



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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

Effective Date 12/15/2008
Next Review Date..... 8/15/2010
Coverage Policy Number 0142

Table of Contents

| | |
|----------------------------------|----|
| Coverage Policy | 1 |
| General Background | 1 |
| Coding/Billing Information | 6 |
| References | 8 |
| Policy History | 11 |

Hyperlink to Related Coverage Policies

Down Syndrome Screening
Fetal Surgery

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2008 CIGNA

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. The higher the frequency of the sound, the more shallow the depth of penetration, but the better the resolution of the image produced. 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 type 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. Techniques are available to measure structures both manually and automatically. Volume measurements may be accomplished by masking multiple, individual slices or by masking a structure that has been isolated using an editing tool. Once the area of interest is masked, the volume is calculated automatically. This technique allows the volumes of irregular or disconnected structures to be measured with as much accuracy as rounded structures. Three-dimensional ultrasound also allows for the evaluation of the presence of vessels in relation to surrounding anatomic structures. Varying degrees of opacity and transparency can be applied, allowing for visualization of underlying fetal vessels. 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.

Today, 60-70% of pregnant women in the United States receive an ultrasound examination in the course of their pregnancy. The American College of Obstetricians and Gynecologists (ACOG) recommends that in low-risk pregnancies use of ultrasound generally be reserved for answering specific medical questions, rather than as a routine offering to all women. 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.

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.

First-Trimester Ultrasound Screening

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. The premise is that the estimated date of confinement (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 expected date of delivery (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. According to the ACOG guidelines on the management of post-term pregnancy, obtaining an accurate EDD using ultrasonography early in the pregnancy can reduce the incidence of pregnancies diagnosed as post-term and minimize unnecessary interventions.

In a Cochrane review, Neilson (2000) assessed the use of routine ultrasound compared to the selective use of ultrasound in early pregnancy (i.e., before 24 weeks). A total of nine controlled trials were included. The reviewers found that compared to selective examinations, routine ultrasound examination in early pregnancy resulted in reduced rates of induction of labor for post-term pregnancy (odds ratio 0.61, 95% CI 0.52–0.72) as well as earlier detection of multiple pregnancies for twins undiagnosed at 26 weeks (odds ratio 0.08, 95% CI

0.04–0.16). There were no differences found for substantive clinical outcomes such as perinatal mortality (Neilson, 2000).

An Institute of Clinical Systems Improvement (ICSI) technology assessment found that routine ultrasound in early pregnancy (i.e., before 24 weeks gestation) may be of benefit for the determination of gestational age, detection of multiple pregnancies, induction of labor for post-term pregnancies, and earlier detection of clinically unsuspected fetal malformation. The report further stated that routine ultrasound in early pregnancy has not been shown to reduce perinatal mortality. Likewise, routine ultrasound in late pregnancy (i.e., after 24 weeks gestation) has not been shown to reduce perinatal mortality or morbidity (ICSI, 2002).

Bukowski and associates (2003) studied 3588 women who had first- and second-trimester ultrasounds as part of the multicenter First and Second Trimester Evaluation for Aneuploidy Trial (FASTER) 2000. In this study, it was shown that gestational age determination using CRL-measurement in the first trimester as opposed to last menstrual period (LMP) significantly affected the proportion of pregnancies considered greater than 41 weeks (8.2% versus 22.1%). The percentage of pregnancies considered greater than 41 weeks was decreased in the first-trimester screening group compared with the second-trimester screening group (6.7% versus 16.3%). The results were comparable to those in the study conducted by Bennett and colleagues (Bukowski, et al., 2003).

