Obstetrical Ultrasound

Policy Number: UMR2025T0628G
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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 (refer to the note below*):
  - 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
    - To diagnose or evaluate multiple gestations
    - To confirm fetal viability
  - 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
    - Evaluation of placental location
  - 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

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
- Three-Dimensional (3-D) Prenatal Ultrasounds

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

***Note**: This policy does not apply to obstetrical ultrasound procedures rendered in the emergency room, during outpatient Observation Care, or in an 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), 2017, updated 2021]

High-Risk Pregnancy: A pregnancy where the mother, fetus, or neonate is at increased risk of morbidity or mortality before, during, or after delivery. (Merck Manual, 2022)

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.

Coding Clarification: If a complete study is intended but one of the required elements cannot be visualized (e.g., obscured by bowel gas or absent), the reason for non-visualization must be documented in the report in order to assign a complete study CPT code. Without this documentation, the limited study CPT code 76815 should be assigned. CPT code 76815 should be billed for the selected limited examination of any individual element of any OB study found to be non-visualized previously.

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)
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

CPT Code	Description
Standard Ultrasound, Including Limited Ultrasound (76815 and 76816)	
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

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: Ultrasound in Pregnancy (2016, updated 2020) 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" (also called basic), "limited," and "specialized" (also referred to as "detailed") to describe various types of ultrasound examinations performed during the second or third trimesters (ACOG, 2021).

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

Viñals et al. (2023) conducted an observational study to assess the feasibility of identifying fetal brain structures and anatomic landmarks included in the anterior complex (AC) and posterior complex (PC), as well as the proximal hemisphere (PH). This was a prospective observational multicenter study of healthy pregnant women evaluated by ultrasound (US) screening at 24 to 36 + 6 weeks' gestation. Six physicians performed transabdominal ultrasound, to obtain the planes required to visualize the AC, PC, and PH. Blind analysis by an expert and non-expert operator in fetal neuro-sonography was used to assess the structures included in each plane view. In the population studied (n=366), structure detection rates for AC were over 95%, with an agreement of 96% when comparing expert and non-expert examiners. Visualization of the corpus callosum crossing the midline was detected in over 97 and 96% of cases for the AC and PC, respectively, with an agreement of over 96%. The PH plane, particularly through the posterior access via the mastoid fontanelle, enabled visualization of the proximal anatomical structures in almost 95% of cases. Detection of the corpus callosum through the AC and PC, both proximal/distal germinal matrix (AC) and proximal Sylvian fissure through the anterior access (PH) in the 24-25 + 6, 26-31 + 6 and 32-36 + 6 weeks' gestation groups were successful in over 96% of cases with high level of agreement. The authors concluded that inclusion of AC, PC, and PH later in pregnancy proves feasible with a high level of agreement between both expert and non-expert operators. The primary limitation of this observational study is that further prospective research is needed to confirm its usefulness for improving fetal brain anomalies detection. The authors stated, however, that the results of this study could help to standardize fetal CNS anatomical evaluation in the second half of pregnancy, to improve suspicion and detection of subtle and unilateral cerebral anomalies which may develop late in pregnancy.

