CLINICAL MEDICAL POLICY	
Policy Name:	Fetal Aneuploidy Testing Using Noninvasive Cell-Free Fetal DNA
Policy Number:	MP-003-MD-DE
Responsible Department(s):	Medical Management
Provider Notice Date:	08/15/2019; 10/15/2018; 10/01/2017
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Revision Date:	07/16/2019; 09/11/2018; 08/09/2017
Products:	Highmark Health Options Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 10

DISCLAIMER

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options provides coverage for laboratory benefit under the medical benefits of the Company's Medicaid products for medically necessary, noninvasive, circulating cell-free DNA prenatal testing of fetal aneuploidy as screening tools for trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome) or trisomy 13 (Patau syndrome). Circulating cell-free fetal DNA crosses the placenta and can be isolated in maternal plasma.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Aneuploidy – An abnormal number of chromosomes in the cell.

Trisomy 13 – A rare condition associated with more severe structural malformations than trisomy 21 or 18. Patau syndrome is an example of trisomy of chromosome 13.

Trisomy 18 – The second most common autosomal trisomy detected in the second trimester. This condition is almost always lethal in early childhood. Edwards syndrome is an example of trisomy of chromosome 18.

Trisomy 21 – The most common single cause of birth defects. Down syndrome is an example of trisomy of chromosome 21.

PROCEDURES

1. The following tests are commercially available:
   A. Harmony™ Prenatal Test
   B. MaterniT21™ Plus
   C. verifi® Prenatal Test
   D. Panorama
   E. informaSeq℠
   F. QNatal™ Advanced

2. These tests are considered eligible as advanced screening technology for pregnant women at high risk, as determined by any of the following:
   A. The patient underwent genetic pretest counseling in order to inform persons being tested about the advantages and limitations of the test as applied to a unique person; AND
   B. The current pregnancy is not a multiple gestation; AND
   C. Advanced maternal age (pregnant women aged 35 years and older at expected time of delivery); OR
   D. Testing is offered anytime from 10 weeks gestational age on through the duration of pregnancy in women with singleton gestation; OR
   E. Fetal ultrasonography findings predictive of increased risk of fetal aneuploidy (i.e., absent or hypoplastic nasal bone, choroid plexus cyst, echogenic bowel, echogenic intracardiac focus, fetal pyelectasis, nuchal translucency, nuchal fold, ventriculomegaly, and shortened femur or humerus); OR
   F. Positive screening test for an aneuploidy, including first trimester, sequential, or integrated screen, or a positive quadruple screen; OR
   G. History of a prior maternal pregnancy with an aneuploidy; OR
   H. Parental balanced Robertsonian translocation with increased risk for fetal trisomy 13 or trisomy 21; OR
   A. Noninvasive prenatal testing using the cell-free DNA test for trisomies 21, 18, and 13 is to be used in pregnant women at increased risk in lieu of amniocentesis; AND

3. When Noninvasive Cell-Free Fetal DNA is not covered
   A. Services for DNA-based noninvasive tests of fetal aneuploidy in pregnant women who do not meet

the above criteria or in women who are pregnant with multiple gestations are unproven; therefore investigational; OR

B. Services for DNA-based prenatal microdeletion and micro-duplication syndromes are unproven; therefore investigational; OR
C. Use of noninvasive prenatal testing using the cell-free DNA test for the determination of fetal sex or fetal RHD genotyping is not medically necessary and will require case-by-case review; OR
D. Women with positive cell free DNA tests should be offered invasive prenatal diagnostic testing(amniocentesis or chorionic villus sampling) and detailed counseling

4. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

5. Genetic Counseling
   Pre- and post-test genetic counseling is required to be performed by an independent (not employed by a genetic testing lab) genetic provider prior to genetic counseling for mutations. This service is necessary in order to inform persons being tested about the benefits and limitations of a specific genetic test for the specific patient. Genetic testing for mutation requires documentation of medical necessity from one of the following providers who has evaluated the patient and intends to see the person after testing has been performed for counseling:
   A. Board Eligible or Board Certified Genetic Counselor
   B. Advanced Genetics Nurse
   C. Genetic Clinical Nurse
   D. Advanced Practice Nurse in Genetics
   E. Board Eligible or Board Certified Clinical Geneticist
   F. A physician or other obstetrical provider specializing for the indications(s) for genetic testing

6. Place of Service
   The place of service for testing to be administered is outpatient.

GOVERNING BODIES APPROVAL

The cell-free DNA tests are laboratory developed tests that do not require premarket approval by the FDA. These types of tests are regulated by the Centers for Medicare & Medicaid as part of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The regulations of the CLIA Amendments do not include validation of specific tests but rather that there is procedural compliance.
Commercially available tests include but are not limited to the following:

- Sequenom MaterniT21™ PLUS test: Tests for trisomy 21, 18, and 13 and fetal sex aneuploidies. Their enhanced sequencing series includes testing for trisomies 16 and 22 and 7 microdeletions: 22q deletion syndrome (DiGeorge syndrome), 5p (cri du chat syndrome), 15q (Prader-Willi and Angelman syndromes), 1p36 deletion syndrome, 4p (Wolf-Hirschhorn syndrome), 8q (Langer-Giedion syndrome), and 11q (Jacobsen syndrome). The test uses massive parallel sequencing (MPS) and reports results as positive or negative. The enhanced sequencing series is offered on an opt-out basis.
- Harmony™ Prenatal test: (Ariosa was acquired by Roche in January 2015). Tests for trisomies 21, 18, and 13. Uses directed DNA analysis, results reported as risk score.
- Natera Panorama™ prenatal test: Tests for detecting trisomy 21, 18, and 13, as well as select sex

chromosome abnormalities. Uses single-nucleotide polymorphisms technology; results reported as risk score. An extended panel tests for 5 microdeletions: 22q deletion syndrome (DiGeorge syndrome), 5p (cri du chat syndrome), 15q11-13 (Prader-Willi and Angelman syndromes), and 1p36 deletion syndrome. Screening for 22q11.2 will be included in the panel unless the opt-out option is selected; screening for the remaining 4 microdeletions is offered on an opt-in basis.

- Verifi® prenatal test: Tests for trisomy 21, 18, and 13 and fetal sex chromosome aneuploidies. The test uses MPS and calculates a normalized chromosomal value [NPS]; reports results as 1 of 3 categories: No Aneuploidy Detected, Aneuploidy Detected, or Aneuploidy Suspected.
- InformaSeqSM prenatal test: Tests for detecting trisomy 21, 18, and 13, with optional additional testing for select sex chromosome abnormalities. Uses Illumina platform and reports results in similar manner.
- QNatal™ Advanced (Quest Diagnostics): Tests for trisomies 21, 18, and 13.

Additional information is available online at:
http://www.fda.gov/medicaldevices/deviceregulationandguidance/ivdregulatoryassistance/ucm124105.htm

CODING REQUIREMENTS

Procedure Codes

CPT Codes	Description
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. & 21
81507	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
0009M	Fetal aneuploidy (trisomy 21, and 18) DNA sequencing of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy

*Non-covered Procedure Code

CPT Code	Description
81422	Fetal chromosomal microdeletions(s) genomic sequence analysis (e.g., DiGeorge syndrome, Cri-du-chat-syndrome), circulating cell-free DNA in maternal blood
0060U	Twin zygosity, genomic target sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood

**All requests for this procedure must be referred to a Medical Director for approval.*

Diagnosis Codes

ICD-10 Codes	Description
O09.291	Supervision of pregnancy with other poor reproductive or obstetric history, first trimester
O09.292	Supervision of pregnancy with other poor reproductive or obstetric history, second trimester
O09.293	Supervision of pregnancy with other poor reproductive or obstetric history, third trimester
O09.299	Supervision of pregnancy with other poor reproductive or obstetric history, unspecified trimester
O09.511	Supervision of elderly primigravida, first trimester
O09.512	Supervision of elderly primigravida, second trimester
O09.513	Supervision of elderly primigravida, third trimester

