Clinical Policy Bulletin: Ultrasound for Pregnancy

Revised February 2015

Number: 0199

Policy

I. Aetna considers ultrasounds not medically necessary if done solely to determine the fetal sex or to provide parents with a view and photograph of the fetus.

II. Aetna considers a fetal ultrasound with detailed anatomic examination medically necessary for the following indications:

A. To evaluate the fetus for amniotic band syndrome (also known as amniotic constriction band syndrome); or

B. To evaluate fetuses with soft sonographic markers of aneuploidy:
   1. Absent or hypoplastic nasal bone; or
   2. Choroid plexus cyst; or
   3. Echogenic bowel; or
   4. Echogenic intracardiac focus; or
   5. Fetal pyelectasis; or
   6. Increased nuchal translucency (fetal nuchal translucency measurement of 3.5 mm or greater in the first trimester); or
   7. Shortened long bones (femur or humerus); or

C. If there are known or suspected fetal anatomic abnormalities, including:
   1. Anatomic abnormalities due to genetic conditions (see attached ICD-9 coding); or
2. Pregnancies resulting from advanced reproductive technology (ART)*; or

3. Severe obesity (body mass index [BMI] of 35 or more) complicating pregnancy.

III. More than 1 detailed ultrasound fetal anatomic examination per pregnancy per practice is considered experimental and investigational, as there is inadequate evidence of the clinical utility of multiple serial detailed fetal anatomic ultrasound examinations during pregnancy.

IV. Aetna considers detailed ultrasound fetal anatomic examination experimental and investigational for all other indications including routine evaluation of pregnant women who are on bupropion (Wellbutrin) or levetiracetam (Keppra), pregnant women with low pregnancy-associated plasma protein A, and pregnant women who smoke or abuse cannabis. There is inadequate evidence of the clinical utility of detailed ultrasound fetal anatomic examination for indications other than evaluation of suspected fetal anatomic abnormalities. Detailed ultrasound fetal anatomic examination is not considered medically necessary for routine screening of normal pregnancy, or in the setting of maternal idiopathic pulmonary hemosiderosis.

V. Aetna considers three-dimensional (3D) and four-dimensional (4D) fetal ultrasounds experimental and investigational because of a lack of evidence that 3D and 4D ultrasounds alter management over standard two-dimensional (2D) ultrasounds such that clinical outcomes are improved.

* Assisted Reproductive Technology (ART) is a form of complex infertility treatment where the egg and sperm are fertilized outside the body and the resulting embryo is transferred back into the uterus. The most well-recognized forms of ART include in-vitro fertilization (IVF), frozen embryo transfers (FET), and intra-cytoplasmic sperm injection (ICSI).

For Aetna's policy on first trimester ultrasonographic assessment of fetal nuchal skinfold thickness, see CPB 0282 - Noninvasive Down Syndrome Screening.

See also: CPB 0106 - Fetal Echocardiograms.

Background

This policy is based in part on The American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin on Ultrasonography in Pregnancy and guidelines from the Society for Maternal-Fetal Medicine (SMFM).

Ultrasonography in pregnancy should be performed only when there is a valid medical indication. ACOG (2009) stated, "The use of either two-dimensional or three-dimensional ultrasonography only to view the fetus, obtain a picture of the fetus, or determine the fetal sex without a medical indication is inappropriate and contrary to responsible medical practice."
Indications for a first-trimester ultrasound (performed before 13 weeks and 6 days of gestation) include:

- As adjunct to chorionic villus sampling, embryo transfer, or localization and removal of an intra-uterine device
- To assess for certain fetal anomalies, such as anencephaly, in patients at high risk
- To confirm cardiac activity
- To confirm the presence of an intra-uterine pregnancy
- To diagnosis or evaluate multiple gestations
- To estimate gestational age
- To evaluate a suspected ectopic pregnancy
- To evaluate maternal pelvic or adnexal masses or uterine abnormalities
- To evaluate pelvic pain
- To evaluate suspected hydatidiform mole
- To evaluate vaginal bleeding
- To screen for fetal aneuploidy.

ACOG recommended that in the absence of specific indications, the optimal time for an obstetric ultrasound examination is between 18 to 20 weeks of gestation because anatomically complex organs, such as the fetal heart and brain, can be imaged with sufficient clarity to allow detection of many major malformations. This recommendation is based primarily on consensus and expert opinion (Level C).

ACOG stated that it may be possible to document normal structures before 18 weeks of gestation but some structures can be difficult to visualize at that time because of fetal size, position, and movement; maternal abdominal scars; and increased maternal abdominal wall thickness. A 2nd or 3rd trimester ultrasound examination, however, may pose technical limitations for an anatomic evaluation due to suboptimal imaging, and when this occurs, ACOG recommended documentation of the technical limitation and that a follow-up examination may be helpful.

ACOG uses the terms "standard" (also called basic), "limited," and "specialized" (also called detailed) to describe various types of ultrasound examinations performed during the 2nd or 3rd trimesters.

**Standard Examination**

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

- Abdomen (stomach, kidneys, bladder, umbilical cord insertion site into the fetal abdomen, umbilical cord vessel number)
- Chest (heart)
- Extremities (presence or absence of legs and arms)
- Head, face and neck (cerebellum, choroid plexus, cisterna magna, lateral cerebral ventricles, midline falx, cavum septi pellucidi, upper lip)
- Sex (medically indicated in low-risk pregnancies only for the evaluation of multiple gestations).
Spine (cervical, thoracic, lumbar, and sacral spine).