Bennett et al. (2004) investigated the use of first-trimester ultrasound screening versus second-trimester ultrasound screening in determining post-term labor induction rates in a randomized controlled trial. The study compared first-trimester ultrasounds measuring crown-rump length (CRL) to second-trimester ultrasounds measuring biometry alone. Two hundred and eighteen women were randomly assigned to receive either first-trimester or second-trimester ultrasound screening to establish the EDC. Of 104 women assigned to the first trimester screening group, 41.3% had their gestational age adjusted on the basis of CRL measurement. Of 92 women assigned to the second-trimester screening group, 10.9% were corrected as a result of biometry. The study revealed that five women in the first trimester screening group and 12 women in the second trimester screening group were labor-induced for post-term pregnancy. The authors concluded that the results of this trial suggest that dating by CRL measurement in the first trimester is superior to second trimester biometry alone in providing an accurate estimation of the EDC. The application of a program of first-trimester ultrasound to the obstetric population would reduce errors in estimating gestational age and thereby reduce post-term labor-induction rates (Bennett, et al., 2004).

Use of 2D Versus 3D and 4D Ultrasound

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 U.S. Food and Drug Administration (FDA) states that the existence of these effects means that prenatal ultrasound cannot be considered completely harmless. There is increasing concern regarding the use of ultrasound solely for the purpose of providing enhanced photographs and videos of a fetus. The FDA views the use of ultrasound in this manner as unapproved use of a medical device. These high-resolution images are produced by more advanced ultrasound technologies, using higher frequencies for longer exposure times. Animal studies have been done to investigate the effects of ultrasound on a fetus, but human studies are not feasible due to the risk of subjecting unborn babies to unknown effects.

The ultimate impact of 3D and 4D ultrasound as new diagnostic imaging technologies has been difficult to characterize due to the rapidly changing technological advances in the medical imaging industry. Currently, much of the scientific literature regarding potential clinical applications during pregnancy has been limited to case reports and retrospective studies involving a relatively small number of subjects. Dyson et al. (2000) scanned 63 patients with 103 suspected fetal anomalies with both 2D and 3D ultrasound. Each anomaly was reviewed by one or more fetal imaging specialists to determine whether the 3D ultrasound data were advantageous, equivalent, or disadvantageous when compared with 2D ultrasound images. Clinical impact and pathologic or clinical outcome were determined in all cases. The 3D ultrasound images provided additional information in 53 anomalies (51%), were equivalent to 2D ultrasound images in 46 anomalies (45%), and were disadvantageous in four anomalies (4%). The 3D ultrasound images were disadvantageous in two fetuses with multiple anomalies and two with cardiac anomalies. The 3D ultrasound was most effective in evaluating fetuses with facial anomalies, hand and foot abnormalities and axial spine and neural tube defects. Additional

information provided by 3D ultrasound images impacted clinical management in 5% of patients. The authors noted that 3D ultrasound is most helpful as an adjunct to 2D ultrasound imaging (Dyson, et al., 2000).

Scharf and colleagues (2001) set out to assess the validity of 3D ultrasound diagnostics and to evaluate its impact on clinical routine. A total of 433 pregnant women were examined with 2D and 3D sonography by the same physician. 3D visualization in healthy fetuses was reported to be inferior in quality to 2D visualization of the internal organs, extremities, face, and heart. A clear 3D view of the gender was possible for 7.9% of the fetuses compared to a 95% visualization rate with 2D sonography. 3D imaging provided a slightly better description of the given malformation in only one case and this did not result in a different therapeutic approach. It was proposed that 3D imaging can be useful for specific malformations under the condition that these examinations be performed in specific ultrasound departments. In the opinion of the authors, further evaluations of 3D imaging must be performed to clearly define the range of indication for 3D imaging.

Michailidis and associates (2002) conducted a comparative study to examine routine fetal ultrasound results obtained from 2D ultrasound versus 3D ultrasound. One hundred and fifty-nine women who had routine, early pregnancies were scanned at 12-13 weeks gestation. A survey of the fetal anatomy was obtained by 2-D ultrasound. Subsequently, two volumes of the whole fetus were acquired using 3D ultrasound. A complete anatomical survey was achieved in 93.7% of the cases with 2D ultrasound as compared to 80.5% of the cases with 3-D volume acquisition. It was concluded that while 3D ultrasound can be a useful addition to clinical practice, 2D ultrasound remains the best way to examine fetal anatomy in the first trimester.

