Non-Invasive Prenatal Testing (NIPT)
MPM 20.15

Disclaimer
Refer to the member’s specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in these criteria.

Prior Authorization may or may not be required. Please use the Prior Authorization/Benefit Certification Guide to determine when a prior authorization/benefit certification is required.
https://ds.phs.org/preslogin/index.jsp

Description
Genetic testing is the use of specific assays to determine the genetic status of individuals already suspected to be at high risk for a particular inherited condition. High risk means that the individual has a known family history or classic symptoms of the disorder. Genetic testing includes a variety of techniques that test for genetic diseases and analyzes genetic risk factors that may contribute to disease. Techniques involve the examination of a blood sample, or other body fluid, or tissue to indicate the presence, absence, or alteration (mutation) of genes linked to specific diseases or conditions.

Non-invasive prenatal testing (NIPT) employs genetic sequencing technology to magnify fetal cell-free DNA (cfDNA) obtained from maternal bloodstream. Through a variety of techniques, fetal DNA is prenatally identified in the first and/or second trimester, as early as 9 to 10 weeks. Screening is performed for the presence of fetal aneuploidy, specifically trisomy 13 (Patau Syndrome), trisomy 18 (Edwards Syndrome) and trisomy 21 (Down Syndrome). It is estimated that 6% to 11% of stillbirths and neonatal deaths result from aneuploidy. The tests cannot diagnose or exclude the possibility of a chromosome disorder.

The use of NIPT is offered as an alternative to invasive procedures such as amniocentesis and chorionic villus sampling (CVS), and the potential risks of infection, bleeding, fetal injury and pregnancy termination.

NIPT does produce a non-result in 4-5% of cases due to lack of sufficient quantity of cell-free fetal DNA in the sample. False-positive rate is less than 1%. NIPT uses molecular techniques such as massively parallel sequencing (MPS) to sequence analyze millions of DNA fragments at the same time. Each NIPT assay is different with respect to its exact
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methodology and algorithms for data analysis.

Current clinical literature supports the genetic sequencing technology behind the Harmony Prenatal Test (Ariosa Diagnostic Inc), MaterniT21 PLUS (Sequenom laboratories) and Panorama Prenatal Test (Natera Inc).

Current clinical literature does not support the genetic sequencing technology behind the informaSeq (Integrated Genetics) (Hayes Level D) and the Verifi Prenatal Test (Illumina Inc.)(Hayes Level D).

Products Covered

Harmony Prenatal Test (Ariosa Diagnostics Inc.)
MaterniT21 PLUS (Sequenom Laboratories)
Panorama Prenatal Test (Natera Inc.)

Clinical Indications

General Requirements

1. Pregnant woman with a singleton pregnancy and one of the following criteria:
   a. Age 35 years or older at time of delivery, or
   b. Fetal ultrasound findings predicting an increased risk of fetal aneuploidy, such as fetal nuchal translucency, absent/hypoplastic nasal bone, echogenic bowel, Pyelectasis, Shortened long bones (humerus, femur), echogenic intracardiac focus, Choroid plexus cysts; or
   c. History of prior pregnancy with aneuploidy/trisomy 21, 18, or 13; or
   d. Positive screening test for aneuploidy, including first-trimester, sequential or integrated screen; or
   e. Positive quadruple screen; or
   f. Either parent has been identified as having a balanced Robertsonian translocation with increased risk for fetal trisomy or trisomy 21.

2. Individual must have the capacity to make fully informed decisions and consent for treatment.

3. Individual must receive genetic counseling from a certified genetic counselor or a qualified healthcare professional.
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Medicare Specific Coverage Determinations
There is no current Centers for Medicare and Medicaid Services National Coverage Determination regarding coverage of NIPT. In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Regulatory Status
No Food and Drug Administration regulatory information for NIPT. Genetic tests are regulated under the Clinical Laboratory Improvement Amendments (CLIA) certifications.

Exclusions
Presbyterian Health Plan considers NIPT for all other indications to be experimental or investigational, including average-risk and multiple-gestation pregnancies and the detection of microdeletions.

Definitions
Aneuploidy: any deviation from an exact multiple of the haploid number of chromosomes

Triple Screen: Alpha-fetoprotein (AFP) + Human Chorionic Gonadotropin (hCG) + Estriol

Quadruple Screen: Alpha-fetoprotein (AFP) + Human Chorionic Gonadotropin (hCG) + Estriol + Inhibin-A

Coding
The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.


<table>
<thead>
<tr>
<th>Laboratory</th>
<th>Test Name</th>
<th>Method Used</th>
<th>CPT Codes</th>
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<tbody>
<tr>
<td>Ariosa Diagnostics</td>
<td>Harmony Prenatal Test</td>
<td>t-MPS</td>
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<tr>
<td>Natera Inc</td>
<td>Panorama</td>
<td>SNP</td>
<td>81420</td>
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<td>MaterniT21Plus</td>
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### ICD-10 Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10© Diagnosis</th>
<th>Codes requiring a 7th character are represented by &quot;+&quot;</th>
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<tbody>
<tr>
<td>O09.511</td>
<td>Supervision of elderly primigravida, first trimester</td>
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<tr>
<td>O09.512</td>
<td>Supervision of elderly primigravida, second trimester</td>
</tr>
<tr>
<td>O09.521</td>
<td>Supervision of elderly multigravida, first trimester</td>
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<tr>
<td>O09.522</td>
<td>Supervision of elderly multigravida, second trimester</td>
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<tr>
<td>O28.3</td>
<td>Abnormal ultrasonic finding on antenatal screening of mother</td>
</tr>
<tr>
<td>O28.5</td>
<td>Abnormal chromosomal and genetic finding on antenatal screening of mother</td>
</tr>
<tr>
<td>O35.1+</td>
<td>Maternal care for (suspected) chromosomal abnormality in fetus (conditions in Q90-Q99)</td>
</tr>
<tr>
<td>O35.2+</td>
<td>Maternal care for (suspected) hereditary disease in fetus</td>
</tr>
<tr>
<td>O35.9+</td>
<td>Maternal care for (suspected)fetal abnormality and damage, unspecified</td>
</tr>
</tbody>
</table>

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**Reviewed by**

Ashley Solomon-Nelson CGC and Michelle Maxedon CGC, Perinatal Associates, Albuquerque, New Mexico

**References**

1. Hayes, Cell-Free DNA (cfDNA) [Formerly NIPS, NIPT], Screening for Fetal Trisomy 21, 18, and 13 in High-Risk Women, Publication Date Feb 16, 2018. [Cited 03/14/19].
3. American College of Obstetricians and Gynecologists, Committee Opinion: Cell-free DNA Screening for Fetal Aneuploidy (Number 640, September 2015)

**Approval Signatures**

Clinical Quality Committee: **Norman White MD**

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Not every Presbyterian health plan contains the same benefits. Please refer to the member’s specific benefit plan and Schedule of Benefits to determine coverage. [MPMPPC051001]
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Medical Policy

Medical Directory: David Yu MD

Approval Dates

March 27, 2019

Publications History

07/01/2015 Original effective date
01/01/2016 Update
01/24/2018 Annual review. No change
03/27/2019 Annual review. Update CPT and ICD-10 codes, also added additional information for fetal ultrasound findings on increased risk of fetal aneuploidy from article on Sonographic findings associated with fetal aneuploidy from UpToDate.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: Click here for Medical Policies

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