**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 1st trimester to evaluate interval growth, estimate amniotic fluid volume, evaluate the cervix, and 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.

Indications for a 2nd and 3rd trimester ultrasound include the following:

- Adjunct to amniocentesis or other procedure
- Adjunct to cervical cerclage placement
- Adjunct to external cephalic version
- Determination of fetal presentation
- Estimation of gestational age
- Evaluation for abnormal biochemical markers
- Evaluation for fetal well-being
- Evaluation for premature rupture of membranes of premature labor
- Evaluation in those with a history of previous congenital anomaly
- Evaluation of abdominal and pelvic pain
- Evaluation of cervical insufficiency
- Evaluation of fetal condition in late registrants for prenatal care
- Evaluation of fetal growth
- Evaluation of pelvic mass
- Evaluation of suspected amniotic fluid abnormalities
- Evaluation of suspected ectopic pregnancy
- Evaluation of suspected fetal death
- Evaluation of suspected multiple gestation
- Evaluation of suspected placental abruption
- Evaluation of suspected uterine abnormality
- Evaluation of vaginal bleeding
- Examination of suspected hydatidiform mole
- Follow-up evaluation of a fetal anomaly
- Follow-up evaluation of placental location for suspected placenta previa
- Significant discrepancy between uterine size and clinical dates
- To assess for findings that may increase the risk of aneuploidy
- To screen for fetal anomalies.
The Society for Maternal-Fetal Medicine (SMFM) has stated that a fetal ultrasound with detailed anatomic examination (CPT 76811) is not necessary as a routine scan for all pregnancies (SMFM, 2004). Rather, this scan is necessary for a known or suspected fetal anatomic or genetic abnormality (i.e., previous anomalous fetus, abnormal scan this pregnancy, etc.), or increased risk for fetal abnormality (e.g. AMA, diabetic, fetus at risk due to teratogen or genetics, abnormal prenatal screen). Thus, the SMFM has stated that 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 (SMFM, 2004; SMFM, 2012).

SMFM has also determined that no more than 1 fetal ultrasound with detailed anatomic examination is necessary per pregnancy, per practice, when medically necessary (SMFM, 2004; SMFM, 2012). Once this detailed fetal anatomical examination is done, a second one should not be performed unless there are extenuating circumstances with a new diagnosis. The SMFM has stated that it is appropriate to repeat the detailed fetal anatomical ultrasound examination when a patient is seen by another maternal-fetal medicine specialist practice, for example, for a second opinion on a fetal anomaly, or if the patient is referred to a tertiary center in anticipation of delivering an anomalous fetus at a hospital with specialized neonatal capabilities.

A focused ultrasound assessment is sufficient for follow-up to provide a re-examination of a specific organ or system known or suspected to be abnormal, or when doing a focused assessment of fetal size by measuring the bi-parietal diameter, abdominal circumference, femur length, or other appropriate measurements (SMFM, 2004).

An ultrasound without detailed anatomic examination is appropriate for a fetal maternal evaluation of the number of fetuses, amniotic/chorionic sacs, survey of intra-cranial, spinal and abdominal anatomy, evaluation of a 4-chamber heart view, assessment of the umbilical cord insertion site, assessment of amniotic fluid volume, and evaluation of maternal adenexa when visible and appropriate (SMFM, 2004).

Amniotic band sequence refers to a highly variable spectrum of congenital anomalies that occur in association with amniotic bands. Amniotic banding affects approximately 1 in 1,200 live births. It is also believed to be the cause of 178 in 10,000 miscarriages. Up to 50 % of cases have other congenital anomalies including cleft lip, cleft palate, and clubfoot deformity. Hand and finger anomalies occur in up to 80 %. The diagnosis is based upon the presence of characteristic structural findings on prenatal ultrasound or postnatal physical examination. The diagnosis should be suspected when limb amputations or atypical body wall or craniofacial defects are present, or when bands of amnion are seen crossing the gestational sac and adherent to the fetus.

In a practice bulletin on screening for fetal chromosomal anomalies, ACOG (2007) has stated that patients who have a fetal nuchal translucency measurement of 3.5 mm or greater in the 1st trimester, despite a negative result on an aneuploidy screen, normal fetal chromosomes, or both, should be offered a targeted ultrasound examination, fetal echocardiogram, or both, because such fetuses are
at a significant risk for non-chromosomal anomalies, including congenital heart defects, abdominal wall defects, diaphragmatic hernias, and genetic syndromes.

The ACOG practice bulletin on the use of psychiatric medications during pregnancy and lactation (2008) stated that atypical anti-depressants are non-tricyclic anti-depressants and non-selective serotonin reuptake inhibitors antidepressants that work by distinct pharmacodynamic mechanisms. The atypical anti-depressants include bupropion, duloxetine, mirtazapine, nefazodone, and venlafaxine. The limited data of fetal exposure to these anti-depressants do not suggest an increased risk of fetal anomalies or adverse pregnancy events. In the one published study of bupropion exposure in 136 patients, a significantly increased risk of spontaneous abortion, but not an increased risk of major malformations, was identified. In contrast, the bupropion registry maintained at GlaxoSmithKline has not identified any increased risk of spontaneous abortion, although these data have not undergone peer review.