Kurjak et al. (2002) scanned 98 fetuses to classify types of first trimester fetal movements in normal pregnancies as seen by 4D sonography. It was found that compared with 2D ultrasound, 4D scanning detected fetal motions one week earlier. However, maternal outcomes or change in patient management based on this information were not reported.

In a small randomized study, Rustico et al. (2005) assessed whether a 4D ultrasound scan in the second/third trimester of pregnancy facilitates maternal recognition of specific fetal structures and movements and causes an emotional impact, as subjectively reported on two questionnaires. Women were assigned to undergo 2D ultrasound only (n=52) or 2D plus 4D ultrasound (n=48). Although the questionnaire scores were similar in the two groups, there were more women with positive quality, intensity and global attachment among those who had undergone a 4D scan. According to the investigators study, results indicated that the addition of 4D ultrasound does not significantly change the perception that women have of their baby nor their antenatal emotional attachment compared with conventional 2D ultrasound (Rustico, et al., 2005).

Merz and Welter (2005) evaluated 3472 fetuses with 2D and 3D ultrasonography. All examinations were carried out as part of a detailed ultrasound for fetal anomalies. The total number of defects detected was 1012, excluding 48 fetal heart defects. Fetal heart defects were excluded from the study because a reliable demonstration of these defects was not possible by 3D ultrasound. Comparing the 2D and 3D techniques, 3D ultrasonography proved advantageous in 60.8 % of the defects. The advantage of the 3D scans was said to be related to the favorable demonstration of targeted areas in different views (e.g., multiplanar, surface) and the combination of views. In 42 of the 1012 malformations (4.2 %), a defect was accurately identified or verified with 3D ultrasound only. According to the investigators, 3D ultrasound used as an adjunct to 2D ultrasound allowed for a better assessment of the severity of fetal defects. "3D sonography is not a competitive, but complementary technique to 2D ultrasound" (Merz and Welter, 2005).

A Hayes review of the evidence found that overall the studies suggest that compared with conventional 2D ultrasound, 3D sonography can provide additional and more specific diagnostic information on high-risk and normal fetuses in the second trimester. However, there was insufficient evidence to conclude that 3D or 4D ultrasound can replace the 2D technique for obstetrical examinations. Also, none of the studies identified examined the impact of 3D and/or 4D ultrasound on clinical outcomes and appropriate clinical roles for the technology have not been established (Hayes, 2005).

Goncalves et al. (2006) performed ultrasound examinations on 99 fetuses to detect any congenital anomalies. Initial examinations were done by 3D/4D volume ultrasonography. After establishing an initial diagnostic impression by 3D/4D ultrasound, a blinded independent examiner performed a 2D ultrasound examination. Information provided by 3D/4D ultrasound examinations was found to be consistent with results of 2D ultrasonography in 90% of cases. A total of six anomalies were missed by 3D/4D when compared to 2D

ultrasonography. The authors concluded that the evaluation of fetal anatomy and diagnosis of congenital anomalies are possible using 3D/4D volume datasets alone.

Lapaire et al. (2008) conducted a small prospective randomized pilot study of 60 low risk women with singleton fetuses in the second and third trimester to assess the impact of three-dimensional (3D) versus two-dimensional (2D) ultrasound (US) on maternal-fetal bonding. Patients were randomly assigned either to receive a 2D US first, followed by a 3D US, or to receive a 3D US first, followed by a 2D US. One trained operator (RP) performed all ultrasound examinations. The examiner's rating on image quality was reported to be slightly higher for the 2D scan compared to the 3D scan. 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. It was noted that based on these study results, 3D US should not yet be promoted as a standard obstetric screening tool.

Professional Societies/Organizations

The National Collaborating Centre for Women's and Children's Health recommends that pregnant women be offered an ultrasound scan to screen for structural anomalies, ideally between 18 and 20 weeks' gestation, by an appropriately trained sonographer and with equipment of an appropriate standard. This scan will also help to ensure consistency of gestational age assessments, improve the performance of mid-trimester serum screening for Down's syndrome, and reduce the need for induction of labour after 41 weeks. The guideline states that the evidence does not support the routine use of ultrasound scanning after 24 weeks' gestation and therefore it should not be offered (National Collaborating Centre for Women's and Children's Health, 2003).

