### Description

First trimester noninvasive prenatal screening (NIPS) is usually done between 11 to 14 gestational weeks to check for chromosomal abnormalities and can be completed in a single combined test or in a multistep process. A blood sample, taken from a pregnant woman, is analyzed for free β-human chorionic gonadotropin (hCG) and pregnancy-associated plasma protein A (PAPP-A) levels. In addition, an ultrasound may be performed to measure nuchal translucency (thickness of the space between the back of the fetal neck and overlying skin). The results of these tests (and consideration of maternal age) are used to calculate specific risk for fetal chromosomal disorders. If these results demonstrate a significant probability of a fetal abnormality, invasive testing such as amniocentesis or chorionic villus sampling (CVS), may be performed.
Second trimester NIPS may include maternal serum testing for alpha-fetoprotein (AFP) levels to check for neural tube defects. This test is generally performed between 16 to 18 weeks of pregnancy. Multiple marker screening (also referred to as triple screen or quad screen) may be performed during the second trimester and includes testing maternal serum levels of AFP, hCG, unconjugated estriol (uE3) and/or inhibin-A to combine screening for chromosome abnormalities and neural tube defects. This panel is usually done around 15 to 20 gestational weeks when abnormal levels could indicate that further evaluation may be needed with invasive testing.

For information regarding prenatal invasive diagnostic genetic testing, please refer to the Prenatal Invasive Diagnostic Genetic Testing Medical Coverage Policy.

Prenatal cell-free deoxyribonucleic acid (cfDNA) noninvasive screening tests are laboratory studies that examine changes in human DNA, chromosomes, genes or gene products (such as proteins) of cfDNA sequences that are isolated in the maternal plasma during pregnancy. Examples include:

- Genome testing (eg, MaterniT Genome, PreSeek, Resura, VERAgene, Vistara) analyzes fetal chromosomes for extra or missing parts of chromosomes or other whole chromosome changes. (Refer to Coverage Limitations section)

- Sequencing-based trisomy tests for fetal aneuploidy detect chromosome abnormalities. These advanced screening tests (eg, ClariTest, Harmony prenatal test, InformaSeq prenatal test, Invitae NIPS, MaterniT21, Nifty Test, Panorama prenatal screen, Preclude prenatal screen, Prequel prenatal screen, QNatal Advanced screen, Verifi prenatal test) are used to detect one or more of the following:
  - Aneuploidies involving chromosomes 13, 18 and 21
  - Aneuploidies involving sex chromosomes (Refer to Coverage Limitations section)
  - Microdeletions/microduplications (Refer to Coverage Limitations section)
  - Screening for single gene variants (Refer to Coverage Limitations section)

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Screening for twin zygosity (Refer to Coverage Limitations section)

Pre-eclampsia is a disorder of pregnancy characterized by the onset of high blood pressure and protein in the urine which typically begins after the twentieth week of pregnancy. Monitoring of maternal blood pressure is routinely used as a screening tool to evaluate for pre-eclampsia during prenatal visits. Available tests include but not may not be limited to:

- Maternal Fetal Screen|T1 analyzes five biochemical markers in the maternal blood sample: AFP, dimeric inhibin A (DIA), free Beta hCG, PAPP-A and PIGF in combination with an ultrasound (nuchal translucency, nasal bone and uterine artery Doppler pulsatility index [UtAD-PI]) to purportedly provide quantitative risk assessments for trisomies 13, 18 and 21 and early onset pre-eclampsia (EOPE). 

- PlGF 1-2-3 Assay is a biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum and predictive algorithm that is used as a risk score for preeclampsia. 

- Pre-eclampsiaScreen|T1 is a screening test to measure three biochemical markers in the mother's serum associated with preeclampsia: AFP, PAPP-A and PIGF (placental growth factor). Together, these three biochemical markers purportedly contribute to accurate prediction of risk for early onset preeclampsia.

Preterm birth (delivery prior to 37 weeks gestation) occurs in approximately 10% of pregnancies in the United States. The PreTRM test is purported to predict spontaneous preterm birth as early as 19 weeks of gestation in asymptomatic, singleton pregnancies by analyzing multiple maternal serum proteins and other clinical data.