In a Cochrane review, Stampalija and colleagues (2010) evaluated the effects on pregnancy outcome, and obstetric practice, of routine utero-placental Doppler ultrasound in 1st and 2nd trimester of pregnancy in pregnant women at high- and low-risk of hypertensive complications. These investigators searched the Cochrane Pregnancy and Childbirth Group's Trials Register (June 2010) and the reference lists of identified studies. Randomized and quasi-randomized controlled trials of Doppler ultrasound for the investigation of utero-placental vessel waveforms in 1st and 2nd trimesters compared with no Doppler ultrasound were included in this review. These researchers excluded studies where uterine vessels have been assessed together with fetal and umbilical vessels. Two authors independently assessed the studies for inclusion, assessed risk of bias and carried out data extraction. They found 2 studies involving 4,993 participants. The methodological quality of the trials was good. Both studies included women at low-risk for hypertensive disorders, with Doppler ultrasound of the uterine arteries performed in the 2nd trimester of pregnancy. In both studies, pathological finding of uterine arteries was followed by low-dose aspirin administration. They identified no difference in short-term maternal and fetal clinical outcomes; identified no randomized studies assessing the utero-placental vessels in the 1st trimester or in women at high-risk for hypertensive disorders. The authors concluded that present evidence failed to show any benefit to either the baby or the mother when utero-placental Doppler ultrasound was used in the 2nd trimester of pregnancy in women at low-risk for hypertensive disorders. However, this evidence can not be considered conclusive with only 2 studies included. There were no randomized studies in the 1st trimester, or in women at high-risk. They stated that more research is needed to examine if the use of utero-placental Doppler ultrasound may improve pregnancy outcome.

Three-Dimensional and Four-Dimensional Ultrasound in Obstetrics

Three-dimensional (3D) ultrasound can furnish a 3D image of the fetus. To create a 3D image, a transducer takes a series of thin slices of the subject, and a computer translates these images and presents them in 3 dimensions.

Proponents of 3D ultrasound scanning have argued that volumetric measurements from 3D ultrasound scan are more accurate and that both clinicians and parents can better appreciate a certain abnormality with a 3D scan than a standard 2-
dimensional (2D) scan. In addition, there is the possibility of increasing psychological bonding between the parents and the baby (Ji et al, 2005).

In the diagnosis of congenital anomalies, there is evidence to suggest that smaller defects such as spina bifida, cleft lip and palate, and polydactyly may be more lucidly demonstrated with 3D ultrasound (Gonçalves et al, 2005; Kurjak et al, 2007). Other more subtle features such as low-set ears, facial dysmorphia or clubblying of feet may be better assessed, which has the potential to lead to more effective diagnoses of chromosomal abnormalities.

In addition, the use of 3D technology can reduce scanning time while maintaining adequate visualization of the fetus in obstetrical ultrasound (Benacerraf et al, 2005; Benacerraf et al, 2006).

Jones et al (2010) examined the intra- and inter-observer reproducibility of 3D power Doppler (3DPD) data acquisition from women at 12 weeks gestation, which were then subsequently measured by a single observer. Women with an uncomplicated, viable singleton pregnancy were scanned between 12 + 0 and 13 + 6 weeks gestations with a Voluson 730 Expert. 3DPD data were acquired of the whole placenta by 2 observers: the first observer captured 2 data sets and the second a single dataset. Each data set was analysed using VOCAL in the A plane with 9 degree rotation steps. A total of 18 low-risk women were recruited with a total of 54 data sets analyzed. The intra-class correlation coefficient (ICC) was highest for the vascular indices vascularization index (VI) and vascularization-flow index (VFI), greater than 0.75. Intra-class correlation coefficient for flow index (FI) showed moderate correlation at 0.47 to 0.65. Bland Altman plots showed the most precise vascular index to be the FI (-15 % to 10 % for inter-observer agreement). There was no bias between datasets. Prospective studies are now required to identify if this analysis tool and method is sensitive enough to recognise patients with early-onset placental dysfunction.

More recently, 4-dimensional (4D) or dynamic 3D scanners have come on the market, with the attraction of being able to look at fetal movements. These have also been referred to as "reassurance scans" or "entertainment scans." Proponents argue that 4D scans may have an important catalytic effect for mothers to bond to their babies before birth. However, the impact of 4D scans on diagnosis and management of fetal abnormalities is unknown.

Three-dimensional ultrasound appears to have been useful in research on fetal embryology. However, there is no evidence that the results of 3D ultrasound alters clinical management over standard 2D ultrasound such that clinical outcomes are improved. Whether 3D ultrasound will provide unique, clinically relevant information remains to be seen.

Current guidelines on ultrasonography in pregnancy from ACOG (2009) state: "The technical advantages of 3-dimensional ultrasonography include its ability to acquire and manipulate an infinite number of planes and to display ultrasound planes traditionally inaccessible by 2-dimensional ultrasonography. Despite these technical advantages, proof of a clinical advantage of 3-dimensional ultrasonography in prenatal diagnosis in general is still lacking. Potential areas of promise include fetal facial anomalies, neural tube defects, and skeletal malformations where 3-dimensional ultrasonography may be helpful in diagnosis.
Ultrasound for Pregnancy

as an adjunct to, but not a replacement for, 2-dimensional ultrasonography. Until clinical evidence shows a clear advantage to conventional 2-dimensional ultrasonography, 3-dimensional ultrasonography is not considered a required modality at this time."