Karim et al. (2022) performed a systematic review and meta-analysis to determine the diagnostic accuracy of ultrasound at 11-14 weeks' gestation, performed by two independent reviewers, in the detection of fetal cardiac abnormalities and to evaluate factors that impact the detection rate. Prospective and retrospective studies evaluating pregnancies at any prior level of risk and in any healthcare setting was eligible for inclusion. The reference standard used was the detection of a cardiac abnormality on postnatal or postmortem examination. Data were extracted from the included studies to populate 2 × 2 tables. Meta-analysis was performed using a random-effects model to determine the performance of first-trimester ultrasound (US) in the detection of major cardiac abnormalities overall and individual types of cardiac abnormality. Data were analyzed separately for high-risk and non-high-risk populations. Preplanned secondary analyses were conducted to assess factors that may impact screening performance, including the imaging protocol used for cardiac assessment (including the use of color-flow Doppler), ultrasound modality, year of publication and the index of sonographer suspicion at the time of the scan. Risk of bias and quality assessment were undertaken for all included studies using the Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) tool. The electronic search yielded 4108 citations. Following review of titles and abstracts, 223 publications underwent full-text review, of which 63 studies, reporting on 328,262 fetuses, were selected for inclusion in the meta-analysis. In the non-high-risk population (45 studies, 306,872 fetuses), 1445 major cardiac anomalies were identified (prevalence, 0.41% (95% CI, 0.39-0.43%)). Of these, 767 were detected on first-trimester ultrasound examination of the heart and 678 were not detected. First-trimester ultrasound had a pooled sensitivity of 55.80% (95% CI, 45.87-65.50%), specificity of 99.98% (95% CI, 99.97-99.99%) and positive predictive value of 94.85% (95% CI, 91.63-97.32%) in the non-high-risk population. The cases diagnosed in the first trimester represented 63.67% (95% CI, 54.35-72.49%) of all antenatally diagnosed major cardiac abnormalities in the non-high-risk population. In the high-risk population (18 studies, 21,390 fetuses), 480 major cardiac anomalies were identified (prevalence, 1.36% (95% CI, 1.20-1.52%)). Of these, 338 were detected on first-trimester ultrasound examination and 142 were not detected. First-trimester ultrasound had a pooled sensitivity of 67.74% (95% CI, 55.25-79.06%), specificity of 99.75% (95% CI, 99.47-99.92%) and positive predictive value of 94.22% (95% CI, 90.22-97.22%) in the high-risk population. The cases diagnosed in the first trimester represented 79.86% (95% CI, 69.89-88.25%) of all antenatally diagnosed major cardiac abnormalities in the high-risk population. The imaging protocol used for examination was found to have an important impact on screening performance in both populations ($P < 0.0001$), with a significantly higher detection rate observed in studies using at least one outflow-tract view or color-flow Doppler imaging (both $P < 0.0001$). Different types of cardiac

anomaly were not equally amenable to detection on first-trimester ultrasound. The authors concluded that first-trimester ultrasound examination of the fetal heart allows identification of over half of fetuses affected by major cardiac pathology. Future first-trimester screening programs should follow structured anatomical assessment protocols and consider the introduction of outflow-tract views and color-flow Doppler imaging, as this would improve detection rates of fetal cardiac pathology.

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.

Zheng et al. (2021) conducted a retrospective cross-sectional study aimed at determining the prenatal diagnosis of congenital facio-cervical masses, its management, and outcome in a large tertiary referral center. The authors collected information on prenatal clinical data, pregnancy outcomes, survival information, and final diagnosis. Out of 130 cases of facio-cervical masses, a total of 119 cases of lymphatic malformations (LMs), 2 cases of teratoma, 2 cases of thyroglossal duct cyst, 4 cases of hemangioma, 1 case of congenital epulis, and 2 cases of dermoid cyst were reviewed. The accuracy of prenatal ultrasound (US) was 93.85% (122/130). Observations of diameters using prenatal ultrasound revealed that the bigger the initial diameter is, the bigger the relative change during pregnancy. Magnetic resonance imaging (MRI) revealed that 2 cases of masses were associated with airway compression. The authors concluded that US has a high overall diagnostic accuracy of fetal face and neck deformities. Prenatal US can enhance the management of ambulatory monitoring and classification. Furthermore, MRI provided a detailed assessment of fetal congenital malformations, as well as visualization of the trachea, presenting a multi-dimensional anatomical relationship. A potential limitation is that this study was a single-center cross-sectional study of a retrospective nature, which may be biased. Perinatal management of congenital facio-cervical masses require special delivery strategies. Fetal and perinatal imaging is essential in the initial work-up, prenatal management, counseling, perinatal management, and follow-up of these fetuses.

