Anthem

Medical Policy

Subject: Use of 3-D, 4-D or 5-D Ultrasound in Maternity Care
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Description/Scope

This document addresses the use of three-dimensional (3-D), four-dimensional (4-D) and five-dimensional (5-D) fetal ultrasound in maternity care and does not apply to ultrasound performed for non-pregnancy related conditions. Fetal ultrasound is a test performed during pregnancy, either to assess the gestational age or to evaluate fetal size, position, heartbeat, congenital malformations, suspected multiple fetuses or placental abnormalities. Two-dimensional (2-D) ultrasound is most commonly used. The 3-D and 4-D ultrasounds create computer-generated images viewed on a video monitor that provide more detail and almost life-like images of the fetus. 5-D ultrasounds automate the process of reconstructing 3-D images to create 2-D images.

Note: Please see the following related document for additional information:

- CG-MED-42 Maternity Ultrasound in the Outpatient Setting

Position Statement

Investigational and Not Medically Necessary:

The use of 3-D, 4-D or 5-D fetal ultrasound is considered **investigational and not medically necessary** in all cases.

Rationale

Although 3-D fetal ultrasound can produce more “realistic” and recognizable images than conventional 2-D ultrasound, the clinical significance of this remains unclear. The perceived superiority of 3-D ultrasound for a number of fetal abnormalities has not been definitively established, and 2-D imaging remains the principal diagnostic modality (Meyer-Wittkopf, 2003; Schellpefeffer, 2013; Voss, 2015).

Michailidis and colleagues (2002) noted that real-time 2-D ultrasound is the best way to examine fetal anatomy in the first trimester. A comparison of the diagnostic capabilities of 2-D and 3-D sonography for the study of conjoined twins revealed that 2-D sonography provided more definitive and specific information about shared organs and 2-D sonography is the primary modality for diagnosing and evaluating conjoined twins.

Pretorius (2001) reports that although 3-D ultrasound may be useful in evaluating abdominal abnormalities such as bowel obstruction, gastroschisis, omphalocele, and wall defects secondary to bands, the advantages compared with 2-D ultrasound have not been identified. While 3-D ultrasound may be superior to 2-D ultrasound in demonstrating cleft lip or palate and for accurate identification of the level of spine involvement by a neural tube defect, the significance of this in terms of improved clinical outcomes has not been demonstrated. Dyson and colleagues (2000) performed 3-D ultrasound imaging on 63 individuals in whom a 2-D study suggested an anomaly and 3-D imaging was thought likely to provide useful information. Obstetrical management was said to “change” in 3 individuals (5%) based on the additional information provided by the 3-D study. Two of these “changes” referred to the individual’s decision regarding termination of the pregnancy because of better clarification of a cleft lip and palate and in the third, where the level of a neural tube defect was better identified, there is no information as to management decisions taken.

Several authors (Timor-Tritsch, 2000; Bubb, 2004) have noted that it is difficult to evaluate the net effect of 3-D ultrasound on obstetric practice and on outcome. They also note that no comparative studies are available to support the superiority of 3-D ultrasound versus 2-D for evaluation of the central nervous system. Although the uterine cervix in pregnancy has become a focus of 3-D ultrasound, insufficient data is available to fully assess the additional clinical advantage of 3-D ultrasound in this context.

While fetal ultrasound may be viewed as a benign imaging format, Whitworth and colleagues (2010) point out that there is still debate concerning the long-term outcomes associated with fetal exposure to ultrasound, particularly when associated with multiple exposures or the use of color Doppler in the first trimester.

Schellpfeffer (2013) states the following about 3-D/4-D fetal ultrasound and souvenir or keepsake fetal imaging:

> Unfortunately, 3-D/4-D technology has also spurned a huge industry of non-medical imaging of fetuses, so-called “souvenir imaging of the fetus” or “keepsake fetal imaging.” This type of imaging is not condoned by any of the national or international ultrasound organizations for a number of reasons, but continues to flourish throughout the world.

The American Congress of Obstetricians and Gynecologists (ACOG) and the American Institute of Ultrasound in Medicine (AIUM) guideline on ultrasonography in pregnancy (December 2016) include the following:

> The technical advantages of three-dimensional ultrasonography include its ability to acquire and manipulate a large number of planes and to display ultrasound planes traditionally inaccessible by two-dimensional ultrasonography. Despite these technical advantages, proof of a clinical advantage of three-dimensional ultrasonography in prenatal diagnosis in general is still lacking. Potential areas of promise include fetal facial anomalies, neural tube defects, fetal tumors, and skeletal malformations for which three-dimensional ultrasonography may be helpful in diagnosis as an adjunct to, but not a replacement for two-dimensional ultrasonography.

