

MEDICAL POLICY

SUBJECT: OBSTETRICAL ULTRASOUND	EFFECTIVE DATE: 02/28/13 ARCHIVED DATE: 02/27/14 EDITED DATE: 02/26/15, 02/25/16, 02/23/17, 2/22/18, 06/28/18
POLICY NUMBER: 6.01.42 CATEGORY: Contract Clarification	PAGE: 1 OF: 4
<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

- I. One obstetric ultrasound during pregnancy to allow the obstetrician to determine fetal size, age and number is considered **medically appropriate** in an uncomplicated pregnancy in the first trimester (e.g., 1-12 weeks).
- II. One fetal nuchal translucency obstetric ultrasound is considered **medically appropriate** during an uncomplicated pregnancy between 11 and 14 weeks gestation.
- III. One obstetric ultrasound during pregnancy to allow the obstetrician to determine fetal size, location, age and number is considered **medically appropriate** in an uncomplicated pregnancy between 18 - 22 weeks of gestation or one ultrasound after 18-20 weeks if initial presentation is late.
- IV. Additional obstetric ultrasounds during pregnancy are considered **medically necessary** for the following indications:
 - A. suspected ectopic pregnancy;
 - B. suspected hydatidiform mole;
 - C. threatened or missed abortion;
 - D. congenital malformation, fetal or maternal;
 - E. polyhydramnios/oligohydramnios;
 - F. placenta previa;
 - G. abruptio placenta; or
 - H. vaginal bleeding.
- V. Additional obstetric ultrasounds for diagnosing other conditions affecting the fetus and/or delivery are considered **medically necessary** for the following indications:
 - A. suspected abnormal presentation;
 - B. suspected multiple gestation;
 - C. significant discrepancy between uterine size and dates;
 - D. elevated maternal serum alpha-fetoprotein;
 - E. suspected fetal death;
 - F. suspected anatomical uterine abnormality;
 - G. maternal high risk factors such as: personal or family history of congenital anomalies, chronic systemic disease (e.g., hypertension, diabetes, sickle cell disease), post datism (when pregnancy is over 42 weeks), history of infertility or substance abuse;
 - H. identify fetal abnormality or fetal growth abnormality;
 - I. determine gestational age for uncertain gestational date;
 - J. elderly primigravida;
 - K. pre and post amniocentesis studies; or
 - L. women who travelled to an area with Zika virus transmission who were pregnant or might have been pregnant.
- VI. Obstetric ultrasound for the sole purposes of determining gender or visualization of the fetus is considered **not medically necessary**.

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VII. Based upon our criteria and review of the peer-reviewed literature, obstetric ultrasound with 3D or 4D images are considered **not medically necessary** because there is a lack of evidence that 3D and 4D ultrasounds alter management and improve outcomes over standard two-dimensional (2D) ultrasounds.

Refer to Corporate Medical Policy #2.02.25 regarding First Trimester Screening for Down Syndrome.

POLICY GUIDELINES:

- I. The Health Plan will reimburse for one complete two-dimensional obstetrical ultrasound per uncomplicated pregnancy. Claims for additional ultrasounds must contain support diagnoses and documentation.
- II. Eligibility for reimbursement for obstetrical ultrasound is based on the benefits and limitations outlined in the member’s contract in effect on the date of service.

DESCRIPTION:

Real-time obstetrical ultrasonography is an accurate method of determining gestational age, fetal number, viability, and placental location and is necessary to confirm the presence of fetal life through observation of cardiac activity and active movement. This is accomplished with the use of a hand-held transducer that transmits high-frequency sound waves through tissues of varying density as the transducer is passed over the abdominal surface. Images are created by the echoes of the sound waves transmitted from the transducer to a monitor screen. The most common frequencies of sound waves used in OB/GYN ultrasound are 2-5 Mhz which allows sufficient penetration in most patients while providing adequate resolution.

Various types of ultrasound examinations are performed during the second or third trimesters. A *standard* obstetric ultrasound examination includes an evaluation of fetal presentation, amniotic fluid volume, cardiac activity, placental position, fetal biometry, and fetal number, plus an anatomic survey.

A *limited* examination does not replace a standard examination and is performed when a specific question requires investigation such as, confirmation of cardiac activity in a woman who is experiencing vaginal bleeding. A *limited* examination also may be performed in any trimester to evaluate interval growth, estimate amniotic fluid volume, evaluate the cervix, and assess the presence of cardiac activity.

When an anomaly is suspected on the basis of history, laboratory abnormalities, or the results of either the limited or standard examination, a *detailed or targeted anatomic* examination is performed. Specialized examinations are performed by an operator with experience and expertise in such ultrasonography.