Ultrasonography (ultrasound) is commonly used in the second trimester of pregnancy to monitor fetal development and maternal well-being. Two-dimensional (2D) ultrasound may be performed to determine gestational age, number of fetuses, fetal cardiac activity and placental location. In addition, many congenital structural anomalies and significant abnormalities in fetal growth may be identified.
Three-dimensional (3D) ultrasound uses special probes and software to acquire a 2D static display of 3D data. Although the indications for its use have not been well-defined, 3D technology can purportedly reduce scanning time and better demonstrate abnormalities previously detected with 2D sonography including facial abnormalities and neural tube defects. Four-dimensional (4D) ultrasound (also called dynamic 3D sonography) refers to 3D images that can be viewed in real-time. Five-dimensional (5D) ultrasound (also known as high-definition live) includes a software package on the ultrasound unit that purportedly enhances facial skin tone and depth perception through lighting techniques which results in high-resolution images. (Refer to Coverage Limitations section)

Fetal magnetocardiography is a noninvasive technique for recording magnetic fields generated by the electrical activity of the fetal heart. It is a passive recording technique utilizing high sensitivity Superconducting Quantum Interference Device (SQUID) sensors. These sensors amplify signals that are naturally occurring, yet weak. (Refer to Coverage Limitations section)

Coverage Determination

Any state mandates for noninvasive prenatal screening take precedence over this clinical policy.

For NIPS for Zika virus, please refer to the Centers for Disease Control and Prevention (CDC) for the current guidelines.

Humana members may be eligible under the Plan for NIPS for chromosomal abnormalities using ONE of the following:

- Multiple marker screening (ie, inhibin-A, free or total hCG, PAPP-A and/or uE3 levels) with or without 2D ultrasonography* (ie, measurement of nuchal translucency); OR


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Humana members may be eligible under the Plan for NIPS for neural tube defects performed in the second-trimester using 2D ultrasonography* (ie, screening for fetal anomalies) with or without maternal serum AFP.

*2D ultrasonography may be performed up to the terms and conditions of the member’s individual contract.

**These tests offer add-on screening options for microdeletions, sex chromosome aneuploidies and/or trisomies other than 13, 18 and 21. (Refer to Coverage Limitations section)

Note: The criteria for NIPS for chromosomal abnormalities are not consistent with the Medicare National Coverage Policy and therefore may not be applicable to Medicare members. Refer to the CMS website for additional information.

Coverage Limitations

Humana members may NOT be eligible under the Plan for the following NIPS tests for any indication:

- 3D, 4D or 5D ultrasonography
- Fetal magnetocardiography
- First trimester ultrasound assessment of the nasal bone

These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may NOT be eligible under the Plan for cfDNA sequence-based prenatal screening for fetal trisomy aneuploidy (13, 18 and 21) (eg, 81420, 81507) (eg, Harmony prenatal test, informaSeq prenatal test, Invitae NIPS, MaterniT21 PLUS CORE, Nifty Test, Panorama prenatal screen, Prelude prenatal screen, Prequel prenatal screen, QNatal Advanced screen and verifi prenatal test) for any indications other than those listed above in the coverage determination section including, but may not be limited to, the following:

- Duplicative or repeat (ie, during the same pregnancy) testing for low fetal fraction or test failure); OR
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- Duplicative or repeat NIPS testing for chromosomal abnormalities (eg, multiple marker screening with or without 2D ultrasound for nuchal translucency) has been performed during the current pregnancy; OR

- Expanded testing of microdeletion/microduplication analysis (eg, DiGeorge syndrome, Prader-Willi syndrome) (ie, 81422) (eg, Panorama Plus 22q11.2 deletion, MaterniT21 Plus ESS); OR

- Multiple gestation pregnancy; OR

- Screening for monogenic disorders (eg, beta thalassemia, hemophilia, sickle cell anemia); OR

- Screening for sex chromosome aneuploidies (eg, MaterniT21 PLUS + SCA); OR

- Screening for single gene variants (eg, known familial mutation); OR

- Screening for trisomies other than 13, 18 and 21; OR

- Screening for twin zygosity (ie, 0060U)