Yagel et al (2009) described the state of the science of 3D/4D ultrasound (3D/4D US) applications in fetal medicine. They noted that 3D/4D US applications are many and varied. Their use in fetal medicine varies with the nature of the tissue to be imaged and the challenges each organ system presents, versus the advantages of each ultrasound application. The investigators stated that 3D/4D US has been extensively applied to the study of the fetus. Fetal applications include all types of anatomical assessment, morphometry and volumetry, as well as functional assessment. The authors concluded that 3D/4D US provides many advantages in fetal imaging; however, its contribution to improving the accuracy of fetal scanning over rates achieved with 2D US, remains to be established.

In a prospective study, Chen et al (2009) examined the feasibility and reproducibility of measurements of nasal bone length using a 3D US in the 1st trimester. A total of 118 consecutive pregnant women attending for Down syndrome screening at 11- to 13(+6)-week were recruited. They had successful fetal nasal bone measurement by 2D US by 4 operators. Three-dimensional volumes were recorded in the mid-sagittal plane of fetal profile by the 5th operator and examined using multi-planar techniques. Another independent investigator randomly compared his measurements with 1 of the 4 operators. In the subsequent 3D examination, the nasal bone length could be examined in 94 cases (79.7 %). The mean difference between the 2D and 3D measurements was 0.19 mm [95 % confidence interval (CI): 0.08 to 0.31] (p < 0.05). Limits of agreement were -0.73 to 1.11. The mean differences between these 2 observers were 0.66 mm (95 % CI: -0.47 to 0.86) (p < 0.05). The authors concluded that there was significant inter-method difference between the results obtained by 2D and 3D, as well as substantial inter-observer variation in 3D measurement of fetal nasal bone length in the 1st trimester. They stated that independent 3D measurement of nasal bone offers no additional advantages over 2D US.

Kurjak and colleagues (2010) stated that an evolving challenge for obstetricians is to better define normal and abnormal fetal neurological function in utero in order to better predict ante-natally which fetuses are at risk for adverse neurological outcome. In a multi-center study, these investigators examined the use of 4D US in the assessment of fetal neurobehavior in high-risk pregnancies. Pre-natal neurological assessment was carried out in high-risk fetuses using 4D US applying the recently developed Kurjak ante-natal neurodevelopmental test (KANET). Post-natal neurological assessment was performed using Amiel Tison's neurological assessment at term (ATNAT) for all live-borns and general movement (GM) assessment for those with borderline and abnormal ATNAT. Inclusion criteria were met by 288 pregnant women in 4 centers of whom 266 gave birth to a live-born baby. It was revealed that 234 fetuses were neurologically normal, 7 abnormal and 25 borderline. Out of 7 abnormal fetuses ATNAT was borderline in 5 and abnormal in 2, whereas GM assessment was abnormal in 5 and definitely abnormal in 2. Out of 25 KANET borderline fetuses, ATNAT was normal in 7, borderline in 17 and abnormal in 1, whereas the GM assessment was as follows: normal optimal in 4, normal suboptimal in 20, and abnormal in 1. In summary, out
of 32 borderline and abnormal fetuses, ATNAT was normal in 7, borderline in 22 and abnormal in 3; GM assessment was normal optimal in 4, normal suboptimal in 20, abnormal in 6 and definitely abnormal in 2. The authors concluded that 4D US requires further studies before being recommended for wider clinical practice.

Hata et al (2011) presented 2 cases of amniotic band syndrome diagnosed using 2D ultrasound with 3D/4D ultrasound in early pregnancy. In case 1, at 13 weeks' gestation, multiple amniotic bands, acrania, the absence of fingers and amputation of the toes bilaterally were clearly shown using trans-vaginal 3D/4D ultrasound. In case 2, at 15 weeks' gestation, several amniotic bands, acrania and a cleft lip were depicted with trans-abdominal 3D/4D ultrasound. The spatial relationship between the amniotic bands and the fetus was clearly visualized and easily discernible by 3D/4D ultrasound. The parents and families could readily understand the fetal conditions and undergo counseling; they then choose the option of termination of pregnancy. The authors concluded that 3D/4D ultrasound has the potential to be a supplement to conventional 2D ultrasound in evaluating amniotic band syndrome.

In a pilot study, Antsaklis et al (2011) evaluated the use of 3D ultrasonography as an alternative for examining fetal anatomy and nuchal translucency (NT) in the first trimester of pregnancy. A total of 199 low-risk pregnant women undergoing 1st trimester ultrasound scan for fetal anomalies were included in this study. The NT and fetal anatomy were evaluated by 3D ultrasonography after the standard 2D examination. The gold standard in this study was the 2D ultrasonography. In some of the evaluated parameters, the 3D method approaches the conventional 2D results. These parameters are the crown-rump length (CRL), the skull-brain anatomy (93.5 %), the spine (85.4 %), the upper limbs (88.4 %) and the lower limbs (87.9 %) and the examination of the fetal abdomen (98.5 %). Some of the anatomic parameters under evaluation revealed a statistically significant difference in favor of the 2D examination. During the 3D examination the nasal bone was identified in 62.1 % of the cases, the stomach in 85.9 %, and the urinary bladder in 57.3 % of the cases. The NT was assessed accurately in 50 % of the cases compared to 2D examination. The authors concluded that the 3D ultrasound is insufficient for the detailed fetal anatomy examination during the 1st trimester of pregnancy.

An UpToDate review on "Idiopathic pulmonary hemosiderosis" (Milman, 2012) does not mention the use of detailed ultrasound fetal anatomic examination.