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).

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).

ACOG has stated that the clear advantage of 3D ultrasonography in prenatal diagnosis is not present when compared to 2D imaging performed by an experienced clinician. Therefore, 3D imaging is not considered a required modality at this time (ACOG, 2004).

The measurement of nuchal translucency (NT) via ultrasound has allowed for earlier, noninvasive screening for chromosomal abnormalities, which when combined with serum screening in the first trimester, have detection rates comparable to standard second-trimester screening. In June 2004, ACOG issued a position on first-trimester screening methods. According to the committee opinion, first-trimester screening for genetic defects is now an option for pregnant women. The committee opinion goes on to emphasize that sonographer training and ongoing quality assurance are essential if NT is to be used as a screening method. Since small differences in NT measurement can significantly affect the risk prediction of Down syndrome, sonographers will need to be monitored closely. ACOG does not recommend the use of NT measurement by itself to screen for Down syndrome, as the test has a high-positive screen rate when used without serum markers. First-trimester screening should be used only if ALL of the following criteria are met:

- Appropriate ultrasound training and ongoing quality monitoring programs are in place.
- Sufficient information and resources are available to provide comprehensive counseling to women regarding the different screening options and limitations of these tests.
- Access to an appropriate diagnostic test is available when screening tests are positive.

Summary

Although some controversy still exists regarding whether routine ultrasound screening of all obstetric patients improves pregnancy outcomes, one ultrasound examination per pregnancy is 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: This list of codes may not be all-inclusive.

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 |
| 76941 | Ultrasonic guidance for intrauterine fetal transfusion or cordocentesis, imaging supervision and interpretation |
| 76945 | Ultrasonic guidance for chorionic villus sampling, imaging supervision and interpretation |
| 76946 | Ultrasonic guidance for amniocentesis, imaging supervision and interpretation |

| ICD-9-CM Diagnosis Codes | Description |
|---------------------------------|------------------------|
| 622.5 | Incompetence of cervix |
| 630 | Hydatiform mole |

| | |
|--------------------|---|
| 631 | Other abnormal product of conception |
| 632 | Missed abortion |
| 633.00 - 633.91 | Abdominal pregnancy |
| 640.0 | Threatened abortion |
| 640.8 | Other specified hemorrhage in early pregnancy |
| 640.9 | Unspecified hemorrhage in early pregnancy |
| 641.00 – 641.93 | Antepartum hemorrhage, abruption placentae, and placenta previa |
| 643.00 – 643.91 | Excessive vomiting in pregnancy |
| 644.00 – 644.21 | Early or threatened labor |
| 645.1 | Post term pregnancy |
| 645.2 | Prolonged pregnancy |
| 646.00 – 646.93 | Other complications of pregnancy, not elsewhere classified |
| 647.00 – 647.94 | Infectious and parasitic conditions in the mother classifiable elsewhere, but complicating pregnancy, childbirth, or the puerperium |
| 648.00 – 648.94 | Other current conditions in the mother classifiable elsewhere, but complicating pregnancy, childbirth, or the puerperium |
| 651.00 – 651.93 | Multiple gestation |
| 652.00 – 652.93 | Malposition and malpresentation of the fetus |
| 654.00 – 654.94 | Abnormality of organs and soft tissues of pelvis |
| 655.00 – 655.93 | Known or suspected fetal abnormality affecting management of mother |
| 656.00 – 656.93 | Other fetal and placental problems affecting management of mother |
| 657.00 – 657.03 | Polyhydramnios |
| 658.00 – 658.93 | Other problems associated with amniotic cavity and membranes |
| 764.00 - 764.99 | Slow fetal growth and fetal malnutrition |
| 766.0 - 766.22 | Disorders relating to long gestation and high birthweight |
| 768.0 | Fetal death from asphyxia or anoxia before onset of labor or at unspecified time |
| V22.0 | Supervision of normal first pregnancy |
| V22.1 | Supervision of other normal pregnancy |
| V22.2 | Pregnant state, incidental |
| V23.0 - V23.9 | Supervision of high risk pregnancy |
| V28.0 - V28.9 | Antenatal screening for abnormalities |

