JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Medical Policy Manual** **Medical Policy**	*Policy Number*	CMS16.19
		Effective Date	04/01/2024
		Approval Date	01/16/2024
	Subject **Prenatal Obstetrical Ultrasound**	*Supersedes Date*	05/01/2023
		Page	1 of 8

This document applies to the following Participating Organizations:

Advantage MD	Johns Hopkins Health Plan of Virginia Inc. (JHHPVA)	Priority Partners	US Family Health Plan

Keywords: Prenatal Obstetrical, Ultrasound

Table of Contents		Page Number
I.	ACTION	1
II.	POLICY DISCLAIMER	1
III.	POLICY	1
IV.	POLICY CRITERIA	2
V.	DEFINITIONS	4
VI.	BACKGROUND	4
VII.	CODING DISCLAIMER	5
VIII.	CODING INFORMATION	6
IX.	REFERENCE STATEMENT	7
X.	REFERENCES	7
XI.	APPROVALS	8
Appendix A: Appendix A High Risk Diagnosis List		Click Here
Appendix B: Appendix B Exceptions to Outpatient Hospital Setting (Regulated Space) Redirection List		Click Here

I. ACTION

	New Policy	
X	Revising Policy Number	CMS16.19
	Superseding Policy Number	
	Retiring Policy Number	

II. POLICY DISCLAIMER

Johns Hopkins Health Plans (JHHP) provides a full spectrum of health care products and services for Advantage MD, Employer Health Programs, Johns Hopkins Health Plan of Virginia Inc., Priority Partners, and US Family Health Plan. Each line of business possesses its own unique contract, benefits, regulations, and regulators' clinical guidelines that supersede the information outlined in this policy.

III. POLICY

For Advantage MD: refer to: Medicare Coverage Database

- National Coverage Determination (NCD) 220.5 Ultrasound Diagnostic Procedures
- No Local Coverage Determinations (LCDs) identified (Accessed 01/04/2024)

For Johns Hopkins Health Plan of Virginia, Inc. (JHHPVA): refer to: Medicare Coverage Database

- National Coverage Determination (NCD) 220.5 Ultrasound Diagnostic Procedures

- No Local Coverage Determinations (LCDs) identified (Accessed 01/04/2024)

For Priority Partners (PPMCO) refer to: Code of Maryland Regulations

- No specific information is located at COMAR 10.67.01 – 10.67.13 (Accessed 01/04/2024)

For Uniformed Services Family Health Plan (USFHP), refer to: Tricare Policy Manuals

- TRICARE Policy Manual 6010-63-M, April 2021. Chapter 5, Section 2.1 Diagnostic Ultrasound

IV. POLICY CRITERIA

A. General Considerations for Medical Necessity

1. When benefits are provided under the member's contract, JHHP considers the provision of up to three (3) two dimensional (2-D) prenatal obstetrical ultrasounds medically necessary during the course of a pregnancy for the following indications:
   a. Dating/Estimated gestational age
   b. Nuchal translucency measurement
   c. Screening for fetal anomalies
2. Additional medical necessity indications for 2-D prenatal ultrasounds include, but is not limited to, the following:
   a. First trimester:
      i. Confirmation of intrauterine pregnancy
      ii. Suspected ectopic pregnancy
      iii. Evaluation of vaginal bleeding, pelvic pain, or uterine masses
      iv. Multiple gestations
      v. Assessment of fetal cardiac activity
      vi. Assessment of fetal anomalies such as anencephaly
      vii. Evaluation of suspected hydatiform mole
   b. Second and third trimester:
      i. Evaluation of fetal growth
      ii. Evaluation of vaginal bleeding, pelvic pain, pelvic mass, or uterine abnormality
      iii. Evaluation of cervical insufficiency
      iv. Adjunct to cervical cerclage
      v. Assessment of fetal presentation
      vi. Adjunct to external cephalic version
      vii. Adjunct to amniocentesis or other procedure
      viii. Evaluation of discrepancy between uterine size and clinical dates
      ix. Evaluation of fetal well-being
      x. Follow-up evaluation of placental location for suspected placenta previa
      xi. Suspected placental abruption
      xii. Evaluation of premature rupture of membranes and/or premature labor
      xiii. Evaluation of abnormal biochemical markers
      xiv. History of previous congenital anomaly
      xv. Follow-up evaluation of a fetal anomaly
      xvi. Evaluation of fetal condition in late registrants for prenatal care
      xvii. Assessment for findings that may increase the risk for aneuploidy

