04.01.06 Four - Dimensional (4-D) and Five - Dimensional (5-D) Fetal Ultrasound(s)

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Summary

Description

Note: This evidence review addresses the use of 4-D, and 5-D fetal ultrasounds in maternity care. For review of 3-D fetal ultrasounds through eviCore, refer to Wellmark's Authorization Table. This evidence review does not apply to ultrasound performed for non-pregnancy related conditions.

A fetal ultrasound is a test performed during pregnancy to assess for pregnancy and rule out ectopic pregnancy and confirm gestational age early on. As the pregnancy advances typically in the second and third trimesters ultrasounds are utilized to assess the fetal size and position, heartbeat, congenital malformations, placental abnormalities, and measuring the volume of amniotic fluid.

4-D ultrasounds create computer generated images viewed on a video monitor that provide more detail and can produce more life-like images of the fetus.

5-D ultrasounds have been proposed to automate ultrasounds through artificial intelligence to reduce exposure time, dependency on operator skill and experience and increase reproducibility.

Summary of Evidence

For individuals who are pregnant who receive a four-dimensional (4-D) or five-dimensional (5-D) ultrasound(s) for the diagnosis of fetal cardiac abnormalities the evidence includes 2 observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. No clinical utility studies were identified. All of the studies evaluated the diagnostic accuracy of 4D-US. None of the studies evaluated 5D-US. All but one study were conducted in non-United States. Findings from these studies are inconclusive as they were heterogenous in the types of fetal abnormalities evaluated and they did not provide adequate details on variance of effect to assess level of precision. The evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

For individuals who are pregnant who receive a four-dimensional (4-D) or five-dimensional (5-D) ultrasound(s) for the diagnosis of fetal noncardiac abnormalities the evidence included 4 diagnostic accuracy studies. Relevant outcomes are diagnostic accuracy, symptoms, functional outcomes, quality of life, and treatment-related morbidity. No clinical utility studies were identified. All of the studies evaluated the diagnostic accuracy of 4D-US. None of the studies evaluated 5D-US. None were conducted in the United States. Findings from these studies are inconclusive as they were heterogenous in the types of fetal abnormalities evaluated and they did not provide adequate details on variance of effect to assess level of precision. The evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

Additional Information

Not applicable

OBJECTIVE

The objective of this evidence review is to determine whether the use four-dimensional (4-D) or five-dimensional (5-D) fetal ultrasound(s) improves the net health outcomes.

PRIOR APPROVAL

Not applicable.

POLICY

Note: This evidence review addresses the use of 4-D, and 5-D fetal ultrasounds in maternity care. For review of 3-D fetal ultrasounds through eviCore, refer to Wellmark's Authorization Table. This evidence review does not apply to ultrasound performed for non-pregnancy related conditions.

The use of four-dimensional (4-D) and/or five-dimensional (5-D) fetal ultrasound(s) is considered **investigational** for all indications because the evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

POLICY GUIDELINES

Coding

See the Codes table for details.

BACKGROUND

According to the Centers for Disease Control and Prevention (CDC) (CDC, 2023) in the United States, annually, there are 3% of newborns with birth defects that are a major cause of infant mortality. They contribute to 20% of all infant deaths.

Ultrasound is the transmission of high-frequency sound waves through tissues of varying densities. The echoes produced by the high-frequency sound waves at interfaces between tissues and reflect off the body to make visual images. Images created by the echoes of the sound waves are transmitted from the transducer to a CRT or television monitor. The most common frequencies of sound waves used in OB/GYN ultrasound are 2–5 Mhz. A two-dimensional (2-D) ultrasound is most widely used due to its non-invasive nature. The images created by the 2-D ultrasounds are black-and-white, flat and single-planed. 2-D ultrasounds provide a cross-sectional image which may some argue reduces the diagnostic accuracy thus, four-dimensional (4-D) and five-dimensional (5-D) ultrasounds have been purposed to be used in feal ultrasounds.

Four-Dimensional (4-D) Ultrasound

Four-dimensional (4-D) ultrasonography also known as dynamic 3-D sonography 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 or a time-lapse which creates the impression of real-time images showing fetal movement and expressions.