According to the Product Insert of Keppra (Pregnancy Category C), there are no adequate and well-controlled studies in pregnant women. In animal studies, levetiracetam produced evidence of developmental toxicity, including teratogenic effects, at doses similar to or greater than human therapeutic doses. Keppra should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. As with other anti-epileptic drugs, physiological changes during pregnancy may affect levetiracetam concentration. There have been reports of decreased levetiracetam concentration during pregnancy. Discontinuation of anti-epileptic treatments may result in disease worsening, which can be harmful to the mother and the fetus.

In a Cochrane review, Grivell et al (2012) noted that policies and protocols for fetal surveillance in the pregnancy where impaired fetal growth is suspected vary
widely, with numerous combinations of different surveillance methods. These researchers evaluated the effects of ante-natal fetal surveillance regimens on important peri-natal and maternal outcomes. These investigators searched the Cochrane Pregnancy and Childbirth Group's Trials Register (February 29, 2012). Randomized and quasi-randomized trials comparing the effects of described ante-natal fetal surveillance regimens were selected for analysis. Review authors independently assessed trial eligibility and quality and extracted data. They included 1 trial of 167 women and their babies. This trial was a pilot study recruiting alongside another study, therefore, a separate sample size was not calculated. The trial compared a twice-weekly surveillance regimen (biophysical profile, non-stress tests, umbilical artery and middle cerebral artery Doppler and uterine artery Doppler) with the same regimen applied fortnightly (both groups had growth assessed fortnightly). There were insufficient data to assess this review's primary infant outcome of composite peri-natal mortality and serious morbidity (although there were no peri-natal deaths) and no difference was seen in the primary maternal outcome of emergency caesarean section for fetal distress (risk ratio (RR) 0.96; 95 % CI: 0.35 to 2.63). In keeping with the more frequent monitoring, mean gestational age at birth was 4 days less for the twice-weekly surveillance group compared with the fortnightly surveillance group (mean difference (MD) -4.00; 95 % CI: -7.79 to -0.21). Women in the twice-weekly surveillance group were 25 % more likely to have induction of labor than those in the fortnightly surveillance group (RR 1.25; 95 % CI: 1.04 to 1.50). The authors concluded that there is limited evidence from randomized controlled trials to inform best practice for fetal surveillance regimens when caring for women with pregnancies affected by impaired fetal growth. They stated that more studies are needed to evaluate the effects of currently used fetal surveillance regimens in impaired fetal growth.

A choroid plexus cyst is a small fluid-filled structure within the choroid of the lateral ventricles of the fetal brain. Choroid plexus cysts are identified in approximately 1% to 2% of fetuses in the second trimester and they occur equally in male and female fetuses. According to the Society for Maternal-Fetal Medicine (SMFM, 2013), when a choroid plexus cyst is identified, the presence of structural malformations and other sonographic markers of aneuploidy should be assessed with a detailed fetal anatomic survey performed by an experienced provider. Detailed examination of the fetal heart (4-chamber view and outflow tracts view) and hands (for “clenching” or other abnormal positioning) should be included, as well as fetal biometry for assessment of intrauterine growth restriction. If no other sonographic abnormalities are present, the choroid plexus cyst is considered isolated.

Gindes et al (2013) evaluated the ability of 3D ultrasound for demonstrating the palate of fetuses at high-risk for cleft palate. A total of 57 fetuses at high-risk for cleft palate were referred to specialist for ultrasonography at 12 to 40 weeks’ gestation. A detailed assessment of palate was made using both 2D and 3D ultrasounds on the axial plane. Antenatal diagnoses were compared with postnatal findings. Cleft palate was suspected in 13 (22.8 %); a normal palate was demonstrated in 38 (67 %), and in 6 (10.2 %), the palate view could not be obtained. Mean gestational age at the first visit was 27 weeks 6 days (range of 12 to 40 weeks 3 days). Examination after delivery revealed that 1 of the 38 fetuses with presumed normal palate had a cleft hard palate, and 1 had a cleft soft palate.
false negative = 5 %). Among the 13 fetuses with suspected cleft palate, 3 had an intact palate (false-positive = 23 %). Sensitivity, specificity, positive-predictive value, and negative-predictive value of detection of palatal clefts were 71.4 %, 91.9 %, 62.5 %, and 94.4 %, respectively. The authors concluded that using 3D ultrasounds, they diagnosed a cleft palate in 83 % of high-risk cases, with 5 % false negative. They stated that 3D technology might produce some technical artifacts resulting in a 23 % false-positive rate.

Kanenishi et al (2013) evaluated the frequency of fetal facial expressions at 25 to 27 weeks of gestation using 4D ultrasound. A total of 24 normal fetuses were examined using 4D ultrasound. The face of each fetus was recorded continuously for 15 mins. The frequencies of tongue expulsion, yawning, sucking, mouthing, blinking, scowling, and smiling were assessed and compared with those observed at 28 to 34 weeks of gestation in a previous study. Mouthing was the most common facial expression at 25 to 27 weeks of gestation; the frequency of mouthing was significantly higher than that of the other 6 facial expressions (p < 0.05). Yawning was significantly more frequent than the other facial expressions, apart from mouthing (p < 0.05). The frequencies of yawning, smiling, tongue expulsion, sucking, and blinking differed significantly between 25 to 27 and 28 to 34 weeks (p < 0.05). The authors concluded that the results indicated that facial expressions can be used as an indicator of normal fetal neurologic development from the 2nd to the 3rd trimester. They stated that 4D ultrasound may be a valuable tool for assessing fetal neurobehavioral development during gestation. These preliminary findings need to be validated by well-designed studies.