Experimental/Investigational/Unproven/Not Covered:

| 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. |

†**Note: Experimental/Investigational/Unproven and Not Covered when used to report 3D ultrasound in pregnancy.**

| ICD-9-CM Diagnosis Codes | Description |
|--------------------------|-------------------|
| | No specific codes |

***Current Procedural Terminology (CPT®) ©2007 American Medical Association: Chicago, IL.**

References

1. American College of Obstetricians and Gynecologists (ACOG) Committee on Ethics. ACOG Committee Opinion. Number 297, August 2004. Nonmedical use of obstetric ultrasonography. *Obstet Gynecol.* 2004 Aug;104(2):423-4.
2. American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins. ACOG Practice Bulletin No. 58. Ultrasonography in pregnancy. *Obstet Gynecol.* 2004 Dec;104(6):1449-58.
3. American Institute of Ultrasound in Medicine, AIUM Practice Guidelines for the Performance of Obstetric Ultrasound Examinations. 2007 Oct. Accessed June 30, 2008. Available at URL address: <http://www.aium.org/publications/clinical/obstetric.pdf>
4. American Institute of Ultrasound in Medicine, Official Statement on 3D technology, 1999. Revised November 12, 2005. Accessed June 30, 2004, July 10, 2006. Available at URL address: <http://www.aium.org/provider/statements/statements.asp>
5. Barnett SB, Maulik D; International Perinatal Doppler Society. Guidelines and recommendations for safe use of Doppler ultrasound in perinatal applications. *J Matern Fetal Med.* 2001 Apr;10(2):75-84.
6. Benacerraf BR, Benson CB, Abuhamad AZ, Copel JA, Abramowicz JS, Devore GR, et al. Three- and 4-dimensional ultrasound in obstetrics and gynecology: proceedings of the american institute of ultrasound in medicine consensus conference. *J Ultrasound Med.* 2005 Dec;24(12):1587-97.
7. Bennett KA, Crane JM, O'Shea P, Lacelle J, Hutchens D, Copel JA. First trimester ultrasound screening is effective in reducing post-term labor induction rates: A randomized controlled trial. *Am J Obstet Gynecol.* 2004 Apr;190(4):1077-81.
8. Bricker L, Garcia J, Henderson J, et al. Ultrasound screening in pregnancy: A systematic review of the clinical effectiveness, cost-effectiveness and women's views. *Health Technol Assess.* 2000;4(16):i-vi, 1-193.
9. Bofill JA, Sharp GH. Obstetric sonography. Who to scan, when to scan and by whom. *Obstet Gynecol Clin North Am.* 1998 Sep;25(3):465-78.
10. Demianczuk NN, Van Den Hof MC, Farquharson D, Lewthwaite B, Gagnon R, Morin L, et al. The use of first trimester ultrasound. *J Obstet Gynaecol Can.* 2003 Oct;25(10):864-75.
11. Dulay AT, Copel JA. First-trimester ultrasound: current uses and applications. *Semin Ultrasound CT MR.* 2008 Apr;29(2):121-31.
12. Dyson RL, Pretorius DH, Budorick NE, Johnson DD, Sklansky MS, Cantrell CJ, et al. Three-dimensional ultrasound in the evaluation of fetal anomalies. *Ultrasound Obstet Gynecol.* 2000 Sep;16(4):321-8.