Five-Dimensional (5-D) Ultrasound

Five-dimensional (5-D) ultrasonography builds upon 4-D sonography, automating the process of acquiring diagnostic images based upon volume data with a software package using artificial intelligence. This improves the detail and quality of the image, improves efficiency, and reduces human error.

The 5-D technology includes:

- 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 is utilized in clinical practice with the following:

- 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.

Regulatory Status

An ultrasound is a procedure and, therefore, not subject to U.S. Food and Drug Administration (FDA) regulation. However, any medical devices used as a part of this procedure may be subject to FDA regulation. Many devices for use in ultrasound are available. These devices have FDA clearance under product codes IYN, ITX, and IYO, for marketing in the United States.

The FDA recommends that health care providers consider ways to minimize exposure while maintaining diagnostic quality when using ultrasound. As with all other imaging modalities, the principles of As Low As Reasonably Achievable (ALARA) should be practiced by health care providers.

The FDA reports “the use of ultrasound solely for non-medical purposes such as obtaining fetal ‘keepsake’ videos has been discouraged.” They report. “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.” Refer to the following for more information: Ultrasound Imaging | FDA.

Please note this section is not intended to be all-inclusive.

RATIONALE

This evidence review was created in April 1999 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through January 2025.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Four - Dimensional (4-D) and Five - Dimensional (5-D) Ultrasound(s) for the Diagnosis of Fetal Cardiac Abnormalities

Clinical Context and Test Purpose
The purpose of four-dimensional (4-D) and five-dimensional (5-D) ultrasound for the diagnosis of fetal cardiac abnormalities is to provide an alternative to or an improvement to existing therapies such as a 2-D ultrasound.

Populations
The relevant population of interest are individuals who are pregnant.

Interventions
The therapy being considered is four-dimensional (4-D) and five-dimensional (5-D) ultrasound(s) for the diagnosis on fetal noncardiac abnormalities.

Comparators
Comparators of interest is a 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.

Review of Evidence

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

A January 2024 Hayes Evidence Analysis Research Brief on Four-Dimensional and Five-Dimensional Ultrasound for Diagnosis of Fetal Cardiac Abnormalities identified 2 Class I studies of Clinical Validity (Turan et al, 2014; Wang et al, 2019) that includes a comparison reference test. All evaluated the diagnostic accuracy of 4D-US. None evaluated 5D-US. One was conducted in the United States. Findings from these studies are inconclusive as they were heterogenous in the types of fetal abnormalities evaluated and they did not provide adequate details on variance of effect to assess level of precision.

Observational Studies
Wang et al (2019) conducted a diagnostic accuracy study on the identification of cardiac malformations of a fetus by both a 2-D ultrasound and 4-D ultrasound. A total of 206 high-risk individuals analyzed retrospectively analyzed. The two-dimensional ultrasounds identified 100 cardiac malformations. The four-dimensional ultrasound identified 120 cardiac malformations. When both 2-D and 4-D ultrasounds were used 135 cardiac malformations were diagnosed. " The sensitivity, specificity, diagnostic coincidence rate, negative predictive value, and positive predictive value of two-dimensional ultrasound diagnosis were 70.92, 78.46, 73.30, 55.43 and 87.72%, respectively; the sensitivity, specificity, diagnostic coincidence rate, negative predictive value, and positive predictive value of four-dimensional ultrasound diagnosis were 85.11, 89.23, 86.41, 73.42 and 94.49%, respectively; the sensitivity, specificity, diagnostic coincidence rate, negative predictive value and positive predictive value of two-dimensional ultrasound diagnosis combined with four-dimensional ultrasound diagnosis were 95.74, 67.69, 86.89, 88.00 and 86.54%, respectively. The sensitivity of two-dimensional ultrasound diagnosis combined with four-dimensional ultrasound diagnosis was significantly higher than that of two-dimensional ultrasound diagnosis and four-dimensional ultrasound diagnosis, the difference was statistically significant (P<0.05). The sensitivity of four-dimensional ultrasound diagnosis was significantly higher than that of two-dimensional ultrasound diagnosis, the difference was statistically significant (P<0.05). The specificity and

positive predictive value of four-dimensional ultrasound diagnosis were significantly higher than those of two-dimensional ultrasound diagnosis and two-dimensional ultrasound diagnosis combined with four-dimensional ultrasound diagnosis, the difference was statistically significant (P<0.05)." While a combination of 2D- and 4D US may be beneficial in screening for fetal CMs, more research is indicated to analyze the diagnostic value.