O09.519	Supervision of elderly primigravida, unspecified trimester
O09.521	Supervision of elderly multigravida, first trimester
O09.522	Supervision of elderly multigravida, second trimester
O09.523	Supervision of elderly multigravida, third trimester
O09.529	Supervision of elderly multigravida, unspecified trimester
O28.1	Abnormal hematological finding on antenatal screening of mother
O28.2	Abnormal cytological finding on antenatal screening of mother
O28.3	Abnormal ultrasonic finding on antenatal screening of mother
O28.4	Abnormal radiological finding on antenatal screening of mother
O28.5	Abnormal chromosomal and genetic finding on antenatal screening of mother
O28.8	Other abnormal findings on antenatal screening of mother
O28.9	Unspecified abnormal finding on antenatal screening of mother
O35.0XX9	Maternal care for (suspected) chromosomal nervous system malformation in fetus, other fetus
O35.1XX0	Maternal care for (suspected) chromosomal abnormality in fetus, not applicable or unspecified
O35.1XX1	Maternal care for (suspected) chromosomal abnormality in fetus, fetus 1
O35.1XX9	Maternal care for (suspected) chromosomal abnormality in fetus, other fetus
Q90.0	Trisomy 21, nonmosaicism (meiotic nondisjunction)
Q90.1	Trisomy 21, mosaicism (mitotic nondisjunction)
Q90.2	Trisomy 21, translocation
Q90.9	Down syndrome, unspecified
Q91.0	Trisomy 18, nonmosaicism (meiotic nondisjunction)
Q91.1	Trisomy 18, mosaicism (mitotic nondisjunction)
Q91.2	Trisomy 18, translocation
Q91.3	Trisomy 18, unspecified
Q91.4	Trisomy 13, nonmosaicism (meiotic nondisjunction)
Q91.5	Trisomy 13, mosaicism (mitotic nondisjunction)
Q91.6	Trisomy 13, translocation
Q91.7	Trisomy 13, unspecified
Q92.0	Whole chromosome trisomy, nonmosaicism (meiotic nondisjunction)
Q92.1	Whole chromosome trisomy, mosaicism (mitotic nondisjunction)
Q92.2	Partial trisomy
Q92.5	Duplication with other complex rearrangements; partial trisomy due to unbalanced translocations
Q92.61	Marker chromosomes in normal individual
Q92.62	Marker chromosomes in abnormal individual
Q92.7	Triploidy and polyploidy
Q92.8	Other specified trisomies and partial trisomies of autosomes
Q92.9	Trisomy and partial trisomy of autosomes, unspecified
Q95.0	Balanced translocation and insertion in normal individual
Q95.1	Chromosome inversion in normal individual
Q95.2	Balanced autosomal rearrangement in abnormal individual
Q95.3	Balanced sex/autosomal rearrangement in abnormal individual
Q95.5	Individual with autosomal fragile site
Q95.8	Other balanced rearrangements and structural markers
Q95.9	Balanced rearrangement and structural marker, unspecified
Z13.71	Encounter for nonprocreative screening for genetic disease carrier status
Z13.79	Encounter for screening for other specified diseases and disorders
Z31.438	Encounter for other genetic testing of female for procreative management

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

Fetal chromosomal abnormalities occur in approximately 1 out of 160 live births (Lalani, 2017). There are many fetal chromosomal abnormalities that are aneuploidies. Aneuploidies are defined as an abnormal number of chromosomes and trisomy syndromes are aneuploidies involving 3 copies of 1 chromosome. Maternal age is the most important risk factor for trisomy syndromes, for instance the approximate risk for a trisomy 21 (T21; Down syndrome) of a fetus is 1 in 1100 affected births at age 25 to 29 (Hook, 1983). The approximate risk for trisomy 21 increases to 1 in 250 affected births at age 35 and to 1 in 75 at age 40 (Hook, 1983). In addition to T21, other trisomy syndromes include T18 (Edwards syndrome) and T13 (Patau Syndrome).

