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- No specific information located in COMAR 10.67.01 – 10.67.13 (Accessed 5/1/2020).

For Employer Health Program (EHP) refer to:

- Plan specific Summary Plan Descriptions

For US Family Health Plan, refer to: [Tricare Policy Manuals](#)

- TRICARE Policy Manual 6010.60-M, April 1, 2015, Chapter 5, Section 2.1 Diagnostic Ultrasound


IV. POLICY CRITERION

A. General Considerations for Medical Necessity (Applicable to EHP, PPMCO, USFHP)

- When benefits are provided under the member's contract, JHHC considers the provision of up to three (3) prenatal obstetrical ultrasounds medically necessary during the course of a normal or low-risk pregnancy for the following indications:
 - Dating (first trimester)
 - Blood and nuchal translucency (first trimester, 10-14 weeks)
 - Anatomy scan (second trimester, 18-22 weeks)
- When benefits are provided under the member's contract, JHHC considers a three-dimensional (3-D) prenatal obstetrical ultrasound medically necessary for ANY of the following, when ordered by Maternal Fetal Medicine specialists:
 - Diagnosis of fetal brain and general fetal head abnormalities
 - Prenatal diagnosis of cleft lip and cleft palate, fetal facial anomalies
 - Diagnosis of fetal ear anomalies
 - neural tube defects
 - fetal tumors
 - skeletal malformations
- Unless specific benefits are provided under the member's contract, JHHC considers the following services not medically necessary:
 - Four dimensional (4-D) ultrasounds
 - Prenatal obstetrical ultrasound for the determination of gender of the fetus for nonmedical reasons
 - Prenatal obstetrical ultrasound done solely to provide an image of the fetus for parents

B. Site of Service - Prenatal Obstetrical Ultrasounds

- JHHC considers *free-standing facilities* to be an appropriate place of service for most obstetrical prenatal ultrasounds and takes into consideration the individual needs of the member and the availability of services in the local delivery system and their ability to meet the member's needs in the application of this policy. (Refer to Definitions section)
- Prenatal obstetrical ultrasounds may be performed without preauthorization at a *free-standing facility* as follows: (*Applicable to PPMCO and USFHP*)
 - For members with a high risk pregnancy diagnosis (Refer to Appendix A - High Risk Diagnosis List)
 - Up to (3) ultrasounds for members with a normal or low-risk pregnancy diagnosis (Refer to Appendix B - Low Risk Diagnosis List)
- Prenatal obstetrical ultrasounds NOT meeting or in excess of the medical necessity criteria in section (A) above require pre-authorization and documentation to support the medical necessity if performed at a *free-standing facility* OR *outpatient hospital setting including: (Applicable to EHP, PPMCO, USFHP)*
 - All 3-D prenatal obstetrical ultrasounds

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- b. Four or more prenatal obstetrical ultrasounds for normal or low-risk pregnancy
4. Prenatal obstetrical ultrasounds related to an emergent or life-threatening condition DO NOT require preauthorization at a *free-standing facility OR outpatient hospital setting*. (*Applicable to EHP, PPMCO, USFHP*)
5. JHHC recognizes that not all obstetrical prenatal ultrasounds for NON-emergent or life-threatening conditions can be performed at a *free-standing facility* due to member condition or facility limitations. Prenatal obstetrical ultrasounds may be performed in an *outpatient hospital setting* with pre-authorization and documentation to support the medical necessity of the site of service for the following indications: (*Applicable to PPMCO and USFHP*)
 - a. Prenatal obstetrical ultrasound ordered for member with one the diagnoses on the Exception List (Refer to Appendix C - Exceptions to Outpatient Hospital Setting Redirection List)
 - b. One of the prenatal obstetrical ultrasounds on the Exception List has been ordered (Refer to Appendix C - Exceptions to Outpatient Hospital Setting Redirection List)
 - c. 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)
 - d. Member with a High Risk Diagnosis (Appendix A) and a prenatal obstetrical ultrasound is being performed by a network maternal fetal specialist whose office is in an *outpatient hospital setting*.
6. Multiple prenatal obstetrical ultrasounds may be requested on a single pre-authorization request in order to facilitate care.