Turan et al (2014) conducted a diagnostic accuracy study on utilizing 4D ultrasound/echocardiogram in pregnant individuals who are at high risk of carrying a fetus with congenital heart disease. Abnormalities were detected in 20 fetuses, most commonly an atrioventricular canal defect (n=9). The first trimester scan missed two CSH cases. Those two cases were caught on a second trimester scan. The "first-trimester echocardiography scan showed a sensitivity of 91% (95% CI, 71–99%), a specificity of 100% (95% CI, 97–100%), a positive predictive value of 100% (95% CI, 83–100%) and a negative predictive value of 99% (95% CI, 95–100%)." A first trimester scan is limited by overall image resolution, gestational age, and identifiable overall small anatomical size and landmarks. A sonographer in a general office setting is likely to have a skill set that differs than those who were included in this study. Further research is needed to decipher how long it takes to acquire these skills, interpret the findings, or have analysis online. Bais may exist since this study was completed at a single center and the STIC operator is not blinded. While 4D echocardiogram may be beneficial in screening high risk individuals for a fetus effected by CDH further research is indicated to analyze the effectiveness.

Section Summary: Clinically Valid

Four-Dimensional and Five-Dimensional Ultrasound for Diagnosis of Fetal Cardiac Abnormalities identified 2 Class I studies of Clinical Validity (Wang et al., 2019; Turan et al. 2014). All evaluated the diagnostic accuracy of 4D-US. None evaluated 5D-US. One study was conducted in the United States. Findings from these studies are inconclusive as they were heterogenous in the types of fetal abnormalities evaluated and they did not provide adequate details on variance of effect to assess level of precision.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if individuals receive the correct care, more effective care, or avoid unnecessary therapy or testing.

There were no clinical utility studies that evaluated 4D and 5D ultrasounds for the diagnosis of fetal noncardiac abnormalities identified.

A January 2024 Evidence Analysis Research Brief (EARB) by Hayes Inc regarding Four-Dimensional and Five-Dimensional Ultrasound for Diagnosis of Fetal Cardiac Abnormalities did not identify any clinical utility studies.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials (RCTs).

No randomized or nonrandomized controlled studies were identified that compared health outcomes in individuals when treatment decisions were made with and without the results of four - dimensional (4-D) and five - dimensional (5-D) ultrasound(s) for the diagnosis of fetal cardiac abnormalities.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Section Summary: Clinically Useful

Direct evidence of how 4-D and 5-D fetal ultrasounds for the diagnosis of fetal noncardiac abnormalities to improve outcomes is lacking. In the absence of direct evidence for a diagnostic test, a chain of evidence can sometimes be identified to demonstrate improvement in health outcomes. However, in the case of 4-D and 5-D ultrasound(s) for the diagnosis of fetal noncardiac abnormalities, the chain of evidence about clinical validity and how the test would be used in practice is uncertain; therefore, no inferences can be made about clinical utility.

Four - Dimensional (4-D) and Five - Dimensional (5-D) Ultrasound(s) for the Diagnosis of Fetal Noncardiac Abnormalities

Clinical Context and Test Purpose

The purpose of four-dimensional (4-D) and five-dimensional (5-D) ultrasound for the diagnosis of fetal noncardiac abnormalities is to provide an alternative to or an improvement to existing therapies such as a 2-D ultrasound.

Populations

The relevant population of interest are individuals who are pregnant.

Interventions

The therapy being considered is four-dimensional (4-D) and five-dimensional (5-D) ultrasound(s) for the diagnosis on fetal noncardiac abnormalities.

Noncardiac anomalies may include facial and oral deformities, genetic disorders, limb malformations, neural tube defects, spinal irregularities and others (CDC, 2023; Jabaz and Jenkins, 2023).

Comparators

Comparators of interest is a 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.