In 2015, the American College of Obstetricians and Gynecologists (ACOG) reported that noninvasive prenatal testing using cell-free fetal DNA from the plasma of pregnant women is an important screening tool for fetal aneuploidy. In addition, the ACOG society identified the following indications as appropriate for cell-free DNA:

- Maternal age 35 years or older at time of delivery
- Fetal ultra-sonographic findings predicting increased risk of fetal aneuploidy
- History of prior pregnancy with aneuploidy; positive screening test for aneuploidy, including first trimester, sequential, or integrated screen, or a positive quadruple screen
- Parental balanced Robertsonian translocation with increased risk for fetal trisomy 13 or trisomy 21

In May 2016, ACOG and the Society of Maternal-Fetal Medicine (SMFM) issued new guidelines for prenatal diagnostic and screening tests for genetic disorders. The new guidelines state that fetal aneuploidy testing using cell-free fetal DNA should be offered for **any one** of the following:

- The patient is 35 years of age or older at delivery
- Fetal ultrasound findings indicate an increased risk of aneuploidy
- The patient has had a positive first- or second-trimester screening test results for aneuploidy
- There is a parental balanced Robertsonian translocation with an increased risk of fetal trisomy 13 or trisomy 21.

Furthermore, the guidelines state that cell free DNA screening may be offered anytime from 10 weeks on through the duration of the pregnancy as it is the only screen available in the third trimester. This testing remains a screening test that can have false positives and false negatives. In the situation where no reportable results are available from a serum sample, because these unreportable results have shown to have a higher association with being true positives; unreportable results should be treated as a report of increased risk.

ACOG commented that cell-free DNA testing should not be offered to low-risk women or women with multiple gestations, or be part of routine prenatal laboratory testing because the test has not been evaluated in these groups.

In a nested case-controlled study, Bianchi et al. (2012), reported on the use of massively parallel DNA sequencing to detect fetal aneuploidy with 2,882 high-risk women. The study was termed the "MatErnal BLood IS Source to Accurately diagnose fetal aneuploidy (MELISSA)." These women were scheduled for amniocentesis or chorionic villus sampling at 60 different sites in the United States. The authors reported that 89 of 89 trisomy 18 cases were correctly identified (sensitivity 100%, 95% confidence interval 95.9 to 100), 35 of the 36 trisomy 18 were classified correctly, as were 11 of the 14 trisomy 13 cases and 15 of the 16 monosomy X cases. There were no false positive results for autosomal aneuploidies. However, it was noted that this was a nested case control study and did not represent true population prevalence. Further studies that included larger numbers of unaffected controls were recommended.

The Society for Maternal Fetal Medicine (2015) stated cell-free DNA screening is largely recommended in patients at higher risk for aneuploidy and not the lower risk populations since there is limited studies on this population. The Society for Maternal Fetal Medicine (SMFM) does not consider cell-free DNA screening as first-line screening and that conventional screening methods should be utilized in this group.

In the analysis performed by Norton and colleagues (2013), it was stated that the use of the cell-free DNA in maternal plasma represents a tremendous advance in prenatal diagnosis. In this analysis, it was noted that true cost-utility analysis is necessary to determine the actual clinical effectiveness of this screening in the general prenatal population.

Palomaki et al. (2011) noted that measurement of circulating cell-free DNA in maternal plasma resulted in a Down syndrome detection rate of 98.6% (209/212), a false-positive rate of 0.20% (3/1471), and the testing failed in 13 pregnancies (0.8%); all were euploid. Before unblinding, the primary testing laboratory also reported multiple alternative interpretations. Adjusting chromosome 21 counts for guanine cytosine base content had the largest impact on improving performance.

