

Ultrasound in Maternity Care



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This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and be updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

DESCRIPTION

Note: This policy addresses the use of 3-D, 4-D, and 5-D fetal ultrasound in maternity care.

A 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. Three-dimensional (3-D) and four-dimensional (4-D) ultrasound create computer generated images viewed on a video monitor that provide more detail and can produce more life-like images of the fetus. Five-dimensional (5-D) ultrasound has been proposed to automate the process of navigating the data obtained in a 3-D ultrasound to reduce dependency on ultrasound operator skill and experience and to increase reproducibility.

Three-Dimensional (3-D) Ultrasound

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 established, and 2-D imaging remains the principal diagnostic modality.

Three-dimensional (3-D) or volume ultrasonography acquires a volume (rather than a slice) of ultrasonographic data allowing one to see width, height and depth of images which is then stored. The 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 are not available with two-dimensional ultrasound, because of anatomic constraints for fetal position are available with three-dimensional ultrasound.
- Volume data may be reviewed 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.
- Three-dimensional 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 the 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.

Four-Dimensional (4-D) Ultrasound

Four-dimensional (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 real-time. Fetal movements can be seen, providing a “live action” view. 4-D ultrasonography is also known as dynamic 3-D sonography.

Five-Dimensional (5-D) Ultrasound

Five-dimensional (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.

The 5-D technology includes the following:

- 5-D Heart Color: This automatically displays nine standard fetal echocardiography views with blood flow dynamics simultaneously in a single template. The intuitive workflow can simplify examination of the fetal heart and reduce operator dependency.
- 5-D CNS+: This provides nine planes (axial, coronal, sagittal planes) of the fetal brain with anatomical landmarks and biometric measurements. The 5-D CNS+ combines clinical knowledge-based cues with pattern classification algorithms to determine the best standardization planes that are clinically significant. It complies with the International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) guideline for the fetal brain.
- 5-D Limb Vol: This technology provides an efficient way to rapidly measure fractional limb volume. This soft tissue parameter can be added to conventional 2-D ultrasound measurements of the fetal head (BPD) and abdomen (AC) to improve the precision of estimated fetal weight (EFW) and nutritional status. This computer assisted technology has clinical potential to detect and monitor malnourished fetuses with growth abnormalities.
- 5-D NT: Offers nuchal translucency measurement solutions for first trimester fetal nuchal translucency measurements.
- 5-D LB: Offers intuitive detection and measurement of fetal long bones.

5-D technology in fetal assessment in clinical practice:

- Biometrics to measure biparietal diameter and crown-rump length and determine gestational age.
- Nuchal translucency - manual measurement, semi-automatic; 5-D recognizes the correct mid-sagittal plane and provides improved Herman score.
- Morphological assessment – 3-D and 4-D enhancements offer more capabilities for accurate assessment to aid diagnosis of visible anomalies, invisible anomalies and anomalies requiring analysis: cardiac, face and limbs, spina bifida.
- Diagnosis of chorionicity and aminiocity in twin pregnancies.

- Fetal risk assessment – characterizes risk that include aneuploidies, congenital heart defects, and spina bifida.

Clinical Context and Therapy Purpose

The purpose of three-dimensional (3-D), four-dimensional (4-D) and five-dimensional (5-D) ultrasound is to produce more “realistic” and recognizable images as an option that is an alternative to or an improvement on existing therapies such as a conventional 2-D ultrasound.

Patients

The relevant population of interest are individuals who are pregnant.

Interventions

The therapy being considered is three-dimensional (3-D), four-dimensional (4-D) and five-dimensional (5-D) ultrasound(s).

Comparators

Comparators of interest include two-dimensional (2-D) ultrasound.

Outcomes

The general outcomes of interest test accuracy related to identification of fetal abnormalities, overall survival (OS), and adverse events.

Summary of Evidence

Although three-dimensional (3-D), four-dimensional (4-D) and five-dimensional (5-D) 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, 4-D, and 5-D ultrasound for a number of fetal abnormalities has not been definitively established. Two-dimensional (2-D) imaging remains the principal diagnostic modality.

Based on the review of the peer reviewed medical literature although three-dimensional (3-D), four-dimensional (4-D) and five-dimensional (5-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 two-dimensional ultrasound have not been identified. These ultrasound techniques may also be superior to two-dimensional ultrasound in demonstrating cleft lip or palate and for accurate identification of the level of spine involvement by a neural tube defect, however, the significance of this in terms of improved clinical outcomes has not been demonstrated. Several authors have noted that it is difficult to evaluate the net effect of 3-D, 4-D, and 5-D ultrasound on obstetric practice and on outcome. They also note that no comparative studies are available to support the superiority of these ultrasound techniques 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 good data is available

to assess fully the additional clinical advantage of 3-D, 4-D, and 5-D ultrasound in this context.