Three-dimensional ultrasonography provides three dimensional images of the fetus by transmitting sound waves at different angles rather than straight down as in 2D ultrasound. The sound waves are reflected back and processed to produce 3D volume images of the fetus’s surface or internal organs. 3D may allow fetal facial anomalies, neural tube defects, and skeletal malformations to be detected and may potentially be used as an adjunct to 2D ultrasound. However clinical evidence is still lacking and 3D ultrasound is not considered a required modality at this time. Four dimensional ultrasonography allows for processing the volume images in real time so that movement can be observed. An advantage of 4D ultrasound may include enhanced maternal bonding. While images obtained from 3D or 4D ultrasound are more detailed and identifiable than those obtained from 2D ultrasound, the clinical utility is uncertain. Additional studies are needed to support this technology as replacement for 2D ultrasound.

RATIONALE:

The American College of Obstetricians and Gynecologists (ACOG) (2009) recommend and conclude the following (Level A): Ultrasound examination is an accurate method of determining gestational age, fetal number, viability, and placental location; Ultrasonography can be used in the diagnosis of many major fetal anomalies; Ultrasonography is safe for the fetus when used appropriately. Ultrasonography is helpful in detecting fetal growth disturbances; Ultrasonography can detect abnormalities in amniotic fluid volume (Level B). The optimal timing for a single ultrasound examination in the absence of specific indications for a first-trimester examination is at 18-20 weeks of gestation and the benefits and limitation of ultrasonography should be discussed with all patients (Level C).

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Studies have shown potential advantages of fetal malformation visualization using 3D and 4D ultrasound but the studies are unable to show improved fetal outcomes. Thus 2D ultrasonography continues to be the main ultrasound imaging modality.

The Centers for Disease Control and Prevention have issue preliminary recommendations for women who are pregnant and considering travel to an area with Zika transmission. The CDC recommends that pregnant women in any trimester should consider postponing travel to an area where Zika virus transmission is ongoing. If a pregnant woman is considering travel to one of these areas, she should talk to her healthcare provider. If she travels, she should strictly follow steps to avoid mosquito bites during the trip. Obstetrical providers should obtain a travel history from all pregnant women and use recent travel history to guide decisions about testing. Testing is not indicated for pregnant women without a travel history to an area with Zika virus transmission. Pregnant women with a history of travel to an area with Zika virus transmission and who report two or more symptoms consistent with Zika virus disease (including acute onset of fever, maculopapular rash, arthralgia or conjunctivitis) during or within two weeks of travel should be tested for the ZIKA virus. In addition, pregnant women with a history of travel to an area with Zika virus transmission and who have ultrasound findings of fetal microcephaly or intracranial calcifications should also be tested for Zika virus infection. Testing should be performed in consultation with state or local health departments.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

<u>CPT:</u>	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	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	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	each additional gestation (List separately in addition to code for primary procedure)
	76813	Ultrasound, pregnant uterus, real time with image documentation, first trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach; single or first gestation
	76814	Ultrasound, pregnant uterus, real time with image documentation, first trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach; each additional gestation (List separately in addition to code for primary procedure)
	76815	Ultrasound, pregnant uterus, real time with image documentation, limited (fetal heart beat, placental location, fetal position, and/or qualitative amniotic fluid volume), one or more fetuses

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- 76816 follow-up (eg, re-evaluation of fetal size by measuring standard growth parameters and amniotic fluid volume, re-evaluation of organ system(s) suspected or confirmed to be abnormal on a previous scan), transabdominal approach, per fetus
- 76817 Ultrasound, pregnant uterus, real time with image documentation, transvaginal
- 76376 3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation
- 76377 3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation

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ICD10: Numerous

REFERENCES:

American College of Obstetricians and Gynecologists (ACOG), Committee on Practice Bulletins -- Obstetrics. Ultrasonography in pregnancy. ACOG Practice Bulletin No. 175. Washington, DC: ACOG; December 2016.

BlueCross BlueShield Association. Ultrasound in maternity care. Medical Policy Reference Manual Policy #4.01.07. 2009 Dec 10.

Centers for Disease Control and Prevention (CDC) ” Questions and Answers for Obstetrical Healthcare Providers: Pregnant Women and Zika Virus Infection”. 2015 Jun, Updated July 2017 [http://www.cdc.gov/zika/hc-providers/qa-pregnant-women.html] accessed 1/7/18.

Kurjak A., et al. The potential of 4D sonography in the assessment of fetal neurobehavior – multicentric study in high-risk pregnancies. *J Perinat Med* 2010;38(1):77-82.

Merz E, et al. 3D/4D ultrasound in prenatal diagnosis: is it time for routine use? *Clin Obstet Gynecol* 2012 Mar;55(1):336-351.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Article for Ultrasound Diagnostic Procedures. Please refer to the following website for Medicare Members: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=263&ncdver=3&bc=AgAAgAAAAAAA&>.