Review of Evidence

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

A December 2023 Hayes Evidence Analysis Research Brief on Four-Dimensional and Five-Dimensional Ultrasound for Diagnosis of Fetal Noncardiac Abnormalities identified 4 Class I studies of Clinical Validity (Öcal et al, 2015; Wang et al, 2019; Yu et al, 2022; Zhang et al, 2023). All evaluated the diagnostic accuracy of 4D-US. None evaluated 5D-US. None were conducted in the United States. Findings from these studies are inconclusive as they were heterogenous in the types of fetal abnormalities evaluated and they did not provide adequate details on variance of effect to assess level of precision.

Observational Studies

Zhang et al (2023) conducted a diagnostic accuracy study on the GE-E10 four-dimensional (4D) ultrasound to investigate the efficacy of GE-E10 prenatal ultrasounds in forecasting fetal abnormal weight development. 160 pregnant women were included in this study. All women had both a two-dimensional (2D) and (4D) ultrasound. "Sensitivity and specificity of 2D color ultrasound in diagnosing fetal abnormal development were 78.38% and 82.60%. The sensitivity and specificity of 4D color ultrasound in diagnosing fetal abnormal weight development were 81.15% and 83.43%. Receiver operating characteristic showed that the area under the curve (0.873) of 4D color ultrasound was higher than that 2D color ultrasound (0.827)." However, a limitation of this study is that the clinical and statistical significance of these findings are unclear as they were not reported. Although the results suggest the GE-E10 (4D) ultrasound was more diagnostic than 2D ultrasounds for value for antenatal screening of macrosomia and low birth weight. Zhang et al also referenced Eslamian et al. (2018) which reported the results were had increased accuracy when the proximity of date of birth and the fetal weight date were closer together. When the timing of the date of birth was off the accuracy of the fetal weight estimate was not as reliable. Thus, the application of the 4D ultrasound fetal weight predication "is not realistic" and providers should have careful consideration of effective timing and utilization of the 4D fetal ultrasound in predicting fetal weight. Overall, the authors concluded the 4D ultrasound has a "high value for antenatal screening of macrosomia and low birth weight" however, the 4D ultrasound results were not statistically significant when compared to the 2D ultrasound.

Yu et al (2022) evaluated the diagnostic accuracy of two-dimensional ultrasonography (2D-US) combined with four-dimensional ultrasonography (4D-US) in prenatal ultrasound screening of fetal congenital malformations (CMs) and explores the high-risk factors affecting fetal malformations. From February 2020 to October 2021, 2247, pregnant individuals completed a 2D-US. Of those 2247 those whose suspected fetal malformations were further examined with a 4D-US. "The accuracy, sensitivity, and specificity of 2D-US diagnosis were 81.40%, 43.68%, and 82.92%". For the 4D-US the accuracy, sensitivity, and specificity of diagnosis were, "83.67%, 51.72%, and 84.95%". For 2D- and 4D- US combined accuracy, sensitivity, and specificity diagnosis was statistically higher than 2D- or 4D-US alone with 93.59%, 90.80%, and 91.70%, respectively. Although this study does highlight the combination of 2D- and 4D US may increase the diagnosis rate of fetal malformations there are several limitations to consider. Results for 2D- and 4D-US were not stratified per the gestational week. Individuals were only studied during the second trimester. Additional risk factors which may affect fetal congenital malformations were not evaluated such as the male counterpart's smoking or drinking history, genetic diseases, and radiation. Additionally, the clinical and statistical significance of these findings are unclear as they were not reported. While a combination of 2D- and 4D US may be beneficial in screening for fetal CMs, more research is indicated to analyze the diagnostic value.

Wang et al (2019) evaluated the diagnostic accuracy of two-dimensional (2D) plus four-dimensional (4D) ultrasonography in diagnosis of fetal craniocerebral anomalies. They retrospectively reviewed 83 individuals from January 2013 to December 2017 whom had been suspected of fetal craniocerebral anomalies from 2D and 4D US. 2D US only was used in 56 patients, 4D US only was used in 65 and 2D plus 4D US was used in 74 individuals with identified anomalies. Diagnostic accuracy of 2D US only was 68.67%, 4D US only was 81.93% and 2D plus 4D US was 95.18% ($P<0.05$). However, a limitation of this study is that the clinical and statistical significance of these findings are unclear as they were not reported. The accuracy, sensitivity, and specificity of 2D plus 4D ultrasound was greater than those of 2D ultrasound only and 4D ultrasound only, and the accuracy of 4D ultrasound only was higher than that of 2D ultrasound only ($P<0.05$). Although the results from this study indicate the 2D plus 4D ultrasound and the 4D US alone is more statistically significantly diagnostic for various fetal craniocerebral anomalies when compared to the 2D US alone, however there are limitations of this study. The study design included a small sample size with limited follow-up. Additional, well-designed studies are indicated.