Langlois and colleagues (2013) provided an analysis of published studies on the use of cell-free DNA in maternal plasma for the noninvasive diagnosis of Down syndrome, trisomy 18, and trisomy 13. The authors reported the testing should be an available option to women at increased risk in lieu of amniocentesis. Use of cell-free fetal DNA testing in average-risk pregnancies is not supported as a replacement for the current maternal screening approach using biochemical serum markers with or without fetal nuchal translucency ultrasound.

Norton et al. (2015) published a large study evaluating cell-free DNA testing in a general population sample. The study included adult women with a singleton pregnancy undergoing routine first-trimester aneuploidy screening between 10.0 and 14.3 weeks of gestation. The patients underwent cell-free DNA testing and standard screening with maternal serum markers and nuchal translucency. In addition, the authors conducted a preplanned sub-analysis in 'low-risk' women defined as women younger than 35 years of age and women who had a risk of T21 of less than 1 in 270 on standard screening. There were a total of 15,841 participants, and chromosomal anomalies were identified in 68 cases. There were 83 with T21, 10 with T18, 6 with T13, and the remainder of cases had less common aneuploidies. The Area Under the Curve (AUC) for T21 was 0.999 for cell-free DNA testing and 0.958 for standard screening ($p = 0.001$). In the sub-analysis of the low-risk women, it was reported that cell-free DNA testing correctly identified 19 cases of T21, with six false positives. When low risk was defined as a risk less than 1 in 270 on standard screening, cell-free DNA testing identified all eight cases of T21 with six false positives.

Fetal chromosomal microdeletions in genomic sequence analysis are chromosomal deletions that are too small to be detected by microscopy or conventional cytogenetic methods. Microdeletions and microduplications are known as copy number variations (CNVs). There are several genomic disorders

associated with microdeletions such as DiGeorge syndrome and Cri-du-chat syndrome. These disorders may have distinctive and serious clinical features such as cardiac anomalies, immune deficiency, palatal defects, and developmental delay.

The clinical utility of microdeletion testing is unknown. At this time, there is no data on whether testing for microdeletions improves outcomes in comparison to the current standards of care. Additional clinical studies are needed to gain experience with routine genetic screening for microdeletions as well as clarity on clinical follow-up for detected microdeletions. The American College of Medical Genetics and Genomics (2016) does not recommend microdeletion screening. If this level of information is desired, then appropriate diagnostic testing (e.g., amniocentesis) is recommended.

POLICY SOURCE(S)

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Policy History

Date	Activity
06/07/2016	QI/UM Committee approval
12/01/2016	Provider effective date
02/09/2017	Revisions: format changes and minor grammatical changes; added Procedures #5 Genetic Counseling; Operational Guidelines update; added codes and their descriptions
03/14/2017	QI/UM Review
05/05/2017	Policy revision; Added non-coverage/experimental statement on microdeletions to Position Statement; Added several definitions in that section; Procedure Code table revised separating code 81422 as non-covered; added paragraph to Research Summary related to 81422; Additional references added to reference list. 6/30/17: policy updated to reflect ACOG's May 2016 updates.
08/09/2017	Added Disclaimer Statement in opening of medical policy; Deleted ICD-10 code Q92.6 as ineligible code.
09/27/2017	QI/UM Committee approval
11/01/2017	Provider effective date
09/11/2018	Annual Review: Added a commercially available test to Procedures Section 1; Added and rearranged the criteria to Procedures section 2.A., 2.B., 2.K.; expanded and updated Summary of Literature; Removed 'COVERED' from procedure codes and diagnosis codes; expanded and added literature to *Governing Bodies Approval* section; added references. Removed all hyperlinks in the reference section.
09/11/2018	QI/UM Committee review Approval
11/15/2018	Provider effective date
06/25/2019	Annual Review: No clinical criteria changes; Added procedure code 0060U to the Noncovered Procedure Code table in Attachment B
07/16/2019	QI/UM Committee Review Approval
09/16/2019	Provider effective date

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