In 2012, the United States Food and Drug Administration (FDA) noted the following regarding fetal ultrasound:

> Because of the particular concern for fetal exposures, national and international organizations have advocated prudent use of ultrasound imaging. Furthermore, the use of diagnostic ultrasound for non-medical purposes such as fetal keepsake videos has been discouraged.

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

5-D ultrasound has been proposed as a means to automate the process of navigating the data obtained in 3-D ultrasounds to reduce dependency on ultrasound operator skill and experience and to increase reproducibility. Several studies have evaluated the accuracy of 5-D ultrasound in reconstructing conventional 2-D images from 3-D ultrasound volume data (Hur, 2015; Laban, 2018; Rizzo, 2016). There is early data that appears to indicate that 5-D ultrasound data might be comparable to data obtained from 2-D ultrasounds. However, there is a lack of data to support that any additional benefit or improved outcomes are achieved when using 5-D ultrasounds over conventional 2-D ultrasounds.

Avena-Zampieri and associates (2022) reviewed the imaging modalities available to assess fetal lungs. The authors summarized the available evidence noting:

> Although 3D sonography has been assessed in research settings to evaluate lung volumetry, it is not used routinely in clinical practice because it is too time-consuming and has not been shown to be an accurate predictive tool.

In summary, although 3-D, 4-D and 5-D ultrasound may provide improved imaging for certain areas of fetal anatomy and abnormalities, it has not been demonstrated in clinical studies to result in improved health outcomes when compared to conventional 2-D ultrasound imaging (AboEllail, 2018; Goetzinger, 2018; Pinter, 2018; Tsai, 2018). There are challenges associated with this technology including a high dependence on operator experience, low reproducibility and exposure to a higher intensity power than used in 2D ultrasounds (Wataganara, 2021). There remains some question about the value of 3-D, 4-D or 5-D imaging outside of the controlled clinical setting (Wataganara, 2021). Merz (2012) notes “there are still no studies comparing 2D and 3D US in centers where practitioners are not 3D experts.”

Background/Overview

3-D or volume ultrasonography acquires a volume (rather than slice) of ultrasonographic data allowing one to see width, height and depth of images. The images can be captured and saved for later review. This stored data can be reformatted and analyzed in numerous ways. For example, surface rendering involves projecting the surface of a structure onto the screen, which allows curved structures, such as the fetal face, to be viewed in a single image that appears photographic in nature.

Suggested advantages of 3-D ultrasound compared to 2-D ultrasound in obstetrics include the following:

- Three-dimensional ultrasound appears to be less operator-dependent and provides a superior display of structures with complex anatomy compared to conventional ultrasonography.
- Orientations and planes not available with 2-D ultrasound, because of anatomic constraints or fetal position are available with 3-D ultrasound.
- Volume data may be reviewed millimeter by millimeter after acquisition, simulating real-time scanning.
- Archived volume data with suspected fetal anomalies may be reviewed with other physicians after completion of the ultrasound and data may be transmitted via the internet to other locations.
- 3-D ultrasound has improved accuracy of volume measurements to measure regular and irregular objects.
- Volume-rendered images are easily recognizable by both parents and physicians, which may facilitate decisions by families regarding continuing or terminating the pregnancy and are also said to enable parents to bond more effectively with the fetus. It may also assist them with making lifestyle changes, such as stopping smoking or excessive alcohol intake.

Limitations of 3-D ultrasound of the fetus are as follows:

- Suboptimal volume-rendered images are obtained if there are inadequate amniotic fluids surrounding the structure of interest. This is a major limitation with oligohydramnios and as the fetus progresses towards term. The adjacent structures cannot be excluded from the rendered volume in these cases and this interferes with surface rendering.
- Unacceptable surface rendering occurs with unfavorable fetal position and with adjacent or superimposed structures (e.g., limbs).
- Image processing of the volume data may take additional time on the part of the examiner.
- Real-time capacity is not generally available with three-dimensional ultrasound.

4-D ultrasonography refers to real-time visualization of 3-D images. The time vector (the fourth dimension) makes it possible to perceive a rapid update of the successive individual images displayed on the monitor at very short intervals which creates the impression of a real time. Fetal movements can be seen, providing a “live action” view. Proposed uses include study of fetal movement, fetal heart, and fetal behavioral states. 4-D ultrasonography is also known as dynamic 3-D sonography.

