Cigna Medical Coverage Policy

Subject **Ultrasound In Pregnancy (including 3D and 4D Ultrasound)**

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Coverage Policy

Cigna covers one routine two-dimensional (2D) standard obstetrical ultrasound examination during pregnancy. Cigna covers additional ultrasound examinations as medically necessary when performed for specific medical indications.

Cigna does not cover an obstetrical ultrasound examination performed solely to determine gender or to provide photographic representation of the fetus, because it is considered not medically necessary for the management of a pregnancy.

Cigna does not cover either three-dimensional (3D) or four-dimensional (4D) obstetrical ultrasonography because each 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.

There is no consensus on the best use of ultrasonography in screening for abnormal pregnancies in low-risk populations. 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], 2004a).

ACOG uses the following terms to describe various types of ultrasound examinations performed during the second and third trimesters:

- 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.

Indications for first-trimester ultrasonography include the following (ACOG, 2009):

- 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 hydatidiform mole

Indications for second- and third-trimester ultrasonography include (ACOG, 2009):

- 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 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

First-Trimester Ultrasound Screening
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 EDC 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%. Most cases of post-term pregnancy result 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.

Literature Review: The safety and effectiveness of routine ultrasound in pregnancy has been adequately studied in randomized and quasi-randomized controlled trials. Whitworth et al. (2010) conducted a Cochrane review of ultrasound in early pregnancy which included 11 such trials (n=37505 women). The analysis found routine scanning to be associated with reduced inductions of labor for post-term pregnancy. Early ultrasound was also found to improve the early detection of multiple pregnancies.

There is sufficient evidence in the published peer-reviewed medical literature (Bennett, et al., 2004; Bukowski, et al., 2003; ECRI, 2003) indicating that the use of ultrasound in early pregnancy (i.e., before 24 weeks gestation) may be of benefit in determining gestational age, detecting multiple pregnancies, and decreasing the rates of induction of labor for post-term pregnancies.

Use of 2D Compared to 3D and 4D 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, 2009). 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.

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 no evidence that these physical effects can harm a fetus, the existence of these effects means that prenatal ultrasound cannot be considered completely harmless (U.S. Food and Drug Administration [FDA], 2004). There is increasing concern regarding the use of ultrasound solely for the purpose of providing enhanced photographs and videos of a fetus.

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 (Chen, et al., 2009).

A prospective randomized controlled study (n=60) by Lapaire et al. (2008) 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 (Rizzo, et al., 2011; Kurjak, et al., 2010; Lindell and Marsal, 2009; Goncalves, et al., 2006; Merz and Welter, 2005; Michailidis, et al., 2002; Scharf, et al., 2001; Dyson, et al., 2000).

Although 3D/4D 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 in obstetrics as well as to establish appropriate applications for this method of imaging.

Professional Societies/Organizations
The Institute for Clinical Systems Improvement (ICSI) guideline on prenatal care states that three-dimensional (3D)/four-dimensional (4D) ultrasound is considered investigational and is not routinely recommended at this time (ICSI, 2012).

According to the ACOG guidelines on ultrasound in pregnancy, 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, 2009).

The American Institute of Ultrasound in Medicine (AIUM) states that 2D sonography is currently the primary method of medically-indicated anatomic imaging with ultrasound. While 3D sonography may be helpful in diagnosis, it should be considered only as a developing technology. Its role is restricted to use as an adjunct only, not as a replacement, for 2D ultrasound. The AIUM also states that the use of either 2D or 3D ultrasound solely to view the fetus, obtain a picture of the fetus, or determine the fetal gender without a medical indication, is inappropriate and contrary to responsible medical practice. Although there are no confirmed biological effects on patients caused by exposures from present diagnostic ultrasound equipment, the possibility exists that such biological effects may be identified in the future (AIUM, 2003, 2005).

The Society of Maternal and Fetal Medicine (SMFM) states that only one medically indicated ultrasound per pregnancy, per practice is appropriate. Once this detailed fetal anatomical exam is done, a second one should not be performed unless there are extenuating circumstances with a new diagnosis (SMFM, 2004).

Use Outside of the US
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 guideline on first-trimester fetal ultrasound, routine ultrasound examination is an established part of antenatal care if resources are available and access possible. It 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 4D ultrasound the ISUOG states 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 states 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. This will ensure consistency of gestational age assessment and reduce the incidence of induction of labor for prolonged pregnancy. Ultrasound screening for fetal anomalies should be routinely offered, normally between 18 weeks 0 days and 20 weeks 6 days." The guideline further states that routine use of ultrasound scanning after 24 weeks of gestation is not supported by the evidence and therefore should not be offered (NICE, 2010).

Summary
Although some controversy still exists regarding whether routine ultrasound screening of all obstetric patients improves pregnancy outcomes, one ultrasound examination per pregnancy is generally considered the standard of care. Evidence in the published peer-reviewed medical literature as well as professional society opinions support the efficacy of first-trimester ultrasound screening for decreasing post-term labor induction rates. Two-dimensional (2D) ultrasound remains the primary method of obstetric imaging. At present, there is insufficient evidence in the peer-reviewed medical literature to support the use of three-dimensional (3D) or four-dimensional (4D) ultrasound. Although the use of 3D ultrasound is increasing in many clinical settings, the role of this technology is unclear. It has not been demonstrated that any additional information provided by 3D sonography results in improved health outcomes or impacts treatment decisions. There is also insufficient evidence to indicate that the use of 4D ultrasound results in improved fetal outcomes or enhances fetal-parental bonding.

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.

Covered when medically necessary:

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
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)

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)
76815	Ultrasound, pregnant uterus, real time with image documentation, limited (e.g., fetal heart beat, placental location, fetal position and/or qualitative amniotic fluid volume), one 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
76817	Ultrasound, pregnant uterus, real time with image documentation, transvaginal
76820	Doppler velocimetry, fetal; umbilical artery
76821	Doppler velocimetry, fetal; middle cerebral artery

Experimental/Investigational/Unproven/Not Covered when used to report 3D or 4D ultrasound in pregnancy:

CPT* Codes	Description
76376	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound or other tomographic modality; 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; requiring image postprocessing on an independent workstation.
76499	Unlisted diagnostic radiographic procedure

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