3. When benefits are provided under the member's contract, JHHP considers a three-dimensional (3-D) prenatal obstetrical ultrasound medically necessary for ANY of the following, when ordered by Maternal Fetal Medicine specialists:
    a. Diagnosis of fetal brain and general fetal head abnormalities
    b. Prenatal diagnosis of cleft lip and cleft palate, fetal facial anomalies
    c. Diagnosis of fetal ear anomalies
    d. Neural tube defects
    e. Fetal tumors
    f. Skeletal malformations

B. Documentation Requirements: ***(For PPMCO and USFHP also refer to Site of Service Section D)***
1. Preauthorization is required with documentation to support medical necessity for the following:
    a. Greater than 3, 2-D prenatal obstetrical ultrasounds in the course of a non-high risk pregnancy, AND;
    b. All 3-D ultrasounds
2. Preauthorization is NOT required for the following:
    a. Prenatal ultrasound for an emergent or life-threatening condition.

C. Exclusions:
1. Unless specific benefits are provided under the member's contract, JHHP considers ANY of the following services not medically necessary because they do not meet Technology Evaluation Criteria (TEC) as defined in CMS01.00 Medical Policy Introduction:
    a. Four dimensional (4-D) ultrasounds
    b. Prenatal obstetrical ultrasound for the determination of gender of the fetus for nonmedical reasons
    c. Prenatal obstetrical ultrasound done solely to provide an image of the fetus for parents

D. Site of Service - Prenatal Obstetrical Ultrasounds ***(Applicable to PPMCO and USFHP ONLY***
1. *Free-Standing Facilities (Non-Regulated Space):* JHHP considers *free-standing facilities* to be an appropriate place of service for most obstetrical prenatal ultrasounds. *(Refer to Definitions section)*
    a. Greater than 3, 2 D prenatal ultrasounds require preauthorization for members without a high risk pregnancy, regardless of site of service.
    b. Members with a high risk pregnancy diagnosis are not subject to the limit of 3, 2-D prenatal obstetrical ultrasounds, and preauthorization is NOT required when performed in a *free-standing facility (Refer to Appendix A)*
2. *Outpatient Hospital Setting (Regulated Space):* Prenatal obstetrical ultrasounds may be performed in an *outpatient hospital setting* with documentation to support the medical necessity of the site of service. *(Refer to Definitions section)*
    a. 2-D prenatal obstetrical ultrasounds in the course of a high risk pregnancy or non-high risk pregnancy are permitted in an *outpatient hospital setting* with preauthorization for ANY of the following indications:
        i. There is no in-network *free-standing facility* within the Plans access standards able to perform the requested obstetrical prenatal ultrasound. *(Refer to Definitions section)*
        ii. Prenatal obstetrical ultrasound is being performed by a network maternal fetal specialist whose office is in an *outpatient hospital setting.*
        iii. Prenatal obstetrical ultrasound is ordered for a member with one of the diagnoses on the Exception List. (*Refer to Appendix B - Exceptions to Outpatient Hospital Setting (Regulated Space) Redirection List)*
        iv. One of the prenatal obstetrical ultrasounds on the Exception List has been ordered. *(Refer to Appendix B - Exceptions to Outpatient Hospital Setting (Regulated Space) Redirection List)*
        Note: The high-risk diagnosis list is intended to identify when > than 3, 2-D prenatal ultrasounds are permitted. It is not intended to allow all prenatal ultrasounds in regulated space. Criteria in section 2. a. above must be met for regulated space.
    b. Preauthorization is NOT required for the following when done in an *outpatient hospital setting:*

i. Prenatal obstetrical ultrasounds related to an emergent or life-threatening condition