Öcal et al (2015) evaluated the diagnostic accuracy of 4D ultrasounds in the detection of fetal abnormalities. In 1,379 individuals, 2D and 4D fetal ultrasounds were completed in the same visit. A total of 176 of the pregnant individuals had 194 fetal anomalies. The authors concluded 2D ultrasounds were superior at detecting anomalies ($p < 0.001$). In approximately half of the cases 4D ultrasounds identified the fetal abnormalities and a 15% of cases there was enhanced image quality.

Section Summary: Clinically Valid

Four-Dimensional and Five-Dimensional Ultrasound for Diagnosis of Fetal Noncardiac Abnormalities identified 4 Class I studies of Clinical Validity (Öcal et al, 2015; Wang et al, 2019; Yu et al, 2022; Zhang et al, 2023). All evaluated the diagnostic accuracy of 4D-US. None evaluated 5D-US. None were conducted in the United States. Findings from these studies are inconclusive as they were heterogenous in the types of fetal abnormalities evaluated and they did not provide adequate details on variance of effect to assess level of precision.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if individuals receive the correct care, more effective care, or avoid unnecessary therapy or testing.

There were no clinical utility studies that evaluated 4D and 5D ultrasounds for the diagnosis of fetal noncardiac abnormalities identified.

A December 2023 Evidence Analysis Research Brief (EARB) by Hayes regarding Four-Dimensional and Five-Dimensional Ultrasound for Diagnosis of Fetal Noncardiac Abnormalities did not identify any clinical utility studies.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials (RCTs).

No randomized or nonrandomized controlled studies were identified that compared health outcomes in individuals when treatment decisions were made with and without the results of four - dimensional (4-D) and five - dimensional (5-D) ultrasound(s) for the diagnosis of fetal noncardiac abnormalities.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Section Summary: Clinically Useful

Direct evidence of how 4-D and 5-D fetal ultrasounds for the diagnosis of fetal noncardiac abnormalities to improve outcomes is lacking. In the absence of direct evidence for a diagnostic test, a chain of evidence can sometimes be identified to demonstrate improvement in health outcomes. However, in the case of 4-D and 5-D ultrasound(s) for the diagnosis of fetal noncardiac abnormalities, the chain of evidence about clinical validity and how the test would be used in practice is uncertain; therefore, no inferences can be made about clinical utility.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Obstetricians and Gynecologists (ACOG)

In 2017 ACOG issued practice bulletin No. 723 Guidelines for Diagnostic Imaging During Pregnancy and Lactation which was reaffirmed 2021. This guideline does not specifically discuss the use of 4D or 5D ultrasound.

ACOG issued practice bulletin No. 175 Ultrasound in Pregnancy in 2016 which states, "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."

In 2016 ACOG published a Choosing Wisely ® in 2013 on Five More Things Physicians and Patients Should Question which states, "Don't perform prenatal ultrasounds for non-medical purposes, for example solely to create keepsake videos or photographs. 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 AIUM discourages the non-medical use of ultrasound for entertainment purposes. Keepsake ultrasounds are not medical tests and should not replace a clinically performed sonogram."

American Heart Association (AHA)

In 2014 the AHA released a Scientific Statement on the Diagnosis and Treatment of Fetal Cardiac Disease which stated, "3D/4D fetal cardiac imaging is currently a research tool and is not adequate for use as an alternative to conventional fetal cardiac imaging. However, this technology may be useful to facilitate screening for CHD or for complementary imaging in fetuses identified as having CHD" (IIb/B).

This statement does not specifically mention 5D ultrasounds.