13. Goldberg JD. Routine screening for fetal anomalies: expectations. *Obstet and Gynecol Clin*. 2004 Mar; 31:35-50.
14. Goncalves LF, Lee W, Espinoza J, Romero R. Three- and 4-dimensional ultrasound in obstetric practice: does it help? *J Ultrasound Med*. 2005 Dec;24(12):1599-624.
15. Goncalves LF, Nien JK, Espinoza J, Kusanovic JP, Lee W, Swope B, et al. What does 2-dimensional imaging add to 3- and 4-dimensional obstetric ultrasonography? *J Ultrasound Med*. 2006 Jun;25(6):691-9.
16. HAYES Medical Technology Directory™. Three-Dimensional and Four-Dimensional Ultrasound for High-Risk Pregnancies and Routine Screening. Lansdale PA: HAYES, Inc. ©2006 Winifred S. Hayes, Inc. 2005 Nov.
17. HAYES Medical Technology Directory™. Three-Dimensional and Four-Dimensional Ultrasound for Fetal Cardiovascular Diagnosis. Lansdale PA: HAYES, Inc. ©2006 Winifred S. Hayes, Inc. 2006 Feb.
18. HAYES Medical Technology Directory™. Three-Dimensional and Four-Dimensional Ultrasound for Diagnosis of Fetal Head Abnormalities. Lansdale PA: HAYES, Inc. ©2006 Winifred S. Hayes, Inc. 2005 Nov.
19. HAYES Medical Technology Directory™. Three-Dimensional and Four-Dimensional Ultrasound for Fetal Growth and Volume Measurements. Lansdale PA: HAYES, Inc. ©2006 Winifred S. Hayes, Inc. 2005 Dec.
20. HAYES Medical Technology Directory™. Three-Dimensional and Four-Dimensional Ultrasound for Fetal Limbs and Skeletal Structures. Lansdale PA: HAYES, Inc. ©2006 Winifred S. Hayes, Inc. 2005 Dec.
21. Institute for Clinical Systems Improvement (ICSI). Prenatal ultrasound as a screening test. ICSI Technology Assessment Report No. 16. Updated October 2002. Accessed July 6, 2005. Available at URL address: <http://www.icsi.org/knowledge/detail.asp?catID=107&itemID=607>
22. Institute for Clinical Systems Improvement (ICSI). Health Care Guideline: Routine Prenatal Care. August 2007. Accessed July 1, 2008. Available at URL address: http://www.icsi.org/prenatal_care_4/prenatal_care__routine__full_version__2.html
23. Kurjak A, Vecsek N, Hafner T, Bozek T, Funduk-Kurjak B, Ujevic, B. Prenatal diagnosis: what does four-dimensional ultrasound add? *J Perinat Med*. 2002;30(1):57-62.
24. Lapaire O, Alder J, Peukert R, Holzgreve W, Tercanli S. Two- versus three-dimensional ultrasound in the second and third trimester of pregnancy: impact on recognition and maternal-fetal bonding. A prospective pilot study. *Arch Gynecol Obstet*. 2007 Nov;276(5):475-9. Epub 2007 Apr 25.
25. Lazurus E. What's new in first trimester ultrasound. *Rad Clin of North Amer*. 2003;41(4):663-79.
26. Lee, W. 3D Fetal Ultrasonography. *Clin Obstet and Gynecol*. 2003;46(4):850-66.
27. Merz E, Welter C. 2D and 3D Ultrasound in the evaluation of normal and abnormal fetal anatomy in the second and third trimesters in a level III center. *Ultraschall Med*. 2005 Feb;26(1):9-16.
28. Michailidis GD, Papageorgiou P, Economides DL. Assessment of fetal anatomy in the first trimester using two- and three-dimensional ultrasound. *BR J Radiol*. 2002 Mar;75(891):215-9.
29. National Collaborating Centre for Women's and Children's Health. Antenatal care: routine care for the healthy pregnant woman. London: RCOG Press; 2003 Oct. 286 p. Accessed July 10, 2006. Available at URL address: http://www.guideline.gov/summary/summary.aspx?doc_id=4808&nbr=003470&string=antenatal+AND+c+are

