Medical Coverage Policy

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Ultrasound in Pregnancy (including 3D, 4D and 5D Ultrasound)

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Overview

This Coverage Policy addresses obstetric ultrasound use in pregnancy.

Coverage Policy

Up to two (2) routine two-dimensional (2D) standard or limited obstetrical ultrasound examinations (CPT® codes 76801, 76805, 76811, 76815) are considered medically necessary.

A specialized obstetrical ultrasound (CPT® code 76816) is considered medically necessary when performed to follow up specific medical indications/complications.

An obstetrical ultrasound examination performed solely to determine gender or to provide photographic representation of the fetus is considered not medically necessary for the management of a pregnancy.

Three-dimensional (3D), four-dimensional (4D) or five dimensional (5D) obstetrical ultrasonography is considered experimental, investigational or unproven.

General Background

Ultrasound imaging uses high-frequency sound waves to produce dynamic images of organs, tissues or blood-flow inside the body. The procedure involves the use of a transducer, which sends a stream of high-frequency sound waves into the body and detects their echoes as they bounce off internal structures. The sound waves are converted to electrical impulses, which are processed to form an image displayed on a computer monitor. Obstetricians use ultrasounds at a very low power level to check fetal size, location, age and quantity. Ultrasound is also used in this manner to assess for the presence of some types of birth defects, fetal movement, breathing and heartbeat.

Two-dimensional (2D) ultrasound is considered standard or conventional ultrasound. In conventional 2D scanning the ultrasound image is made up of a series of thin slices and only one slice can be seen at any one time. For three-dimensional (3D) ultrasonography a volume of echoes is taken, which can be stored digitally and shaded to produce life-like pictures of the fetus. It is possible to measure distance, area and volume from volume data with 3D ultrasound. Three-dimensional ultrasound data can be sliced in any orientation, allowing for any diameter or cross-sectional area of the organ to be measured. Four-dimensional ultrasound adds motion to the 3D imaging display. This feature typically involves 3D multiplanar imaging that is acquired at rates that stimulate movement such as heart motion or fetal activity. With 4D ultrasound, the life-like fetal pictures can be seen to move in real time so the activity of the baby inside the womb can be studied. Five-dimensional (5D) ultrasound reconstructs conventional 2D images from 3D ultrasound volume data, automating the process of acquiring diagnostic images through the use of a software package. The ultrasound system WS80A (Samsung Medison Co, Ltd, Seoul, Korea) includes several software packages focusing on specific areas including fetal brain and heart structure, nuchal translucency and fetal biometry.

There is no consensus on the best use of ultrasonography in screening for abnormal pregnancies in low-risk populations. Routine ultrasound has also not been shown to improve outcomes in low-risk pregnancies (Hayes, 2010; 2014). However, many health care providers recommend that one ultrasound examination, usually done between 18 and 20 weeks of pregnancy, be included as a routine part of prenatal care. The use of ultrasonography to assess for potential fetal abnormalities, confirm the site of pregnancy within the uterus, and determine gestational age is considered the standard of care. Also, the use of ultrasound scanning during the first trimester is correlated with reduced post-term labor induction rates as compared to second trimester ultrasound scanning (American College of Obstetricians and Gynecologists [ACOG], 2014; Reaffirmed 2020).

ACOG uses the following terms to describe various types of ultrasound examinations performed during the second and third trimesters (ACOG, 2016; Reaffirmed 2020):

- Standard: includes an evaluation of fetal presentation amniotic fluid volume, cardiac activity, placental position, fetal biometry and an anatomic survey.
- Limited: performed when a specific question requires investigation; appropriate only when the patient has had a prior complete examination.
- Specialized: performed when an anomaly is suspected on the basis of history, biochemical abnormalities or clinical evaluation, or when results from either a limited or standard ultrasound examination are suspicious.

First Trimester Ultrasound Examination
A first trimester ultrasound examination is performed prior to 14 0/7 weeks of gestation for a number of indications which include the following (ACOG, 2016; Reaffirmed 2020):

- confirmation of the presence of an intrauterine pregnancy
- evaluation of a suspected ectopic pregnancy
- evaluation of vaginal bleeding
- evaluation of pelvic pain

- to estimate gestational age
- to diagnosis or evaluate multiple gestations
- to confirm cardiac activity
- as adjunct to chorionic villus sampling, embryo transfer, or localization and removal of an intrauterine device
- assessment of certain fetal anomalies, such as anencephaly, in patients at high risk
- evaluation of maternal pelvic or adnexal masses or uterine abnormalities
- screening for fetal aneuploidy
- evaluation of suspected gestational trophoblastic disease (e.g., hydatidiform mole)