American Institute of Ultrasound in Medicine (AIUM)

The AIUM provides a recommendation on Keepsake Fetal Imaging in 2020 in the statement on Prudent Use and Safety of Diagnostic Ultrasound in Pregnancy which, "encourages patients to make sure that practitioners using ultrasound have received formal education and training in fetal imaging to ensure the best possible results.

The AIUM recognizes the growing pressures from patients for the performance of ultrasound examinations for bonding and reassurance purposes largely driven by advances in image quality of 3-dimensional (3D) sonography and by more widely available information about these advances. Although there is only some scientific evidence that 3D sonography has a positive impact on parental-fetal bonding, the AIUM recognizes that many parents may pursue scanning for this purpose. Such “keepsake imaging” currently occurs in a variety of settings, including the following:

1. Images or video clips given to parents during the course of a medically indicated ultrasound examination.
2. Images or clips given to volunteers who are scanned as part of diagnostic ultrasound education programs or demonstrations, provided that images are not used as an enticement to participate.
3. Freestanding commercial fetal imaging sites, usually without any physician review of acquired images and with no regulation of the training of the individuals obtaining the images; these sites are sometimes called “baby video studios,” and these videos are sometimes called “entertainment videos.”
4. As added-cost visits to a medical facility (office or hospital) outside the coverage of contractual arrangements between the provider and the patient’s insurance carrier. The AIUM believes that added-cost arrangements other than those for providing patients images or copies of their medical records at cost may violate the principles of medical ethics of the American Medical Association (AMA) and the American College of Obstetricians and Gynecologists (ACOG).

The AIUM, therefore, recommends that only scenarios 1 and 2 above are consistent with the ethical principles of the AIUM and those of the AMA and ACOG.

The market for keepsake images is driven in part by past medical approaches that have used medicolegal concerns as a reason not to provide images to patients. Sharing images with patients is unlikely to have a detrimental medicolegal impact. The AIUM encourages sharing images with patients as appropriate when medically indicated obstetric ultrasound examinations are performed.”

This statement does not specifically mention 4D and 5D ultrasounds.

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)

In 2018 AIUM – ACR – ACOG and SRU issued a collaborative practice parameter for the performance of standard diagnostic obstetrical ultrasound examination that was revised in 2023 and does not specifically discuss the use of 4D or 5D ultrasound.

American Society of Echocardiography (ASE)

In 2023 the ASE provided a Guideline and Recommendation for the Performance of the Fetal Echocardiogram stated, “"Other ultrasound technologies may be used to image fetal cardiovascular structure and physiology. [STIC] captures a static or dynamic [3D] volume data set using a specially designed ultrasound transducer and analysis software. Real-time [3D] echocardiographic imaging with this method can be used to enhance detection of anatomic defects and quantify hemodynamics such as ventricular function and cardiac output, although [STIC] has not been validated for clinical use."

This statement does not specifically mention 5D ultrasounds.

International Society of Ultrasound in Obstetrics and Gynecology (ISUOG)

Performance of 11–14-week Ultrasound Scan

The ISUOG updated their Practice Guideline on the Performance of 11–14-week Ultrasound Scan in 2023; For the Role of 3D and 4D ultrasound they stated “3D and 4D ultrasound are not currently used for routine first-trimester fetal anatomical evaluation. However, in experienced hands, these methods may be helpful in evaluation of abnormalities, especially with multiplanar reconstruction of selected diagnostic planes".

This statement does not specifically mention 5D ultrasounds.

Performance of the Routine Mid-Trimester Fetal Ultrasound Scan
The ISUOG updated their Practice Guidelines on the Performance of the Routine Mid-Trimester Fetal Ultrasound Scan which does not specifically discuss the use of 4D or 5D ultrasound.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	76499	Unlisted diagnostic radiographic procedure (*when specified as a 4-D or 5-D rendering of a fetal ultrasound*)
HCPCS		
	No code(s)	
Type of Service	Medical/ Diagnostic	
Place of Service	Outpatient/ Physician's Office	

POLICY HISTORY

Date	Reason	Action
January 2025	Annual Review	Policy Renewed
January 2024	Annual Review	Policy Revised
June 2023	Annual Review	Policy Revised
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:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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