Guideline Title: SHP Screening for Fetal Aneuploidy

ORG/OTC Code: Obstetrics 14

Coverage:

See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.

Application to Products:

Policy is applicable to all products.

Authorization Requirements:

Pre-certification by the Plan is required.

Description of Item or Service:

Noninvasive prenatal testing (NIPT) is a non-invasive screening tool for detecting fetal chromosomal abnormalities such as trisomy 21 (Down Syndrome), trisomy 18 (Edward Syndrome), and trisomy 13 (Patau Syndrome). Circulating cell-free fetal DNA (cfDNA) crosses the placenta and can be isolated in maternal plasma. As early as 8-10 weeks of gestation these fetal DNA fragments can comprise 6-10% of the total cell free DNA in maternal plasma. NIPT has been shown to be a highly accurate screening test with high sensitivity (99%) and specificity (99.5%), which can be used from 10 weeks in pregnancy to determine risk of trisomy 21. It can also be used to screen for the other common chromosomal aneuploidies, trisomy 18 (Edwards syndrome) and trisomy 13 (Patau syndrome). The positive predictive value and negative predictive value of NIPT varies by maternal age.

Maternal serum analysis for free ß-human chorionic gonadotropin (hCG) and pregnancy-associated plasma protein A (PAPP-A) levels may also be used to screen for fetal aneuploidy. This test is usually done between gestational weeks 11–14 and can be completed in a single combined test or in a multistep process. An ultrasound may be performed to measure nuchal translucency (thickness of the space between the back of the fetal neck and overlying skin). A second trimester screen of maternal serum may be performed independently or in conjunction with the first trimester screen. 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. Maternal serum alpha-fetoprotein may also inform the fetal risk of neural tube defects.

For purposes of this policy, these various forms of hCG are considered interchangeable: free beta subunit of hCG, total hCG, or hyperglycosylated hCG (also known as invasive trophoblast antigen [ITA]).

Exceptions and Limitations:

There is insufficient scientific evidence to support the medical necessity of the following Fetal Aneuploidy screenings as they are not shown to improve health outcomes upon technology review:

- Noninvasive prenatal testing (NIPT) including but not limited to the following:
    - screening for a sex-chromosome aneuploidy
    - vanishing twin syndrome
    - screening for other chromosomal disorder other than those specified above
    - screening for microdeletions
    - single-gene disorders
    - whole genome NIPT
    - when used to determine genetic cause of miscarriage (e.g., missed abortion, incomplete
    - abortion)
    - screening for non-medical traits (e.g., biologic sex)
- Noninvasive screening schemes for fetal aneuploidy including but not limited to the following:
    - First-trimester serum analyte testing (hCG and PAPP-A) alone without NT measurement
    - First-trimester ultrasound assessment of the nasal bone
    - First-trimester maternal plasma levels of follistatin-related gene protein
    - First-trimester maternal serum A disintegrin and metalloprotease 12 (ADAM12-S) level
    - First-trimester maternal serum anti-Mullerian hormone level
    - First-trimester maternal serum placental growth factor level
    - Maternal fetal-derived circular RNA (circRNAs)
    - Maternal plasma microRNA
    - Ultrasound evaluation of the right subclavian artery (RSA)

There is insufficient scientific evidence to support the medical necessity of Noninvasive prenatal testing (NIPT) and Noninvasive screening schemes for fetal aneuploidy for uses other than those listed in the clinical indications for procedure section.

Clinical Indications for Procedure:

Screening for Fetal Aneuploidy is considered medically necessary for **1 or more** of the following:

- Non-invasive prenatal testing (NIPT) to screen for fetal trisomy 13, 18 and 21 **once per pregnancy** is considered medically necessary for **1 or more** of the following tests:
    - Individual has a viable pregnancy after 10 weeks but prior to 20 weeks gestation.
    - Individual has a viable pregnancy after 20 weeks gestation when prenatal ultrasound findings demonstrate fetal anomalies consistent with trisomy 13, 18, or 21.
- First-trimester nuchal translucency (NT) testing alone (without serum analyte screening) is considered medically necessary for **ALL of the following**:
    - Individual is pregnant with more than one fetus.

- When performed in a setting of demonstrated ultrasound credentialing and ongoing quality monitoring.