V. DEFINITIONS

Site of Service

- Freestanding Facility (Non-Regulated Space): A freestanding medical facility means a health care facility that is physically separated from the hospital or hospital grounds (Maryland Health Care Commission, 2017). It is a stand-alone center that furnishes health care services and that is neither integrated with, nor a department of, a hospital (Law Insider, 2020). Place of Service (POS) examples; Office (11), Mobile Unit (15), ASC (24), Independent Clinic (49), Federally Qualified Health Center (FQHC) (50) (Centers for Medicare & Medicaid Services, 2024). (For the purposes of this policy a prenatal obstetrical ultrasound performed in an obstetrician's or perinatologist's office not in regulated space would be considered freestanding.)
- Off Campus-Outpatient Hospital (Regulated Space): A portion of an off-campus hospital provider based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization (POS 19) (Centers for Medicare & Medicaid Service, 2024).
- On Campus-Outpatient Hospital (Regulated Space): A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization (POS 22) (Centers for Medicare & Medicaid Services, 2024).

PPMCO Access Standards: A member's travel time for access to radiology should not exceed the following:

a. In urban areas, within 15 minutes or 10 miles
b. In suburban areas, within 30 minutes or 20 miles; and
c. In rural areas, within 40 minutes or 30 miles

VI. BACKGROUND

The American College of Obstetrics and Gynecology recommends an ultrasound study for all pregnant patients. The timing and frequency of the studies depend on the indication for the examination (ACOG, 2016). The use of low-powered obstetrical ultrasound has proved useful for the assessment of anatomic fetal development and growth, screening for evidence of aneuploidy or screening for other obstetrical abnormalities, such as amniotic fluid volume and cervical or placental concerns (Selec Health, 2016). Although ultrasonography is safe for the fetus when used appropriately, it should only be used when there is a valid medical indication and the lowest possible ultrasound exposure settings that obtain adequate image quality are employed and remain consistent with the as low-as reasonably-achievable (ALARA) principle (AIUM, 2019). The number of ultrasounds in pregnancy has increased from 1.5 examinations per pregnancy in the mid-1990s to 2.7 ultrasounds per pregnancy in the mid-2000s and in 2014 the usage in the United States is reported to average 5.2 ultrasounds per pregnancy (Siddique, 2009).

Evidence of Impact:

Routine use of ultrasound in low risk populations in early pregnancy (< 24 weeks) has improved gestational dating, leading to fewer postdate inductions, increased detection of multiple gestations, and enhanced detection of fetal anomalies (Cochrane, 2015). In a low risk population after 24 weeks of gestation, there is weak evidence to demonstrate at a population level the impact of obstetrical ultrasounds on perinatal morbidity and mortality or on mean birth weight.

Systematic studies of evidence found in the medical literature demonstrate the use of ultrasound in low- risk patients caused adjustment in the estimated date of delivery by more than 10 days in a significant percentage of pregnancies from clinical assessment alone. Based upon these studies, such an adjustment occurred in 11 percent to 24 percent of pregnancies. Appropriate dating is important to be able to distinguish intrauterine growth restriction (IUGR). In IUGR, the incorporation

of umbilical artery doppler velocimetry to standard antepartum testing has been shown to reduce the rate of perinatal death by 29%. Moreover, differences in Apgar scores, neonatal intensive care unit (NICU) admissions or newborn mortality rates have been demonstrated on a population level as a result of ultrasound screening during pregnancy.

Nabhan and Faris (2010) performed a meta-analysis for the Cochrane Database and found insufficient evidence to support reducing maternal anxiety over pregnancy outcomes by providing feedback from ultrasound examinations.