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 women 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 = 8; I^2 = 29%), preterm birth less than 37 weeks (RR 0.96, 95% CI 0.85 to 1.08; participants = 17,151; studies = 2; I^2 = 0%), labor induction (RR 0.93, 95% CI 0.81 to 1.07; participants = 22,663; studies = 6; I^2 = 78%), or caesarean section (RR 1.03, 95% CI 0.92 to 1.15; participants = 27,461; studies = 6; 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)

In a 2020 official statement, the AIUM advocates the responsible use of diagnostic ultrasound and strongly discourages nonmedical use and makes the following statements:

- The use of ultrasound without a medical indication to view the fetus, obtain images of the fetus, or identify the fetal external genitalia is inappropriate and contrary to responsible medical practice.
- The prudent use and safety of diagnostic ultrasound in pregnancy should involve a conservative approach that obtains necessary diagnostic information at minimal exposure.
- The AIUM recommends sharing images with patients as appropriate when medically indicated obstetric ultrasound examinations are performed.

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, updated in 2024 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 (1 week-13 weeks + 6 days gestation) ultrasound examinations include but are not limited to:

- Confirmation of the presence of an intrauterine pregnancy
- Evaluation of a suspected ectopic or abnormally implanted pregnancy
- Evaluating the cause of vaginal bleeding
- Evaluation of pelvic pain
- Estimation of gestational age
- Diagnosis or evaluation of multiple gestations, including determination of chorionicity and amnionicity
- Confirmation of cardiac activity
- Evaluation of pelvic masses and/or uterine abnormalities
- Evaluation of suspected gestational trophoblastic disease
- Measurement of nuchal translucency and nasal bone when part of screening for fetal aneuploidy
- Assessment of fetal anomalies detectable in first trimester, 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
- Adjunct to amniocentesis or other procedure
- 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 appearance and location. Includes suspected placenta previa, and evaluation of placenta accreta spectrum
- In certain clinical circumstances, a more detailed examination of fetal anatomy may be indicated

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 code 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 asterisks (**):

- 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 in collaboration with ACR, ACOG, ACOOG, PQF, SDMS, SMFM and SRU published a practice parameter in 2021 for the performance of detailed diagnostic obstetric ultrasound examination in the late first trimester. The document reinforces this is a specialized diagnostic examination (also known as an early comprehensive fetal anatomy ultrasound) is an indication-driven evaluation for women at increased risk of fetal and/or placental anomalies that are potentially detectable between 12 weeks 0 days and 13 weeks 6 days gestation. This ultrasound should not replace a detailed second-trimester anatomic survey.

AIUM published a Practice Parameter for the Performance of Detailed Second- and Third-Trimester Diagnostic Obstetric Ultrasound Examinations in 2019 (updated 2020), 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.

González-Aranceta et al. (2024) performed a longitudinal study to assess the accuracy and reliability of fetal facial measurements in 3D prenatal ultrasound. Additionally, the temporal evolution of measurements is studied, comparing prenatal and postnatal measurements. The study population comprised 49 Caucasian subjects from low-risk pregnancies, meaning without any pathology, or known family cases of craniofacial or syndromic pathologies, which were all carried to term. The data was nearly gender-balanced (53 % female). Three different experts located up to 23 facial landmarks in 49 prenatal 3D ultrasound scans from normal Caucasian fetuses at weeks 20, 26, and 35 of gestation. Intra- and inter-observer variability was obtained. Postnatal facial measurements were also obtained at 15 days and 1 month postpartum. Most facial landmarks exhibited low errors, with overall intra- and inter-observer errors of 1.01 mm and 1.60 mm, respectively. Landmarks on the nose were found to be the most reliable, while the most challenging ones were those located on the ears and eyes. Overall, scans obtained at 26 weeks of gestation presented the best trade-off between observer variability and landmark visibility. The temporal evolution of the measurements revealed that the lower face area had the highest rate of growth throughout the latest stages of pregnancy. The authors concluded that craniofacial landmarks can be evaluated using 3D fetal ultrasound, especially those located on the nose, mouth, and chin. Despite its limitations, this study provides valuable insights into prenatal and postnatal biometric changes over time, which could aid in developing predictive models for postnatal measurements based on prenatal data. When comparing the prenatal to the postnatal measurements, there are some small inconsistencies in some cases, since a few postnatal measurements are smaller than the measurements at gestational age 35 weeks. This could be explained by measurement errors, as these measurements were obtained with a measuring tape and had different accuracy than those obtained by landmarking. Furthermore, postnatal measurements were not always performed at precisely 15 and 30 days after birth, which explains the higher variability these measurements reflect in the plots. An additional limitation is that the ultrasound performed at 26 weeks is outside of low-risk pregnancy control programs. Future work includes expanding this study to an ethnically diverse selection of patients, increasing the scope of the results, and guaranteeing larger-scale applicability.