Votino et al (2013) evaluated prospectively the use of 4D spatio-temporal image correlation (STIC) in the evaluation of the fetal heart at 11 to 14 weeks' gestation. The study involved off-line analysis of 4D-STIC volumes of the fetal heart acquired at 11 to 14 weeks' gestation in a population at high-risk for congenital heart disease (CHD). Regression analysis was used to investigate the effect of gestational age, maternal body mass index, quality of the 4D-STIC volume, use of a trans-vaginal versus trans-abdominal probe and use of color Doppler ultrasonography on the ability to visualize separately different heart structures. The accuracy in diagnosing CHD based on early fetal echocardiography (EFE) using 4D-STIC versus conventional 2D ultrasound was also evaluated. A total of 139 fetuses with a total of 243 STIC volumes were included in this study. Regression analysis showed that the ability to visualize different heart structures was correlated with the quality of the acquired 4D-STIC volumes. Independently, the use of a trans-vaginal approach improved visualization of the 4-chamber view, and the use of Doppler improved visualization of the outflow tracts, aortic arch and inter-ventricular septum. Follow-up was available in 121 of the 139 fetuses, of which 27 had a confirmed CHD. A diagnosis based on EFE using 4D-STIC was possible in 130 (93.5 %) of the 139 fetuses. Accuracy in diagnosing CHD using 4D-STIC was 88.7 %, and the results of 45 % of the cases were fully concordant with those of 2D ultrasound or the final follow-up diagnosis. Early fetal echocardiography using 2D ultrasound was possible in all fetuses, and accuracy in diagnosing CHD was 94.2 %; 5 of the 7 false-positive or false-negative cases were minor CHD. The authors concluded that in fetuses at 11 to 14 weeks' gestation, the heart can be evaluated offline using 4D-STIC in a large number of cases, and this evaluation is more successful the higher the quality of the acquired volume.
Moreover, they stated that 2D ultrasound remains superior to 4D-STIC at 11 to 14 weeks, unless volumes of good to high quality can be obtained.

Ahmed (2014) stated that CHD is the commonest congenital anomaly. It is much more common than chromosomal malformations and spinal defects. Its’ estimated incidence is about 4 to 13 per 1,000 live births. Congenital heart disease is a significant cause of fetal mortality and morbidity. Antenatal diagnosis of CHD is extremely difficult and requires extensive training and expertise. The detection rate of CHD is very variable and it ranged from 35 to 86 % in most studies. In the light of the above, the introduction of the new 3D/4D based STIC is highly welcomed to improve antenatal detection of CHD. Spatio-temporal image correlation is an automated device incorporated into the ultrasound probe and has the capacity to perform slow sweep to acquire a single 3D volume. This acquired volume is composed of a great number of 2D frames. This volume can be analyzed and re-analyzed as required to demonstrate all the required cardiac views. It also provides the examiner with the ability to review all images in a looped cine sequence. The author concluded that this technology has the ability to improve the ability to examine the fetal heart in the acquired volume and decrease examination time; it is a promising tool for the future.

Tonni et al (2014) described the application of a novel 3D ultrasound reconstructing technique (OMNIVIEW) that may facilitate the evaluation of cerebral midline structures at the 2nd trimester anatomy scan. Fetal cerebral midline structures from 300 consecutive normal low-risk pregnant women were studied prospectively by 2D and 3D ultrasound between 19 to 23 weeks of gestation. All the newborn infants underwent pediatric follow-up and were considered normal up to 2 years of life. In addition, 5 confirmed pathologic cases were evaluated and the abnormal features using this technique were described in this clinical series. Offline volume data sets displaying the corpus callosum and the cerebellar vermis anatomy were accurately reconstructed in 98.5 % and 96 % of cases from sagittal and axial planes, respectively. For pathological cases, an agreement rate of 0.96 and 0.91 for mid-sagittal and axial planes, respectively, was observed. The authors concluded that this study demonstrated the feasibility of including 3D ultrasound as an adjunct technique for the evaluation of cerebral midline structures in the 2nd trimester fetus. Moreover, they stated that future prospective studies are needed to evaluate if the application of this novel 3D reconstructing technique as a step forward following 2D second trimester screening scan will improve the prenatal detection of cerebral midline anomalies in the low-risk pregnant population.