In summary, although 3-D, 4-D and 5-D ultrasound may provide improved imaging for certain areas of the fetal anatomy and abnormalities, it has not been demonstrated in clinical studies to alter management over standard two-dimensional (2-D) ultrasounds such that clinical outcomes are improved. Additional studies are needed to support this technology as a replacement for standard 2-D ultrasound. The evidence is insufficient in demonstrating that three-dimensional (3-D), four-dimensional (4-D) and five-dimensional (5-D) ultrasounds alter management over standard two-dimensional (2-D) ultrasounds such that clinical outcomes are improved.

Practice Guidelines and Position Statements

The American College of Obstetricians and Gynecologists (ACOG)

(2016) The American Academy of Obstetricians and Gynecologists (ACOG), issued practice bulletin No. 175 Ultrasound in Pregnancy, which states the following regarding three-dimensional ultrasonography:

- “Three-dimensional ultrasonography represents an advance in imaging technology. With three-dimensional ultrasonography, the volume of a target anatomic region can be calculated. The defined volume then can be displayed in three orthogonal two-dimensional planes representing the sagittal, transverse, and coronal planes of a reference two-dimensional image within the volume. The volume also can be displayed in its rendered format, which depicts the topographic anatomy of the volume. 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 still is 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.”
- The AIUM advocates the responsible use of diagnostic ultrasound. The AIUM strongly discourages the non-medical use of ultrasound for psychosocial or entertainment purposes. The use of either two-dimensional (2-D) or three-dimensional (3-D) ultrasound to only 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 instruments, the possibility exists that such biological effects may be identified in the future. Thus, ultrasound should be used in a prudent manner to provider medical benefit to the patient.
- In summary, although 3-D and 4-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.
(Verified June 2022)

(2016) ACOG presented the following information through Choosing Wisely provided the following information”

- Prenatal ultrasounds are an integral part of a woman’s prenatal care. While obstetric ultrasound has an excellent safety record, the U.S. Food and Drug Administration considers keepsake imaging as an unapproved use of a medical device. The American Institute of Ultrasound in Medicine also discourages the non-medical use of ultrasound for entertainment purposes. Keepsake ultrasounds are not medical tests and should not replace a clinically performed sonogram.
(Accessed June 2022)

Joint Guideline: American Institute of Ultrasound in Medicine (AIUM) - American College of Radiology (ACR) – American College of Obstetricians and Gynecologists (ACOG) - Society of Radiologist in Ultrasound (SRU)

(2018) AIUM – ACR – ACOG and SRU issued a collaborative practice parameter for the performance of standard diagnostic obstetrical ultrasound examination, this guideline does not mention or indicate the use of 3D, 4D or 5D ultrasound. (Accessed June 2022)

Regulatory Status

The Food and Drug Administration (FDA) reported for expectant mothers in fetal ultrasound, three-dimensional (3D) ultrasound allows the visualization of some facial features and possibly other parts such as fingers and toes of the fetus. Four-dimensional (4D) ultrasound is 3D ultrasound in motion. While ultrasound is generally considered to be safe with very low risks, the risks may increase with unnecessary prolonged exposure to ultrasound energy, or when untrained users operate the device.

The FDA considers such use of ultrasounds for keepsake video purposes to be an unauthorized use of a medical device and these vendors have largely been eliminated as a result of enforcement efforts. However, some clinicians continue to market them as a way to enhance prenatal bonding despite a lack of clinical evidence to support this claim.

PRIOR APPROVAL

Not applicable.

POLICY

The use of three-dimensional (3-D), four-dimensional (4-D) or five-dimensional (5-D) fetal ultrasound(s) in maternity care is considered **not medically necessary** for all indications.

Although three-dimensional (3-D), four-dimensional (4-D) and five-dimensional (5-D) ultrasound(s) may provide improved imaging for certain areas of the fetal anatomy and abnormalities, it has not been demonstrated in clinical studies to alter management over standard two-dimensional (2-D) ultrasounds such that clinical outcomes are improved. Additional studies are needed to support this technology as a replacement for standard two-dimensional (2-D) ultrasound, the significance in terms of improved clinical outcomes has not been demonstrated.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 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 (*when specified for 3-D fetal ultrasound*)
- 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 (*when specified for 3-D fetal ultrasound*)
- 76499 Unlisted diagnostic radiographic procedure (*when specified as 4-D and 5-D fetal ultrasound*)

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POLICY HISTORY

Date	Reason	Action
June 2022	Annual Review	Policy Revised
June 2021	Annual Review	Policy Renewed
June 2020	Annual Review	Policy Revised
June 2019	Annual Review	Policy Renewed
June 2018	Annual Review	Policy Revised
June 2017	Annual Review	Policy Renewed
June 2016	Annual Review	Policy Revised
July 2015	Annual Review	Policy Renewed
August 2014	Annual Review	Policy Revised
October 2013	Annual Review	Policy Revised
December 2012	Annual Review	Policy Renewed
December 2011	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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