30. National Institutes of Health (NIH). NIH Consensus Statement. Diagnostic Ultrasound Imaging in Pregnancy. Accessed July 8, 2004. Available at URL address: http://www.consensus.nih.gov/cons/041/041_statement.htm
31. Neilson JP. Ultrasound for fetal assessment in early pregnancy. *Cochrane Database Syst Rev.* 2000;(2):CD000182.
32. Pretorius DH, Borok NN, Coffer MS, Nelson TR. Three-Dimensional ultrasound in obstetrics and gynecology. *Rad Clin of North Amer.* 2001 May;39(3):499-521.
33. Rotten D, Levallant JM. Two- and three-dimensional sonographic assessment of the fetal face. 2. Analysis of cleft lip, alveolus and palate. *Ultrasound Obstet Gynecol.* 2004 Sep;24(4):402-11.
34. Rustico MA, Mastromatteo C, Grigio M, Maggioni C, Gregori D, Nicolini U. Two-dimensional vs. two-plus four-dimensional ultrasound in pregnancy and the effect on maternal emotional status: a randomized study. *Ultrasound Obstet Gynecol.* 2005 May;25(5):468-72.
35. Sailesh K, O'Brien, A. Recent developments in fetal medicine. *BMJ.* 2004;328:1002-6.
36. Scharf A, Ghazwiny MF, Steinborn A, Baier P, Sohn C. Evaluation of two-dimensional versus three-dimensional ultrasound in obstetric diagnostics: a prospective study. *Fetal Diagn Ther.* 2001 Nov-Dec;16(6):333-41.
37. Society for Maternal-Fetal Medicine (SMFM), Coding Committee. White paper on ultrasound code 76811. Announcements. Washington, DC: SMFM; May 24, 2004. Accessed July 8, 2005. Available at URL address: <http://www.smfm.org/index.cfm?zone=news&nav=viewnews&newsID=238&smfmmon=yes>.
38. Tache V, Tarsa M, Romine L, Pretorius DH. Three-dimensional obstetric ultrasound. *Semin Ultrasound CT MR.* 2008 Apr;29(2):147-55.
39. Timor-Tritsch IE, Monteagudo A. Three and four-dimensional ultrasound in obstetrics and gynecology. *Curr Opin Obstet Gynecol.* 2007 Apr;19(2):157-75.
40. Timor-Tritsch IE, Platt LD. Three-dimensional ultrasound experience in obstetrics. *Curr Opin Obstet Gynecol.* 2002 Dec;14(6):569-75.
41. U.S. Food and Drug Administration, FDA Consumer magazine. FDA cautions against ultrasound 'keepsake' images. January- February 2004. Accessed July 8, 2005. Available at URL address: http://www.fda.gov/fdac/features/2004/104_images.html
42. Verrotti C, Caforio E, Gramellini D, Nardelli GB. Ultrasound screening in second and third trimester of pregnancy: an update. *Acta Biomed.* 2007 Dec;78(3):229-32.
43. Wagner RK, Calhoun BC. The routine obstetric ultrasound examination. *Obstet Gynecol Clin North Am.* 1998 Sep;25(3):451-63.

Policy History

| <u>Pre-Merger Organizations</u> | <u>Last Review Date</u> | <u>Policy Number</u> | <u>Title</u> |
|-------------------------------------|-----------------------------|--------------------------|--|
| CIGNA HealthCare | 8/15/2008 | 0142 | Ultrasound In Pregnancy (including 3D and 4D Ultrasound) |

"CIGNA" and the "Tree of Life" logo are registered service marks of CIGNA Intellectual Property, Inc., licensed for use by CIGNA Corporation and its operating subsidiaries. All products and services are provided exclusively by such operating subsidiaries and not by CIGNA Corporation. Such operating subsidiaries include Connecticut General Life Insurance Company, CIGNA Behavioral Health, Inc., Intracorp, and HMO or service company subsidiaries of CIGNA Health Corporation and CIGNA Dental Health, Inc. In Arizona, HMO plans are offered by CIGNA HealthCare of Arizona, Inc. In California, HMO plans are offered by CIGNA HealthCare of California, Inc. and Great-West Healthcare of California, Inc. In Connecticut, HMO plans are offered by CIGNA HealthCare of Connecticut, Inc. In North Carolina, HMO plans are offered by CIGNA HealthCare of North Carolina, Inc. In Virginia, HMO plans are offered by CIGNA HealthCare Mid-Atlantic, Inc. All other medical plans in these states are insured or administered by Connecticut General Life Insurance Company.

Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.