Sharp et al (2014) noted that fetal assessment following PPROM may result in earlier delivery due to earlier detection of fetal compromise. However, early delivery may not always be in the fetal or maternal interest, and the effectiveness of different fetal assessment methods in improving neonatal and maternal outcomes is uncertain. In a Cochrane review, these researchers examined the effectiveness of fetal assessment methods for improving neonatal and maternal outcomes in PPROM. Examples of fetal assessment methods that would be eligible for inclusion in this review include fetal cardiotocography, fetal movement counting and Doppler ultrasound. They searched the Cochrane Pregnancy and Childbirth Group’s Trials Register (June 30, 2014) and reference lists of retrieved studies. Randomized controlled trials (RCTs) comparing any fetal assessment
methods, or comparing one fetal assessment method to no assessment were selected for analysis. Two review authors independently assessed trials for inclusion into the review. The same 2 review authors independently assessed trial quality and independently extracted data. Data were checked for accuracy. These researchers included 3 studies involving 275 women (data reported for 271) with PPROM at up to 34 weeks' gestation. All 3 studies were conducted in the United States. Each study investigated different methods of fetal assessment. One study compared weekly endovaginal ultrasound scans with no assessment (n = 93), one compared amniocentesis with no assessment (n = 47), and one compared daily non-stress testing with daily modified biophysical profiling (n = 135). These investigators were unable to perform a meta-analysis, but were able to report data from individual studies. There was no convincing evidence of increased risk of neonatal death in the group receiving endovaginal ultrasound scans compared with the group receiving no assessment (risk ratio (RR) 7.30, 95% CI: 0.39 to 137.54; 1 study, 92 women), or in the group receiving amniocentesis compared with the group receiving no amniocentesis (RR 1.00, 95% CI: 0.07 to 15.00; 1 study, 44 women). For both these interventions, these researchers inferred that there were no fetal deaths in the intervention or control groups. The study comparing daily non-stress testing with daily modified biophysical profiling did not report fetal or neonatal death. Primary outcomes of maternal death and serious maternal morbidity were not reported in any study. Overall, there were few statistically significant differences in outcomes between the comparisons. The overall quality of evidence was poor, because participant blinding was not possible for any study. The authors concluded that there is insufficient evidence on the benefits and harms of fetal assessment methods for improving neonatal and maternal outcomes in women with PPROM to draw firm conclusions. The overall quality of evidence that does exist is poor. They stated that further high-quality RCTs are needed to guide clinical practice.

Appendix

According to the Society for Maternal Fetal Medicine (SMFM, 2012), a detailed fetal anatomic ultrasound (CPT code 76811) includes all of the components of the routine fetal ultrasound (CPT code 76805), plus a detailed fetal anatomical survey. The SMFM (2012) has stated that the following are fetal and maternal anatomical components for the detailed fetal anatomic ultrasound (CPT code 76811). Not all components will be required. Components considered integral to the code are marked (*).

Evaluation of intracranial, facial and spinal anatomy:

- Lateral ventricles*, third and fourth ventricles
- Cerebellum*, integrity of lobes*, vermis*
- Cavum septum pellucidum
- Cisterna magna measurement*
- Nuchal thickness measurement (15-20 weeks)*
- Integrity of cranial vault
- Examination of brain parenchyma, (e.g. for calcifications)
- Ear position, size
- Face
- Upper lip integrity*
Palate*
Facial profile*
Evaluation of the neck (e.g. for masses)

**Evaluation of the chest:**

Presence of masses*
Pleural effusion*
Integrity of both sides of the diaphragm*
Appearance of ribs

**Evaluation of the heart:**

Cardiac location and axis*
Outflow tracts*

**Evaluation of the abdomen:**

Bowel *
Adrenal glands
Gallbladder
Liver
Spleen
Ascites*
Masses

**Evaluation of genitalia:**

Gender (whether or not parents wish to know sex of child)

**Evaluation of limbs:**

Number, size, and architecture*
Anatomy and position of hands*
Anatomy and position of feet*

**Evaluation of the placenta and cord:**

Placental cord insertion site*
Placental masses*
Umbilical-cord (number of arteries)

**Evaluation of amniotic fluid:**

Amniotic Fluid Index*
Evaluation of the cervix (Not required)
Evaluation of the maternal adnexa when feasible*

Note: If any of the required fetal or maternal components are non-visualized due to fetal position, late gestational age, maternal habitus, etc., it must be clearly noted in the ultrasound report in order to meet the requirements to bill for the service (SMFM, 2012).

Follow-up ultrasound performed after a detailed anatomic ultrasound (CPT code 76811), should be reported as CPT 76816 (Ultrasound, pregnant uterus, real time...
with image documentation, follow-up) (SMFM, 2012). This includes performing a focused assessment of fetal size by measuring the BPD, abdominal circumference, femur length, or other appropriate measurements, or a detailed re-examination of a specific organ or system known or suspected to be abnormal.

CPT code 76805 (Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (greater than or equal to 14 weeks 0 days), would be reported to determine the number of fetuses, amniotic/chorionic sacs, survey of intracranial, spinal, and abdominal anatomy, evaluation of a 4-chamber heart view, assessment of the umbilical cord insertion site, assessment of amniotic fluid volume, and evaluation of maternal adnexa when visible when appropriate (SMFM, 2012).

CPT code 76805 and ICD-9 code V28.3 are reported when performing a routine screening ultrasound (no maternal or fetal indications or abnormal findings) (SMFM, 2012).

**CPT Codes / HCPCS Codes / ICD-9 Codes**

**Routine fetal ultrasounds:**

**CPT codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>76801</td>
<td>Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester (&lt;14 weeks 0 days), transabdominal approach; single or first gestation</td>
</tr>
<tr>
<td>+ 76802</td>
<td>each additional gestation (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>76805</td>
<td>Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (&gt; or = 14 weeks 0 days), transabdominal approach; single or first gestation [second and/or third trimester]</td>
</tr>
<tr>
<td>+ 76810</td>
<td>each additional gestation (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>76815</td>
<td>Ultrasound, pregnant uterus, real time with image documentation, limited (e.g., fetal heart beat, placental location, fetal position, and/or qualitative amniotic fluid volume), 1 or more fetuses</td>
</tr>
<tr>
<td>76816</td>
<td>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</td>
</tr>
</tbody>
</table>
ICD-9 codes covered (for routine fetal ultrasounds) if selection criteria are met:

