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The Department of Vermont Health Access Clinical Criteria

Subject: Noninvasive Prenatal Testing or Serum Marker Screening for Trisomy 13, 18, or 21
Last Review: March 26, 2021*
Past Revisions: 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

A prenatal diagnosis of chromosomal abnormalities requires testing such as: amniocentesis, or chorionic villus sampling for analysis of fetal cells. These invasive procedures carry a risk of fetal loss, and many women choose a non-invasive screening before considering the invasive testing options. The non-invasive prenatal testing (NIPT) is available to analyze the cell-free fetal DNA to detect aneuploidies involving specific chromosomes 21, 18, and 13. This may be performed as early as 9 to 10 weeks gestation. NIPT is a screening test and a positive result requires confirmation by invasive testing.

Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertains to the beneficiary's aid category. Prior Authorization (PA) is only valid if the beneficiary 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
4.101	Medical Necessity for Covered Services
4.104	Medicaid Non-Covered Services

Coverage Position

NIPT may be covered for beneficiaries:

- When the service is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described in their Vermont State Practice Act,

Statute, or rule who is knowledgeable regarding NIPT and who provides medical care to the beneficiary AND
- When the clinical criteria below are met.

Coverage Criteria

NIPT CPT **code 81420** is a screening test and a positive result requires confirmation by invasive testing. Testing may be covered for beneficiaries with a singleton pregnancy after 10 weeks 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 Test) fetal aneuploidy (trisomy 21-Downs Syndrome , 18-Edwards Syndrome, and 13-Patau Syndrome) is a DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy. This is for all pregnant women regardless of age and 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. NIPT test failure and inaccuracy is significantly increased for women greater than 80 kg. 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.

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.

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 (Ariosa Diagnostics Inc.); informaSeq (Integrated Genetics); MateriT21 PLUS (Sequenom Laboratories); Panorama Prenatal Test (Natera Inc.); and Verifi Prenatal Test (Illumina Inc.).

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.

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