Merz et al. (2023) performed a prospective population-based, cross-sectional study to construct new growth charts and tables for fetal growth parameters including biparietal diameter (BPD), occipitofrontal diameter (OFD), head circumference (HC), abdominal transverse diameter (ATD), abdominal sagittal diameter (ASD), abdominal circumference (AC), femur length (Fe), tibia length (Ti), fibula length (Fi), humerus length (Hu), radius length (Ra), and ulna length (Ul). This prospective study was conducted at a level III ultrasound center as a population-based cross-sectional study on 10,225 normal singleton pregnancies with a gestational age between 10 and 41 completed weeks. Gestational age was confirmed in all cases by an ultrasound examination with crown-rump measurement before 10 weeks of gestation. All examinations were performed with 3D probes. BPD, OFD, ATD, and ASD were measured as outer-to-outer measurements (skin-to-skin) after identifying the exact biometric planes by 3D multiplanar display. HC was computed using the formula HC = 2.34 × (BPD2+OFD2 √). For AC the approximate elliptical formula AC = (ATD+ASD)/2 × 3.142 was used. Measurements of the limb bones included the entire ossified shaft. Based on a nonlinear regression model for the age specific mean values, distribution-free reference ranges were calculated for the parameters BPD, OFD, HC, ATD, ASD, AC, Fe, Ti, Fi, Hu, Ra and Ul. The new reference ranges were compared with existing reference ranges published in 1996 as well as with different reference charts published by other authors. The authors concluded that 3D ultrasound allows a controlled demonstration of all fetal planes required for exact biometric measurements. The fetal growth profile including the 12 biometric parameters gives a precise overview of normal or abnormal fetal growth. Three-dimensional ultrasound, in comparison to 2D ultrasound, allows the demonstration of the different biometric parameters in exactly controlled standard planes and thus enables precise measurements. The data from this study could be an integrative component in future automated measurement programs controlling fetal growth profiles. Further research with randomized controlled trials is needed to validate these findings.

Pluym et al. (2021) conducted an observational study to evaluate the accuracy of an automated three-dimensional (3D) ultrasound technique for fetal intracranial measurements compared with manual acquisition. This was a prospective observational study of patients presenting for routine anatomical survey between 18 + 0 and 22 + 6 weeks' gestation. After providing informed consent, each individual underwent two consecutive ultrasound examinations of the fetal head,