640.00 - 676.94 Complications of pregnancy and childbirth
676.94

V22.0 - V23.9 Supervision of pregnancy

V28.3 Encounter for routine screening for malformation using ultrasonics

V28.4 Screening for fetal growth retardation using ultrasonics

V28.81 Encounter for fetal anatomic survey

Detailed fetal ultrasounds:

CPT codes covered if selection criteria are met:

76811 Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach; single or first gestation [second and/or third trimester]

+ 76812 each additional gestation (List separately in addition to code for primary procedure)

Other specified HCPCS codes related to the CPB:

J1953 Other specified HCPCS codes related to the CPB:

ICD-9 codes covered (for detailed fetal ultrasounds) if selection criteria are met:

278.01 Morbid obesity [severe obesity with a BMI of 35 or>]

647.43 Malaria complicating pregnancy, antepartum condition or complication

647.53 Maternal rubella, antepartum

647.63 Other viral diseases complicating pregnancy, antepartum condition or complication

647.83 Other specified infectious and parasitic diseases complicating pregnancy, antepartum condition or complication

648.03 Diabetes mellitus complicating pregnancy, antepartum condition or complication

648.33 Drug dependence complicating pregnancy, antepartum condition or complication

648.53 Congenital cardiovascular disorders complicating pregnancy, antepartum condition or complication
651.03  Twin pregnancy, antepartum condition or complication
651.13  Triplet pregnancy, antepartum condition or complication
651.23  Quadruplet pregnancy, antepartum condition or complication
651.33  Twin pregnancy with fetal loss and retention of one fetus, antepartum condition or complication
651.43  Triplet pregnancy with fetal loss and retention of one or more fetuses, antepartum condition or complication
651.53  Quadruplet pregnancy with fetal loss and retention of one or more fetuses, antepartum condition or complication
651.63  Other multiple pregnancy with fetal loss and retention of one or more fetuses, antepartum
653.63  Hydrocephalic fetus causing disproportion complicating pregnancy, antepartum condition or complication
653.73  Other fetal abnormality causing disproportion complicating pregnancy, antepartum condition or complication
655.03  Central nervous system malformation in fetus complicating pregnancy, antepartum condition or complication
655.13  Chromosomal abnormality in fetus complicating pregnancy, antepartum condition or complication
655.23  Hereditary disease in family possibly affecting fetus complicating pregnancy, antepartum condition or complication
655.33  Suspected damage to fetus from viral disease in the mother complicating pregnancy, antepartum condition or complication
655.43  Suspected damage to fetus from other disease in the mother complicating pregnancy, antepartum condition or complication
655.53  Suspected damage to fetus from drugs, complicating pregnancy, antepartum condition or complication
655.63  Suspected damage to fetus from radiation, complicating pregnancy, antepartum condition or complication
655.83  Other known or suspected fetal abnormality, not elsewhere classified, complicating pregnancy, antepartum condition or complication
655.93  Unspecified known or suspected fetal abnormality affecting management of mother, antepartum condition or complication
656.13  Rhesus isoimmunization complicating pregnancy, antepartum condition or complication
656.23  Isoimmunization from other and unspecified blood-group incompatibility, antepartum condition or complication
656.53  Poor fetal growth complicating pregnancy, antepartum condition or complication
657.03  Polyhydramnios complicating pregnancy antepartum condition or complication
658.03  Oligohydramnios complicating pregnancy, antepartum condition or complication
659.53  Elderly primigravida complicating pregnancy, antepartum condition or complication
659.63  Elderly multigravida complicating pregnancy, antepartum condition or complication
659.73  Abnormality in fetal heart rate or rhythm, antepartum condition or complication
663.83  Other umbilical cord complications, antepartum condition or complication
665.93  Unspecified obstetrical trauma, antepartum condition or complication
742.4  Other specified anomalies of brain [choroid plexus cyst]
793.6  Nonspecific abnormal findings on radiological and other examinations of abdominal area, including retroperitoneum
793.99  Other nonspecific abnormal findings on radiological and other examinations of body structure
V23.81  Supervision of high-risk pregnancy of elderly primigravida
V23.82  Supervision of high-risk pregnancy of elderly multigravida
V23.85  Pregnancy resulting from assisted reproductive technology
V28.1  Screening for raised alpha-fetoprotein levels in amniotic fluid
V28.2  Other antenatal screening based on amniocentesis
V85.35 - V85.45  Body mass index 35.0 - 70 and over, adult

ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):

305.1  Tobacco use disorder
305.20 - 305.23  Cannabis abuse
516.1  Idiopathic pulmonary hemosiderosis

649.00 - 649.04  Tobacco use disorder complicating pregnancy, childbirth, and the puerperium

649.40 - 649.44  Epilepsy complicating pregnancy, childbirth or the puerperium
[Keppra]

ICD-9 codes related to the CPB:

649.13  Obesity complicating pregnancy, childbirth or the puerperium
[covered for severe obesity only]

Three-dimensional (3D) and four-dimensional (4D) fetal ultrasounds:

There are no specific codes for 3D and 4D fetal ultrasound

CPT codes not covered for indications listed in the CPB:

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  requiring image postprocessing on an independent workstation

The above policy is based on the following references:


42. ACOG Committee on Practice Bulletins -- Obstetrics. ACOG Practice Bulletin: Clinical management guidelines for obstetrician-gynecologists number 92, April 2008 (replaces practice bulletin number 87, November


55. Milman N. Idiopathic pulmonary hemosiderosis. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed October 2012.


64. Benacerraf CR. Sonographic findings associated with fetal aneuploidy. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed February 2015.