This is considered experimental/investigational as it is not identified as widely used and generally accepted for any other proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may NOT be eligible under the Plan for the following NIPS tests for any indication:

- First Trimester Screen|Fβ (ie, 0124U); OR

- Maternal Fetal Screen|T1 (ie, 0125U) and Maternal Fetal Screen|T1 +Y (ie, 0126U); OR

- MaterniT GENOME; OR

- PIGF 1-2-3 assay (ie, 0243U); OR

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- PreeclampsiaScreen|T1 (ie, 0127U) and PreeclampsiaScreen|T1 +Y (ie, 0128U); OR
- PreSeek; OR
- PreTRM (ie, 0247U); OR
- Resura; OR
- VERAgene; OR
- Vistara

These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may NOT be eligible under the Plan for multi-panel cfDNA sequence-based prenatal screening tests\(^\text{a}\) unless ALL components being tested in the panel meet the criteria above. Examples of multi-panel tests include, but may not be limited to, the following:

- ClariTest
- Innatal
- MaterniT21 PLUS + SCA/ESS
- Panorama Plus 22q11.2 deletion
- Veracity
- Verifi Plus

These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

\(^\text{a}\)Individual tests within a multi-panel test may be medically necessary when the above criteria are met (eg, aneuploidies involving chromosomes 13, 18 and 21 [ie, 81420])

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Humana members may NOT be eligible under the Plan for NIPS testing for any indications other than those listed above, including the detection of genetic susceptibility to adult-onset/late-onset disorders. This is considered not medically necessary as defined in the member’s individual certificate. Please refer to the member’s individual certificate for the specific definition.

Fetal gender testing is considered integral to the panel of standard blood tests and is not separately reimbursable.

Individual serum levels (eg, AFP, hCG [duplicate form], inhibin-A, PAPP-A, uE3) reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies (eg, 81508, 81509, 81510, 81511, 81512) are not separately reimbursable.

### Medical Alternatives

Alternatives to PGIF 1-2-3 Assay and Preeclampsia Screen include, but may not be limited to, the following:

- Fetal biophysical profile
- Urine analysis

Alternatives to PreTRM include, but may not be limited to, the following:

- Fetal fibronectin testing
- Transvaginal ultrasound exam

Physician consultation is advised to make an informed decision based on an individual’s health needs.

Humana may offer a disease management program for this condition. The member may call the number on his/her identification card to ask about our programs to help manage his/her care.

### Background

Additional information about fetal chromosomal abnormalities may be found from the following websites:

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Noninvasive Prenatal Screening

Provider Claims Codes

Any CPT, HCPCS or ICD codes listed on this medical coverage policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and or reimbursement for a service or procedure.

The table below includes general codes for Noninvasive Prenatal Screening. For codes related to a specific gene and/or genetic condition, please refer to the appropriate genetic testing medical coverage policy.

<table>
<thead>
<tr>
<th>CPT® Code(s)</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>76376</td>
<td>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</td>
<td>Not covered if used to report routine pregnancy ultrasound</td>
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<tr>
<td>76377</td>
<td>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</td>
<td>Not covered if used to report routine pregnancy ultrasound</td>
</tr>
<tr>
<td>76801</td>
<td>Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester (&lt;14 weeks 0 days), transabdominal approach; single or first gestation</td>
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<tr>
<td>76802</td>
<td>Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester (&lt;14 weeks 0 days), transabdominal approach; each additional gestation (List separately in addition to code for primary procedure)</td>
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</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Coverage Status</td>
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</tr>
<tr>
<td>76811</td>
<td>Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach; single or first gestation</td>
<td>Not covered if used to report first trimester ultrasound assessment of the nasal bone</td>
</tr>
<tr>
<td>76812</td>
<td>Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach; each additional gestation (List separately in addition to code for primary procedure)</td>
<td>Not covered if used to report first trimester ultrasound assessment of the nasal bone</td>
</tr>
<tr>
<td>76813</td>
<td>Ultrasound, pregnant uterus, real time with image documentation, first trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach; single or first gestation</td>
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<tr>
<td>76814</td>
<td>Ultrasound, pregnant uterus, real time with image documentation, first trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach; each additional gestation (List separately in addition to code for primary procedure)</td>
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<tr>
<td>76815</td>
<td>Ultrasound, pregnant uterus, real time with image documentation, limited (eg, fetal heart beat, placental location, fetal position and/or qualitative amniotic fluid volume), 1 or more fetuses</td>
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<tr>
<td>76816</td>
<td>Ultrasound, pregnant uterus, real time with image documentation, follow-up (eg, re-evaluation of fetal size by measuring standard growth parameters and amniotic fluid volume, re-evaluation of organ system(s) suspected or confirmed to be abnormal on a previous scan), transabdominal approach, per fetus</td>
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<tr>
<td>81420</td>
<td>Fetal chromosomal aneuploidy (eg, trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21</td>
<td>Not Covered if used to report any test outlined in Coverage Limitations section</td>
</tr>
<tr>
<td>81422</td>
<td>Fetal chromosomal microdeletion(s) genomic sequence analysis (eg, DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood</td>
<td>Not Covered</td>
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</table>