Recently, a number of studies have evaluated the diagnostic value of 3-D imaging in detecting fetal defects for a number of conditions including facial anomalies and defects of the spine, brain, heart and skeleton (Merz, 2012).

5-D ultrasonography builds upon 3-D sonography, automating the process of acquiring diagnostic images based upon volume data through the use of a software package. The ultrasound system WS80A (Samsung Medison Co, Ltd, Seoul, Korea) includes several software packages focusing on specific areas including fetal brain and heart structure, nuchal translucency and fetal biometry. While 5-D ultrasound has been proposed as a way to more accurately reconstruct fetal structure and predict fetal weight, the current studies do not show improved accuracy when compared to 2-D imaging (Hur, 2015; Laban, 2018).

Definitions

Ultrasound: A screening or diagnostic technique in which very high frequency sound waves are passed into the body, and the reflected echoes are detected and analyzed to build a picture of the internal organs or of a fetus in the uterus

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure and diagnosis codes, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

76376	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation
76377	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation
76499	Unlisted diagnostic radiographic procedure [when specified as 4-D or 5-D rendering of fetal ultrasound]

ICD-10 Diagnosis

O09.00-O09.93	Supervision of high-risk pregnancy
O10.011-O16.9	Edema, proteinuria and hypertensive disorders in pregnancy, childbirth and the puerperium
O20.0-O29.93	Other maternal disorders predominantly related to pregnancy
O30.001-O30.93	Multiple gestation
O31.00X0-O31.8X99	Complications specific to multiple gestation
O32.0XX0-O32.9XX9	Maternal care for malpresentation of fetus
O33.0-O33.9	Maternal care for disproportion
O34.00-O34.93	Maternal care for abnormality of pelvic organs
O35.00X0-O35.9XX9	Maternal care for known or suspected fetal abnormality and damage
O36.0110-O36.93X9	Maternal care for other fetal problems
O40.1XX0-O40.9XX9	Polyhydramnios
O41.00X0-O41.93X9	Other disorders of amniotic fluid and membranes
Z03.71-Z03.79	Encounter for suspected maternal and fetal conditions ruled out
Z34.00-Z34.93	Encounter for supervision of normal pregnancy
Z36.0-Z36.9	Encounter for antenatal screening of mother

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Peer Reviewed Publications:

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Government Agency, Medical Society, and Other Authoritative Publications:

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Document History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References section
Reviewed	02/16/2023	MPTAC review. Updated Discussion and References sections.
	09/28/2022	Updated Coding section with 10/01/2022 ICD-10-CM changes; added O35.00X0-O35.9XX9 replacing O35.0XX0-O35.9XX9.
Reviewed	02/17/2022	MPTAC review. Updated Discussion and References sections.
Reviewed	02/11/2021	MPTAC review. Updated References section.
Reviewed	02/20/2020	MPTAC review. Updated References sections. Updated Coding section to correct ICD-10 diagnosis range Z36.0-Z36.9.
Reviewed	03/21/2019	MPTAC review. Updated Discussion and References sections.
Revised	03/22/2018	MPTAC review. Updated policy to include 5-D ultrasound as INV and NMN in all instances. Updated title to include 5-D ultrasounds. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Rationale, Background, Coding and References sections.
Reviewed	05/04/2017	MPTAC review. Updated Rationale and References sections.
Reviewed	05/05/2016	MPTAC review. Updated Description, Rationale, Background, Index and References sections. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review. Description, Rationale and References sections updated. Websites section removed.
Reviewed	05/15/2014	MPTAC review. Description, Rationale, Background, Definition, References and Index sections updated.
Reviewed	05/09/2013	MPTAC review. Description, Rationale and References sections updated.
Reviewed	05/10/2012	MPTAC review. Rationale and References updated.
Reviewed	05/19/2011	MPTAC review. References updated.
	10/01/2010	Updated Coding section with 10/01/2010 ICD-9 changes.
Reviewed	05/13/2010	MPTAC review. References updated.
Reviewed	05/21/2009	MPTAC review. References and coding updated.
Reviewed	05/15/2008	MPTAC review. References updated.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Reviewed	05/17/2007	MPTAC review. References and coding updated; removed CPT 76375 - deleted 12/31/2005.
Reviewed	06/08/2006	MPTAC review. References updated.
	01/01/2006	Updated Coding section with 01/01/2006 CPT/HCPCS changes
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	04/27/2004	RAD.00013	Nuchal Translucency and Use of 3-D and 4-D Ultrasound in Maternity Care
WellPoint Health Networks, Inc.	09/23/2004	4.09.04	Three-Dimensional Ultrasound in Obstetrics

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the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.