First trimester crown-rump measurement via ultrasound is the most accurate means for dating of pregnancy (ACOG, 2016; Reaffirmed 2020). Obtaining an accurate expected date of delivery (EDD) using ultrasonography early in the pregnancy can reduce the incidence of pregnancies diagnosed as post-term and minimize unnecessary interventions. The premise is that the EDD as calculated by menstrual age is often inaccurate and therefore can be the basis for presumed but incorrect diagnosis of post-term pregnancy. The reported frequency of post-term pregnancy is approximately 7%, with most cases of resulting from a prolongation of gestation. Other cases result from an inability to accurately define EDD. The risk of adverse sequelae may be reduced by making an accurate assessment of gestational age and diagnosis of post-term gestation, as well as recognition and management of risk factors. Although detection of some anomalies is possible as early as 11–14 weeks, the use of ultrasonography to screen for major fetal anomalies in the first trimester should not replace the more appropriate screening of fetal anatomy in the second trimester (Wax, et al., 2015).

Second and Third Trimester Ultrasound Examination
Ultrasonography can be beneficial in many situations in the second and third trimesters. Indications for ultrasound examination in the second- (14 0/7 weeks–27 6/7 weeks) and third- (28 0/7 weeks–40 6/7 weeks) trimester include the following (ACOG, 2016; Reaffirmed 2020):

- estimation of gestational age
- evaluation of fetal growth
- evaluation of vaginal bleeding
- evaluation of cervical insufficiency
- evaluation of abdominal and pelvic pain
- determination of fetal presentation
- evaluation of suspected multiple gestation
- adjunct to amniocentesis or other procedure
- significant discrepancy between uterine size and clinical dates
- evaluation of pelvic mass
- examination of suspected gestational trophoblastic disease (e.g., hydatidiform mole)
- adjunct to cervical cerclage placement
- evaluation of suspected ectopic pregnancy
- evaluation of suspected fetal death
- evaluation of suspected uterine abnormality
- evaluation for fetal well-being
- evaluation of suspected amniotic fluid abnormalities
- evaluation of suspected placental abruption
- adjunct to external cephalic version
- evaluation for premature rupture of membranes or premature labor
- evaluation for abnormal biochemical markers
- follow-up evaluation of a fetal anomaly
- follow-up evaluation of placental location for suspected placenta previa
- evaluation for those with a history of previous congenital anomaly
- evaluation of fetal condition in late registrants for prenatal care
- to assess findings that may increase the risk of aneuploidy
- to screen for fetal anomalies

In addition, cervical length screening during the second trimester is a tool that can be utilized to identify women at increased risk for preterm birth. Cervical shortening is one of the first steps in the processes leading to labor and can occur several weeks prior to labor (Berghella, 2020). A short cervix, defined as a transvaginal sonographic cervical length ≤ 25 mm in the mid-trimester of pregnancy, is a significant risk factor for spontaneous preterm birth, with a high predictive accuracy for spontaneous preterm birth < 34 weeks of gestation and a moderate to low predictive accuracy for spontaneous preterm birth < 37 weeks of gestation. Identification of women with a short cervix and treatment with vaginal progesterone can reduce the frequency of preterm birth. Several authors have proposed that universal mid-trimester transvaginal cervical length screening for women with a singleton gestation, followed by treatment with vaginal progesterone for those with a short cervix, meets all of the World Health Organization criteria for endorsing the implementation of a screening test in clinical medicine (Romero, et al., 2018).

Use of 2D Compared to 3D, 4D and 5D Ultrasound
The ultimate impact of 3D and 4D ultrasound as new diagnostic imaging technologies is difficult to characterize due to the rapidly changing technological advances in the medical imaging industry. Potential areas of promise include fetal facial anomalies, neural tube defects, and skeletal malformations where 3D ultrasonography may be helpful in diagnosis as an adjunct to, but not a replacement for, 2D ultrasonography (ACOG, 2016; Reaffirmed 2020). 3D ultrasound may provide additional diagnostic information, however there is a lack of data demonstrating the impact on clinical outcomes. Proponents of the use 4D ultrasound suggest that the real-time movements of the fetus obtained improves maternal bonding, however the impact of 4D ultrasound scanning on the diagnosis and management of fetal abnormalities has also not been demonstrated.