Ultrasound is an energy source that can induce thermal changes in tissues. Studies on the safety of ultrasound on the fetus have not found harmful effects despite concerns over the repeated application of this energy source during pregnancy.

Women whose ultrasounds demonstrate a fetal anomaly have a higher rate of termination of the pregnancy than those whose ultrasounds are normal. This has been found in small-sample-sized studies. Legislation in a number of states has taken the position that women having elective abortions must see a fetal ultrasound prior to the procedure. Policy statements from pro-abortion and anti-abortion advocacy groups purportedly demonstrate women's decision-making as either not influenced or greatly influenced by such studies. However, there is little high-quality scientific evidence on such decision-making. What is clear is that in continuing pregnancies, when a fetal anomaly or fetus suspected of aneuploidy is detected, there is better coordinated care of that mother/baby pair. Special considerations include the timing and number of ultrasound studies in obese patients and pregnancies with multiple gestations (Reddy et al., 2014)

VII. CODING DISCLAIMER

Note: The following CPT/HCPCS codes are included below for informational purposes and may not be all inclusive. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member's specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee of payment. Other policies and coverage determination guidelines may apply. .

Note: All inpatient admissions require pre-authorization.

Adherence to the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits
Advantage MD: Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Johns Hopkins Health Plan of Virginia Inc. (JHHPVA): Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Priority Partners (PPMCO): Regulatory guidance supersedes JHHP Medical Policy. If there are no criteria in COMAR regulations, or other State guidelines, apply the Medical Policy criteria.
US Family Health Plan (USFHP): Regulatory guidance supersedes JHHP Medical Policy. If there are no TRICARE policies, or other regulatory guidelines, apply the Medical Policy criteria.

VIII. CODING INFORMATION

CPT® CODES ARE FOR INFORMATIONAL PURPOSES ONLY	
CPT® CODES	**DESCRIPTION**
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
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	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester, transabdominal approach; each additional gestation.
76805	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after the first trimester, transabdominal approach, single or first gestation.
76810	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after the first trimester, transabdominal approach; each additional gestation.
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	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach, each additional gestation.
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.
76815	Ultrasound, pregnant uterus, real time with image documentation, limited (e.g., Fetal heartbeat, placental location, fetal position and/or qualitative amniotic fluid volume,1 or more fetuses.
76816	Ultrasound, pregnant uterus, real time with image documentation, follow-up (e.g., reevaluation of fetal size by measuring standard growth parameters and amniotic fluid volume, reevaluation 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.
76818	Fetal biophysical profile; with non-stress testing
76819	Fetal biophysical profile; without non-stress testing
76820	Doppler velocimetry, fetal; umbilical artery
76821	Doppler velocimetry, fetal; middle cerebral artery
76825	Echocardiography, fetal, cardiovascular system, real time with image documentation (2D), with or without M-mode recording;

76826	Echocardiography, fetal, cardiovascular system, real time with image documentation (2D), with or without M-mode recording; follow-up or repeat study
76827	Doppler echocardiography, fetal, pulsed wave and/or continuous wave with spectral display; complete
76828	Doppler echocardiography, fetal, pulsed wave and/or continuous wave with spectral display; follow-up or repeat study

IX. REFERENCE STATEMENT

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins Health Plans (JHHP) Medical Policy Team during the development and implementation of this medical policy. The Medical Policy Team will continue to monitor and review any newly published clinical evidence and revise the policy and adjust the references below accordingly if deemed necessary.