one by a sonographer and one by a physician. Each operator obtained manual measurements of the biparietal diameter (BPD), head circumference (HC), transcerebellar diameter (TCD), cisterna magna (CM) and posterior horn of the lateral ventricle (Vp), followed by automated measurements of these structures using an artificial intelligence-based tool, SonoCNS® Fetal Brain. Both operators repeated the automated approach until all five measurements were obtained in a single sweep, up to a maximum of three attempts. The accuracy of automated measurements was compared with that of manual measurements using intraclass correlation coefficients (ICC) by operator type, accounting for patient and ultrasound characteristics. One hundred and forty-three women were enrolled in the study. Median body mass index was 24.0 kg/m2 (interquartile range (IQR), 22.5-26.8 kg/m2) and median subcutaneous thickness was 1.6 cm (IQR, 1.3-2.0 cm). Fifteen (10%) patients had at least one prior Cesarean delivery, 17 (12%) had other abdominal surgery and 78 (55%) had an anterior placenta. Successful acquisition of the automated measurements was achieved on the first, second and third attempts in 70%, 22% and 3% of patients, respectively, by sonographers and in 76%, 16% and 3% of cases, respectively, by physicians. The automated algorithm was not able to identify and measure all five structures correctly in six (4%) and seven (5%) patients scanned by the sonographers and physicians, respectively. The ICCs reflected good reliability (0.80-0.88) of the automated compared with the manual approach for BPD and HC and poor to moderate reliability (0.23-0.50) for TCD, CM and Vp. Fetal lie, head position, placental location, maternal subcutaneous thickness and prior Cesarean section were not associated with the success or accuracy of the automated technique. The authors concluded that automated 3D ultrasound imaging of the fetal head using SonoCNS® reliably identified and measured BPD and HC but was less consistent in accurately identifying and measuring TCD, CM and Vp. While these results are encouraging, further optimization of the automated technology is necessary prior to incorporation of the technique into routine sonographic protocols. A limitation of this study is the inclusion of fetuses with normal intracranial anatomy only, thus limiting the ability to generalize findings to the broader population. Additional limitations of this study include the requirement of a 3D probe to use the tool and that patient characteristics, including ethnicity, lower BMI and nulliparity, may prevent generalizability to the broader population. Furthermore, the sonographer characteristics seen at a high-volume referral perinatal center may differ from those seen in routine obstetric offices, potentially affecting the acquisition rates. Further investigation is needed before clinical usefulness of this procedure is proven.

Sagberg et al. (2021) conducted a prospective study to compare three-dimensional (3D) ultrasound with magnetic resonance imaging (MRI) for measurements of placental volume. Placental volume by 3D ultrasound and MRI in 100 unselected pregnancies at 27 weeks of gestation (25+4 -28+4 weeks) was measured. The 3D ultrasound acquisitions were analyzed offline, and the placental outline was manually traced using the virtual organ computer-aided analysis (VOCAL) 30° rotational technique. The MRI examinations included a T2-weighted gradient echo sequence in the sagittal plane, with 5-mm slices through the entire uterus. The placental outline was manually traced in each slice. The correlation between 3D ultrasound and MRI placental volumes was estimated by intraclass correlation coefficients. Bland-Altman analysis was applied to visualize systematic bias and limits of agreement, in which the ratio MRI placental volume/3D ultrasound placental volume was plotted against the average of the two methods. The intraclass correlation coefficient between 3D ultrasound and MRI measurements was 0.49 (95% confidence interval 0.33-0.63). In general, 3D ultrasound measured smaller placental volumes (median 373 cm3 , interquartile range 309-434 cm3) than MRI (median 507 cm3, interquartile range 429-595 cm3) and the systematic bias was 1.44. The 95% limits of agreement between the two methods were wide (0.68-2.21). The authors concluded that there was poor to moderate correlation between 3D ultrasound and MRI placental volume measurements. Generally, 3D ultrasound measured smaller placental volumes than MRI, suggesting that 3D ultrasound failed to visualize the entire placenta. The findings of this study need to be validated by well-designed studies. Further investigation is needed before clinical usefulness of this procedure is proven.

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.

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The American College of Obstetricians and Gynecologists (ACOG)

ACOG Practice Bulletin 175 (2016, updated 2020) 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 September 18, 2024)

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Policy History/Revision Information

Date	Summary of Changes
01/01/2025	**Definitions** • Updated definition of “Observation Care” **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version UMR2024T0628F

Instructions for Use

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