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The Department of Vermont Health Access Clinical Criteria

Subject: Noninvasive Prenatal Testing for Trisomy 13, 18, and 21
Last Review: May 8, 2023*
Past Revisions: March 26, 2021, June 14, 2018 (technical revision) and June 1, 2018

***Please note: Most current content changes will be highlighted in yellow.**

Description of Service or Procedure

Aneuploidy is a chromosomal anomaly that occurs when cells have either extra or missing chromosomes. When aneuploidies occur in fetal cells, these pregnancies are often nonviable and account for a large proportion of early pregnancy loss. Trisomy is the term utilized to describe an aneuploidy in which there is an extra chromosome. Some of the most common aneuploidies are trisomies involving chromosomes 13 (Patau syndrome), 18 (Edward's syndrome), and 21 (Down syndrome). The incidence of these trisomies increases with maternal age. Diagnostic testing for these trisomies is invasive and carry some risk of fetal harm and include amniocentesis (AMC), chorionic villus sampling (CVS), and cordocentesis.

Noninvasive prenatal testing (NIPT), also known as noninvasive prenatal screening (NIPS) is a newer genetic screening technology that utilizes maternal blood to analyze circulating cell-free fetal DNA for trisomies 13, 18, and 21. This may be performed as early as 10 weeks gestation. Depending on the specific NIPT test performed, results may be reported as a positive or negative, or a risk score. NIPT/NIPS is a screening test only and a positive result should be confirmed by diagnostic testing such as AMC or CVS.

Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertains to the member's aid category. Prior Authorization (PA) is only valid if the member is eligible for the applicable item or service on the date of service.

Medicaid Rule

Medicaid and Health Care Administrative Rules can be found at https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar/adopted-rules

7102.2	Prior Authorization Determination
7405	Laboratory and Radiology Services
4.101	Medical Necessity for Covered Services

Coverage Position

NIPT may be covered for members:

- When the service is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described on the Vermont Office of Professional Regulation's website*, Statute, or rule who is knowledgeable regarding NIPT and who provides medical care to the member AND
- When the clinical criteria below are met.

* Vermont's Office of Professional Regulation's website: https://sos.vermont.gov/opr/

Coverage Criteria

NIPT CPT **code 81420** (Fetal chromosomal aneuploidy (e.g., 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) is a screening test, and a positive result requires confirmation by invasive testing (e.g., CVS, AMC). Testing may be covered for members with a singleton pregnancy after 10 weeks gestation and who will receive pre- and post-counseling for ANY of the following indications:

1. Maternal age 35 years or older at delivery
2. Fetal ultrasonographic findings indicating increased risk of aneuploidy
3. History of previous pregnancy with a trisomy
4. Standard serum screening test positive for aneuploidy or
5. Parental balanced Robertsonian translocation with increased risk of fetal trisomy 13 or trisomy 21

NIPT CPT **code 81507** (Harmony®) (Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy) is also a screening test and utilizes DNA sequence analysis of selected regions using maternal plasma and an algorithm and is reported as a risk score for each trisomy. This test is for all pregnant women regardless of age, includes any of the criteria listed above, and is appropriate for twin pregnancies.

Proportion of fetal to maternal cell-free DNA levels in maternal plasma greatly impacts test reliability. Fetal cell-free DNA increases throughout gestation. Studies have identified that increased maternal weight is associated with lower levels of fetal cell-free DNA. Fraction of fetal cell-free DNA in maternal blood decreases with increased maternal weight and this is correlated to increased NIPT test failure. In considering this testing, patients with increased maternal weight should be informed of this risk. It is important to inform and discuss alternative screening with patients who decline second attempt for testing.

Considerations: Providers requesting this test should provide pre- and post-test genetic counseling for the member and family, if applicable. Timing of redraw for inconclusive screen results should be considered to optimize success of obtaining a test result.

Early and Periodic Screening, Diagnostic and Treatment (EPSDT): Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Please note, Vermont Medicaid Clinical Criteria is reviewed based on available literature, evidence- based guidelines/standards, Medicaid rule and policy, and Medicare coverage determinations that may be appropriate to incorporate when applicable.

Clinical guidelines for repeat service or procedure

- No more than one test per pregnancy unless there is a test failure. Limited to no more than two.
- Harmony® has been validated in singleton and twin pregnancies of at least 10 weeks gestational age. Harmony® is not validated for use in pregnancies with more than two fetuses, demised twin, mosaicism, partial chromosome aneuploidy, translocations, maternal aneuploidy, transplant, malignancy, or in women under the age of 18.
- Parallel or concurrent testing with numerous screening systems for aneuploidy will not be covered.

Type of service or procedure covered

Currently available products include but are not limited to: Harmony ® Prenatal Test, informaSeq®, MaterniT® 21 PLUS, Panorama™ Prenatal Test, and Verifi® Prenatal Test.

Type of service or procedure not covered (this list may not be all inclusive)

- Sex chromosome aneuploidy.
- Screening for single gene disorders.
- Screening for average or low-risk pregnancy.
- Routine cell-free DNA screening for microdeletion syndromes.
- When Karyotyping aneuploidy FISH and/or array CGH have already been performed within 10 weeks of the cell-free fetal DNA test.

Coding guidelines

Please see the Medicaid Portal at http://vtmedicaid.com/#/feeSchedule for fee schedules, code coverage, and applicable requirements.

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