The following are NOT covered for ANY of the following:

- Non-invasive prenatal testing (NIPT) is NOT COVERED for ANY of the following:
  - screening for a sex-chromosome aneuploidy
  - vanishing twin syndrome
  - screening for other chromosomal disorder other than those specified above
  - screening for microdeletions
  - single-gene disorders
  - whole genome NIPT
  - when used to determine genetic cause of miscarriage (e.g., missed abortion, incomplete
  - abortion)
  - screening for non-medical traits (e.g., biologic sex)
- Noninvasive screening schemes for fetal aneuploidy is NOT COVERED for ANY of the following:
  - First-trimester serum analyte testing (hCG and PAPP-A) alone without NT measurement
  - First-trimester ultrasound assessment of the nasal bone
  - First-trimester maternal plasma levels of follistatin-related gene protein
  - First-trimester maternal serum A disintegrin and metalloprotease 12 (ADAM12-S) level
  - First-trimester maternal serum anti-Mullerian hormone level
  - First-trimester maternal serum placental growth factor level
  - Maternal fetal-derived circular RNA (circRNAs)
  - Maternal plasma microRNA
  - Ultrasound evaluation of the right subclavian artery (RSA)

Document History:

Revised Dates:

Reviewed Dates:

Effective Date: 2023:July 1

Coding Information:

CPT/HCPCS codes covered if policy criteria is met:

CPT 76813 - Ultrasound, pregnant uterus, real time with image documentation,
first trimester fetal nuchal translucency measurement,
transabdominal or transvaginal approach; single or first gestation

CPT 76814 - 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)

CPT 81508 - Fetal congenital abnormalities, biochemical assays of two proteins (PAPP-A, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score

CPT 81509 - Fetal congenital abnormalities, biochemical assays of three proteins (PAPP-A, hCG [any form], DIA), utilizing maternal serum, algorithm reported as a risk score

CPT 81510 - Fetal congenital abnormalities, biochemical assays of three analytes (AFP, uE3, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score

CPT 81511 - 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)

CPT 81512 - Fetal congenital abnormalities, biochemical assays of five analytes (AFP, uE3, total hCG, hyperglycosylated hCG, DIA) utilizing maternal serum, algorithm reported as a risk score

CPT/HCPCS codes considered not medically necessary per this Policy:

None

References:

References used include but are not limited to the following:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; Uptodate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

(2023). Retrieved Mar 13, 2023, from MCG 26th Edition: https://careweb.careguidelines.com/ed26/index.html

(2023). Retrieved Mar 13, 2023, from HAYES: https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522Fetal%2520congenital%2520abnormalities%2520risk%2520score%2522,%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%2522:0,%2522size%2522:50%257D,%2522t

(2023). Retrieved Mar 13, 2023, from Carelon Medical Benefits Management: https://guidelines.carelonmedicalbenefitsmanagement.com/chromosomal-microarray-analysis-2023-02-12/?highlight=Fetal+congenital+abnormalities&hilite=Fetal+congenital+abnormalities

(2023). Retrieved Mar 13, 2023, from CMS: https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=Fetal+congenital+abnormalities&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all

ACOG PRACTICE BULLETIN: Screening for Fetal Chromosomal. (2020, Oct 4). Retrieved Mar 13, 2023, from American College of Obstetricians and Gynecologists (ACOG): https://journals.lww.com/greenjournal/Fulltext/2020/10000/Screening_for_Fetal_Chromosomal_Abnormalities_.44.aspx

Noninvasive Prenatal Screening for Fetal Aneuploidy. (2021, Sep 15). Retrieved Mar 14, 2023, from Journal Clinical Advisor: https://www.clinicaladvisor.com/home/topics/ob-gyn-information-center/noninvasive-prenatal-screening-fetal-aneuploidy/

Prenatal screening for common aneuploidies using cell-free DNA. (2023, Jan 11). Retrieved Mar 14, 2023, from UpToDate: https://www.uptodate.com/contents/prenatal-screening-for-common-aneuploidies-using-cell-free-dna?search=Prenatal%20screening%20for%20common%20aneuploidies%20using%20cell-free%20DNA&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

Procedure Fee Files & CPT Codes. (2023). Retrieved Mar 13, 2023, from Department of Medical Assistance Services: https://www.dmas.virginia.gov/for-providers/rates-and-rate-setting/procedure-fee-files-cpt-codes/

Codes:

Add above codes

Keywords:

Fetal Congenital Abnormalities Risk Score Panel, Noninvasive prenatal testing, nuchal translucency, trisomy 18, trisomy 13, trisomy 21, Edwards syndrome, Patau syndrome, ß-human chorionic gonadotropin, hCG

Notes for MCG Implementation:

Upon adoption, would archive Medical 165 and remove from MCG

Add codes to pend list