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<tr>
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<th>Description</th>
<th>Coverage Limitations</th>
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<tr>
<td>81479</td>
<td>Unlisted molecular pathology procedure</td>
<td>Not Covered if used to report any test outlined in Coverage Limitations section</td>
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<tr>
<td>81507</td>
<td>Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score</td>
<td>Not Covered if used to report any test outlined in Coverage Limitations section</td>
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<tr>
<td>81508</td>
<td>Fetal congenital abnormalities, biochemical assays of two proteins (PAPP-A, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score</td>
<td>Individual serum levels reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies are not separately reimbursable</td>
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<tr>
<td>81509</td>
<td>Fetal congenital abnormalities, biochemical assays of three proteins (PAPP-A, hCG [any form], DIA), utilizing maternal serum, algorithm reported as a risk score</td>
<td>Individual serum levels reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies are not separately reimbursable</td>
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<tr>
<td>81510</td>
<td>Fetal congenital abnormalities, biochemical assays of three analytes (AFP, uE3, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score</td>
<td>Individual serum levels reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies are not separately reimbursable</td>
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</tbody>
</table>

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<table>
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<tr>
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<th>Description</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>81511</td>
<td>Fetal congenital abnormalities, biochemical assays of four analytes (AFP, uE3, hCG [any form], DIA) utilizing maternal serum, algorithm reported as a risk score (may include additional results from previous biochemical testing)</td>
<td>Individual serum levels reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies are not separately reimbursable</td>
</tr>
<tr>
<td>81512</td>
<td>Fetal congenital abnormalities, biochemical assays of five analytes (AFP, uE3, total hCG, hyperglycosylated hCG, DIA) utilizing maternal serum, algorithm reported as a risk score</td>
<td>Individual serum levels reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies are not separately reimbursable</td>
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<tr>
<td>81599</td>
<td>Unlisted multianalyte assay with algorithmic analysis</td>
<td>Fetal gender testing is considered integral to the panel of standard blood tests that are taken when assessing for sex chromosome aneuploidies and not separately reimbursable</td>
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<tr>
<td>82105</td>
<td>Alpha-fetoprotein (AFP); serum</td>
<td>Not Covered if used to report any test outlined in Coverage Limitations section</td>
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<tr>
<td>82106</td>
<td>Alpha-fetoprotein (AFP); amniotic fluid</td>
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<tr>
<td>82677</td>
<td>Estriol</td>
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<tr>
<td>84163</td>
<td>Pregnancy-associated plasma protein-A (PAPP-A)</td>
<td>Not Covered if used to report any test outlined in Coverage Limitations section</td>
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<tr>
<td>84702</td>
<td>Gonadotropin, chorionic (hCG); quantitative</td>
<td></td>
</tr>
<tr>
<td>84703</td>
<td>Gonadotropin, chorionic (hCG); qualitative</td>
<td></td>
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</tbody>
</table>

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### Noninvasive Prenatal Screening

**Effective Date:** 03/25/2021  
**Revision Date:** 03/25/2021  
**Review Date:** 10/22/2020  
**Policy Number:** HCS-0430-026  
**Page:** 13 of 22