U.S. Food and Drug Administration (FDA)
A number of ultrasound devices and probes have received FDA approval. The FDA notes that these devices are considered prescription devices and are to be used only with a physician's order. Fetal ultrasound imaging provides real-time images of the fetus. Ultrasound use for fetal scanning is generally considered safe if properly used when information is required about a pregnancy. However, ultrasound is a form of energy and even at low levels, some studies have shown that it can produce physical effects in tissue, such as jarring vibrations and rise in temperature. Although there is a lack of evidence of any harm to the fetus due to ultrasound imaging, prudent use by a trained health care provider is important. The FDA strongly discourages using 3D and 4D ultrasound devices for creating fetal keepsake images and videos (U.S. Food and Drug Administration [FDA], 2014).

Literature Review
The use of 3D and 4D ultrasound has been evaluated in randomized controlled trials (RCTs) and observational studies. A cross-sectional study by Espinoza et al. (2010) assessed the effectiveness of 4D ultrasound for fetal echocardiography. A total of seven international centers uploaded nonconsecutive 4D volume data sets (n=120). Diagnostic indices of 4D ultrasound in the identification of fetuses with congenital heart defects were calculated. Overall, the median (range) sensitivity and specificity were 93% (77%–100%), 96% (84%–100%) respectively, with a positive predictive value (PPV) of 96% (83%–100%), and a negative predictive value (NPV) of 93% (79%–100%). False-positive and negative rates were 4.8% (2.7%–25%), and 6.8% (5%–22%), respectively.

A prospective study (n=118) by Chen et al. (2009) assessed the reproducibility of measurements of nasal bone length using a three-dimensional (3D) ultrasound in the first trimester compared to 2D measurements. The successful rate of measurement of nasal bone length by 3D ultrasound was 79.7%. There was significant inter-method difference between the results obtained by 2D and 3D, substantial variation between observers in 3D measurement of fetal nasal bone length in the first trimester. Independent 3D measurement of nasal bone was found to have no additional advantages over 2D sonography.

A prospective randomized controlled study (n=60) by Lapaire et al. (2007) assessed the impact of 3D versus 2D ultrasound on maternal-fetal bonding. Maternal recognition was higher with 3-D US (p=0.004), however the maternal preference of 3D US had no significant impact on maternal-fetal bonding. Another randomized study (n=100) by Rustico et al., (2005) reported that the addition of 4D ultrasound results did not significantly change the perception that women have of their baby nor their antenatal emotional attachment compared with conventional 2D ultrasound.

Randomized controlled and evaluation studies (n=range of 63–3472) comparing the diagnostic accuracy of the different ultrasonographic techniques for various indications have found the diagnostic information provided by 3D/4D ultrasound to be consistent with that provided by 2D ultrasound and have reported that 3D ultrasound is most helpful as an adjunct to 2D ultrasound imaging (Goetzinger, et al., 2018; Hsu, et al., 2013; Rizzo, et al., 2011; Kurjak, et al., 2010; Goncalves, et al., 2006; Merz and Welter, 2005).

Evidence evaluating 5D ultrasonography is primarily in the form of prospective comparative studies with patient populations ranging from 39–183. The results of the studies suggest that 5D ultrasonography is faster, requires less expertise to interpret, and is comparable to 2D in accuracy. However, there is a lack of data to support that any additional benefit or improved outcomes are achieved when using 5D ultrasounds over conventional 2D ultrasounds (Laban, et al., 2018; Rizzo, et al., Oct 2016; Rizzo, et al., Jul 2016; Hur, et al., 2015).

Although 3D/4D/5D ultrasonography can produce more detailed and recognizable images than conventional 2D ultrasound, the clinical utility of this remains unclear. Additional well designed studies are needed to clearly define the role of 3D/4D/5D in obstetrics as well as to establish appropriate applications for this method of imaging.

Professional Societies/Organizations

American College of Obstetricians and Gynecologists (ACOG)/American Institute of Ultrasound in Medicine (AIUM): A 2016 clinical management guideline on the use of ultrasound in pregnancy issued by ACOG and AIUM stated that the best gestational age for an obstetric ultrasound will depend on the clinical indication for the examination. First trimester ultrasonography is most accurate for patients with uncertain or unreliable menstrual dating or with an indication to confirm viability. When used as part of combined first-trimester screening or integrated screening for aneuploidy, an ultrasound examination with nuchal translucency measurement before 14 0/7 weeks of gestation provides accurate dating of pregnancy and an effective screening test for trisomy 13, trisomy 18, and trisomy 21 when combined with maternal age and serum markers. ACOG stated that in the absence of other specific indications, the optimal time for a single ultrasound examination is at 18–22 weeks of gestation. This timing allows for a survey of fetal anatomy in most women and an accurate estimation of gestational age (ACOG, 2016; Reaffirmed 2020).

