a medical indication and only to view the fetus, determine fetal sex, or obtain a “keepsake” photo is inappropriate. Although there is no evidence that diagnostic ultrasound causes human fetal harm, exposing a fetus to ultrasound waves with no anticipation of medical benefit is not justified.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Manufacturers of ultrasound imaging products are responsible for compliance with all applicable requirements of Title 21 Code of Federal Regulations (Subchapter J, Radiological Health) Parts 1000 through 1005. The FDA recommends that health care providers consider ways to minimize exposure while maintaining diagnostic quality when using ultrasound. As with all other imaging modalities, the principles of As Low As Reasonably Achievable (ALARA) should be practiced by health care providers. The FDA strongly discourages using 3D and 4D ultrasound devices for creating fetal keepsake images and videos.
Refer to the following for more information: Ultrasound Imaging | FDA. Accessed on October14, 2022.

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Policy History/Revision Information

Date	Summary of Changes
01/01/2023	**Applicable Codes** • Added ICD-10 diagnosis codes O20.0, O09.01, and O09.811 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version 2022T0628B

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.