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| Code  | Description                                                                 | Coverage Status                                      
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<tr>
<td>84704</td>
<td>Gonadotropin, chorionic (hCG); free beta chain</td>
<td>Not Covered if used to report any test outlined in Coverage Limitations section</td>
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<tr>
<td>84999</td>
<td>Unlisted chemistry procedure</td>
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<td>Inhibin A</td>
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<tr>
<td>88299</td>
<td>Unlisted cytogenetic study</td>
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<tr>
<td>0060U</td>
<td>Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood</td>
<td>Not Covered</td>
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</table>
| 0124U | Fetal congenital abnormalities, biochemical assays of 3 analytes (free beta-hCG, PAPP-A, AFP), time-resolved fluorescence immunoassay, maternal dried-blood spot, algorithm reported as risk scores for fetal trisomies 13/18 and 21 | Not Covered  
**Deleted Code Effective 06/30/2020** |
| 0125U | Fetal congenital abnormalities and perinatal complications, biochemical assays of 5 analytes (free beta-hCG, PAPP-A, AFP, placental growth factor, and inhibin-A), time-resolved fluorescence immunoassay, maternal serum, algorithm reported as risk scores for fetal trisomies 13/18, 21, and preeclampsia | Not Covered  
**Deleted Code Effective 06/30/2020** |
| 0126U | Fetal congenital abnormalities and perinatal complications, biochemical assays of 5 analytes (free beta-hCG, PAPP-A, AFP, placental growth factor, and inhibin-A), time-resolved fluorescence immunoassay, includes qualitative assessment of Y chromosome in cell-free fetal DNA, maternal serum and plasma, predictive algorithm reported as a risk scores for fetal trisomies 13/18, 21, and preeclampsia | Not Covered  
**Deleted Code Effective 06/30/2020** |
| 0127U | Obstetrics (preeclampsia), biochemical assays of 3 analytes (PAPP-A, AFP, and placental growth factor), time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia | Not Covered  
**Deleted Code Effective 06/30/2020** |

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| 0128U | Obstetrics (preeclampsia), biochemical assays of 3 analytes (PAPP-A, AFP, and placentental growth factor), time-resolved fluorescence immunoassay, includes qualitative assessment of Y chromosome in cell-free fetal DNA, maternal serum and plasma, predictive algorithm reported as a risk score for preeclampsia | Not Covered | Deleted Code Effective 06/30/2020 |
| 0168U | Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma without fetal fraction cutoff, algorithm reported as a risk score for each trisomy | New Code Effective 04/01/2020 |
| 0243U | Obstetrics (preeclampsia), biochemical assay of placentental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia | Not Covered | New Code Effective 04/01/2021 |
| 0247U | Obstetrics (preterm birth), insulin-like growth factor–binding protein 4 (IBP4), sex hormone– binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, combined with clinical data, reported as predictive-risk stratification for spontaneous preterm birth | Not Covered | New Code Effective 04/01/2021 |

<table>
<thead>
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<th>CPT® Category III Code(s)</th>
<th>Description</th>
<th>Comments</th>
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<tr>
<td>0475T</td>
<td>Recording of fetal magnetic cardiac signal using at least 3 channels; patient recording and storage, data scanning with signal extraction, technical analysis and result, as well as supervision, review, and interpretation of report by a physician or other qualified health care professional</td>
<td>Not Covered</td>
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<tr>
<td>0476T</td>
<td>Recording of fetal magnetic cardiac signal using at least 3 channels; patient recording, data scanning, with raw electronic signal transfer of data and storage</td>
<td>Not Covered</td>
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<tr>
<td>0477T</td>
<td>Recording of fetal magnetic cardiac signal using at least 3 channels; signal extraction, technical analysis, and result</td>
<td>Not Covered</td>
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</tbody>
</table>

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<table>
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<th>Description</th>
<th>Coverage</th>
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</thead>
<tbody>
<tr>
<td>0478T</td>
<td>Recording of fetal magnetic cardiac signal using at least 3 channels; review, interpretation, report by physician or other qualified health care professional</td>
<td>Not Covered</td>
</tr>
</tbody>
</table>

No code(s) identified

**References**


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