X. REFERENCES

Aetna. (2022, October 27). *Ultrasound for Pregnancy.* Medical Policy Number 0199. http://www.aetna.com

American College of Obstetricians and Gynecologists. (2016, December). *Ultrasound in Pregnancy*. Practice Bulletin Number 175. https://www.acog.org/

American Institute of Ultrasound in Medicine (AIUM). (2017)). *AIUM Practice Parameter for Ultrasound Examinations in Reproductive Medicine and Infertility*. https://www.aium.org

American Institute of Ultrasound in Medicine (AIUM). (2018). *AIUM-ACR–ACOG–SMFM–SRU Practice Parameter for the Performance of Standard Diagnostic Obstetrical Ultrasound Examinations.* https://www.aium.org

American Institute of Ultrasound in Medicine (AIUM). (2019, May 20). *AIUM Official Statements: Prudent clinical use and safety of diagnostic ultrasound.* https://www.aium.org

Blue Cross Blue Shield of North Carolina. (2023, March). *Maternal and Fetal Diagnostics.* Corporate Medical Policy. https://www.bluecrossnc.com

Centers for Medicare & Medicaid Services (CMS). (2024). *Place of Service Code Set*. https://www.cms.gov

Glanc, P. & Chitayat, D. (2022). Approach to prenatal diagnosis of the lethal (life-limiting) skeletal dysplasias. *UpToDate*. Retrieved January 25, 2023, from www.uptodate-com

Hayes, Inc. (2006, February 9). Three-Dimensional and Four-Dimensional Ultrasound for Fetal Cardiovascular Diagnosis. [Archived 2011, March 9]. http://www.hayesinc.com

Hayes, Inc. (2005, December 5). Three-Dimensional and Four-Dimensional Ultrasound for Fetal Limbs and Skeletal Structures. [Archived 2011, January 5]. http://www.hayesinc.com

Hayes, Inc. (2005, November 24). Three-Dimensional and Four Dimensional Ultrasound for Diagnosis of Fetal Head Abnormalities. [Archived 2010, December 24]. http://www.hayesinc.com

LabCorp. (2021). *First trimester screen with nuchal translucency.* https://www.labcorp.com

Law Insider (2020). Definition of Freestanding Facility. https://www.lawinsider.com

Maryland Health Care Commission. (2017, June 19). *COMAR 10.24.19 State health plan for facilities and services: freestanding medical facilities.* https://mhcc.maryland.gov

Mehta, T.S. (2023). Ultrasonography of pregnancy of unknown location. *UpToDate*. Retrieved January 5, 2024, from www.uptodate-com

Reddy U.M., Abuhamad, A. Z., Levine, D., Saade, G. R., & Fetal Imaging Workshop Invited Participants (2014). Fetal Imaging: executive summary of a joint Eunice Kennedy Shriver National Institute of Child Health and Human Development, Society for Maternal Fetal Medicine, American Institute of Ultrasound in Medicine, American College of Obstetricians and Gynecologists, American College of Radiology, Society for Pediatric Radiology and Society of Radiologists in Ultrasound Fetal Imaging Workshop. *Journal of ultrasound in medicine: official journal of American Institute of Ultrasound in Medicine, 33*(5), 745-757. https://doi.org/10.7863/ultra.33.5.745

Shipp, T. D. (2023). Overview of ultrasound examination in obstetrics and gynecology. *UpToDate*. Retrieved January 5, 2024, from www-uptodate-com.proxy1.library.jhu.edu

Tricare Policy Manual (2015). 6010.60-M. April 2021, Chapter 5, Section 2.1. Diagnostic Ultrasound. https://manuals.health.mil

Whitworth, M., Bricker, L., & Mullan, C. (2015). Ultrasound for fetal assessment in early pregnancy. Cochrane database, systemic reviews, 2015(7), CD007058. https://www.ncbi.nlm.nih.gov

Wilkins-Haug, L. (2023). Etiology, prenatal diagnosis, obstetric management, and recurrence of cleft lip and/or palate. *UpToDate*. Retrieved January 5, 2024, from www.uptodate-com

XI. APPROVALS

Historical Effective Dates: 12/02/2016, 03/03/2017, 12/01/2017, 08/03/2020, 02/01/2022, 05/02/2022, 05/01/2023, 04/01/2024