V. DEFINITIONS

Freestanding Facility: 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 imaging center that furnishes health care services and that is neither integrated with, nor a department of, a hospital (Law Insider, 2020). (For the purposes of this policy a prenatal obstetrical ultrasound performed in an obstetrician's office not in regulated space would be considered freestanding.)

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).

The list of indications per trimester was developed on a consensus basis, and includes:


ACR-ACOG-AIUM-SRU* Consensus- Based First Trimester Indications:

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Confirmation of intrauterine pregnancy	Assessment of fetal cardiac activity.
Evaluation for possible ectopic pregnancy.	Assessment of fetal anomalies such as anencephaly, in high-risk patients.
Evaluation of vaginal bleeding in pregnancy.	Evaluation of uterine masses or abnormalities.
Assessment of pelvic pain.	Measurement of nuchal translucency (NT) as part of screening for fetal aneuploidy.
Enhanced estimation of gestational age.	Evaluation of a suspected hydatidiform mole.
Evaluation of multiple gestations.	Assessment of fetal cardiac activity.
Confirmation of intrauterine pregnancy.	Assessment of fetal anomalies, such as anencephaly, in high-risk patients.

ACR-ACOG-AIUM-SRU* Consensus- Based Second and Third Trimester Indications:

Screening for fetal anomalies.	Suspected ectopic pregnancy.
Evaluation of fetal anatomy.	Suspected fetal death.
Estimation of gestational (menstrual) age.	Suspected uterine abnormality.
Evaluation of fetal growth.	Evaluation of fetal well-being.
Evaluation of vaginal bleeding.	Suspected amniotic fluid abnormalities.
Evaluation of abdominal or pelvic pain.	Suspected placental abruption.
Evaluation of cervical insufficiency.	Adjunct to external cephalic version.
Determination of fetal presentation.	Evaluation of premature rupture of membranes and/or premature labor.
Evaluation of suspected multiple gestation.	Evaluation of abnormal biochemical markers.
Adjunct to amniocentesis or other procedure.	Follow-up evaluation of a fetal anomaly.
Evaluation of significant discrepancy between uterine size and clinical dates.	Follow-up evaluation of placental location for suspected placenta previa.
Evaluation of pelvic mass.	History of previous congenital anomaly.
Evaluation of suspected hydatidiform mole.	Evaluation of fetal condition in late registrants for prenatal care.

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Adjunct to cervical cerclage.	Assessment for findings that may increase the risk for aneuploidy.
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*American College of Radiology (ACR), the American Institute of Ultrasound in Medicine (AIUM), the American College of Obstetricians and Gynecologists (ACOG), and the Society of Radiologists in Ultrasound (SRU).

Evidence of Impact:

Routine use of ultrasound in low risk populations in early pregnancy (< 24 weeks) has improved gestational dating leading to fewer post dates induction, 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 fetal growth restriction. 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 CochraneDatabase and found insufficient evidence to support reducing maternal anxiety over the 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- and antiabortion 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

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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.


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Compliance with the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits

Employer Health Programs (EHP) **See Specific Summary Plan Description (SPD)	Priority Partners (PPMCO) refer to COMAR guidelines then apply policy criteria	US Family Health Plan (USFHP), TRICARE Medical Policy supersedes JHHC Medical Policy. If there is no Policy in TRICARE, apply the Medical Policy Criteria	Advantage MD, LCD and NCD Medical Policy supersedes JHHC Medical Policy. If there is no LCD or NCD, apply the Medical Policy Criteria
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VIII. CODING INFORMATION

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.

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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 HealthCare LLC (JHHC) 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

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XI. APPROVALS

Historical Effective Dates: 12/02/2016, 03/03/2017, 12/01/2017, 08/03/2020