According to the joint guidelines, the technical advantages of 3D ultrasonography include its ability to acquire and manipulate an infinite number of planes and to display ultrasound planes traditionally inaccessible by 2D ultrasonography. Despite these technical advantages, proof of a clinical advantage of 3D ultrasonography in prenatal diagnosis in general is still lacking. Until clinical evidence shows a clear advantage to conventional 2D ultrasonography, 3D ultrasonography is not considered a required modality at this time (ACOG, 2016; Reaffirmed 2020).

American Institute of Ultrasound in Medicine (AIUM)/American College of Radiology (ACR)/American College of Obstetricians and Gynecologists (ACOG)/Society for Maternal-Fetal Medicine (SMFM)/Society of Radiologists in Ultrasound (SRU): The 2018 AIUM-ACR-ACOG-SMFM-SRU practice parameter for the performance of standard diagnostic obstetric ultrasound examinations stated that obstetric ultrasound examinations should only be performed when there is a valid medical reason, and the lowest possible ultrasonic exposure settings should be used. The practice parameter described the key elements of standard ultrasound examinations in the first, second, and third trimesters of pregnancy. A standard obstetric ultrasound examination in the first trimester should consist of an evaluation of the presence, size, location, and number of gestational sacs. The second or third trimester ultrasound can include an evaluation of the fetal number, cardiac activity, presentation, amniotic fluid volume, placental position, fetal biometry, and an anatomic survey. In some cases, it may be necessary to perform a more detailed fetal anatomic examination, such as when an abnormality is found or suspected on the standard examination or in pregnancies at high risk for fetal anomalies.

Use Outside of the US

The Society of Obstetricians and Gynaecologists of Canada (SOGC) guideline on the use of first trimester ultrasounds stated that a first trimester ultrasound is indicated for assessment of threatened abortion to document fetal viability, for incomplete abortion to identify retained products of conception and prior to pregnancy termination. Additionally, it can be used to identify multiple gestations, used during diagnostic or therapeutic procedures requiring visual guidance and to establish early fetal genetic and anatomic screening (e.g., ectopic

pregnancy, molar pregnancy, and suspected pelvic masses). First trimester ultrasound is not recommended to diagnose pregnancy but is recommended to date a pregnancy. If menstrual dating is reliable and an early comprehensive pregnancy ultrasound (11−14 weeks) is planned, dating should be confirmed concurrently with this exam (Van den Hof, et al., 2019).

The International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) is a scientific organization that encourages safe clinical practice and high-quality teaching and research related to diagnostic imaging in women's healthcare. According to the ISOUG practice guidelines, routine ultrasound examination is an established part of antenatal care if resources are available and access possible. A single routine ultrasound is commonly performed in the second trimester, although routine scanning is offered increasingly during the first trimester, particularly in high-resource settings. Regarding three-dimensional (3D) and four-dimensional (4D) ultrasound the ISUOG stated that these modalities are not currently used for routine first-trimester fetal anatomical evaluation, as their resolution is not yet as good as that of 2D ultrasound (Salomon, et al., 2013).

The National Institute for Health and Clinical Excellence (NICE) guideline on the routine care of healthy pregnant women stated that "pregnant women should be offered an early ultrasound scan between 10 weeks 0 days and 13 weeks 6 days to determine gestational age and to detect multiple pregnancies. Ultrasound screening for fetal anomalies should be routinely offered, normally between 18 weeks 0 days and 20 weeks 6 days." The guideline further stated that routine use of ultrasound scanning after 24 weeks of gestation is not supported by the evidence and therefore should not be offered (NICE, 2008; updated 2018).

Medicare Coverage Determinations

	Contractor	Policy Name/Number	Revision Effective Date
NCD	National	Ultrasound Diagnostic Procedures (220.5)	9/28/2007

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when used to report up to two (2) routine two-dimensional (2D) standard or limited obstetrical ultrasound examinations:

CPT®* Codes	Description
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
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
76811	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach; single or first gestation
76815	Ultrasound, pregnant uterus, real time with image documentation, limited (eg, fetal heart beat, placental location, fetal position and/or qualitative amniotic fluid volume), 1 or more fetuses

Considered Medically Necessary when used to report a specialized obstetrical ultrasound used to follow up specific medical indications/complications:

CPT®* Codes	Description
76816	Ultrasound, pregnant uterus, real time with image documentation, follow-up (eg., 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

Considered Experimental/Investigational/Unproven when used to report three-dimensional (3D), four-dimensional (4D) or five-dimensional (5D) obstetrical ultrasonography:

CPT®* Codes	Description
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.
76499	Unlisted diagnostic radiographic procedure

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