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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Prenatal Genetic Testing/Cell Free Genetic Testing Policy

Indication/Usage:

Indication/Usage: Noninvasive Prenatal Testing (NIPT) for aneuploidy, Harmony Prenatal Test, InformaSeq Prenatal Test, MaterniT21 Plus, Panorama Prenatal Test, Verifi Prenatal Test. Each NIPT assay involves the purification of cell-free DNA, maternal and fetal from the maternal blood samples and sequence analysis of DNA fragments in order to detect aneuploidies of chromosomes 21, 18, 13 and the sex chromosomes. Three also test for additional chromosome disorders such as trisomies or microdeletions. NIPT may be considered in women with a singleton pregnancy who have an increased risk of having a baby with an aneuploidy, including women of advanced maternal age (> 35 years old at the time of

delivery), women with abnormal ultrasound or screening test results, and women with a family history of chromosome abnormality. It may also be considered in pregnant women of average or low risk who are interested in pursuing a prenatal diagnosis for fetal aneuploidy and may be performed in women with multiple- gestation pregnancies.

Medical Indications for Authorization Commercial and Medicare Members

SummaCare considers sequencing-based non-invasive prenatal testing (NIPT) to screen for fetal trisomy 13, 18, and 21 is considered medically necessary in a viable single or twin gestation pregnancy ≥ 10 weeks gestation.

SummaCare considers the following tests medically necessary when above criteria is met:

- Harmony Prenatal Test
- MateriT21 Plus
- Panorama Prenatal Test for Prenatal Aneuploidy detection

There are currently no NCD or LCD per CMS

Limitations

NIPT poses no risk of miscarriage. There are no known safety concerns associated with the testing. Ethical concerns have been identified:

- Concern regarding patients being adequately informed about the possible test results
- Test limitations, result implications
- Patients may not receive sufficient, balanced information about the various chromosomal disorders that may be detected
- Tests may contribute to stigmatization of those with these conditions
- Risk of false positive results-patients may make irreversible decisions based on NIPT results without confirmatory testing
- NIPT may detect a previously unidentified maternal condition

Coverage Decisions

Coverage decisions made per CMS, Hayes and industry standards research

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

American College of Medical Genetics (ACMG), Clinical Practice Committee. ACMG Position Statement on Multiple Marker Testing in Women 35 and Older. American College of Medical Genetics Newsletter, Vol. 2. Bethesda, MD: ACMG; January 1994.

American College of Obstetricians and Gynecologists (ACOG). Cell-free DNA to screen for single-gene disorders. ACOG Practice Advisory. Washington, DC: ACOG; February 2019 (re-affirmed September 2023). Available at: https://www.acog.org.

Gregg, A.R. et. al. (2013, February 8). ACMG Policy Statement. Retrieved November 11, 2017, from acmg.net: https://www.acmg.net/docs/nips-GiM_galley_text_130301.pdf

American College of Obstetricians and Gynecologists (ACOG), Society for Maternal Fetal Medicine (SMFM). Screening for Fetal Aneuploidy. ACOG Practice bulletin No. 163. Washington, DC: ACOG; May 2016.

Bellver J, Lara C, Soares SR, et al. First trimester biochemical screening for Down's syndrome in singleton pregnancies conceived by assisted reproduction. Hum Reprod. 2005;20(9):2623-2627.

Benn P, Borrell A, Chiu RW, et al. Position statement from the Chromosome Abnormality Screening Committee on behalf of the Board of the International Society for Prenatal Diagnosis. Prenat Diagn. 2015;35(8):725-734.

Bianchi DW, Platt LD, Goldberg JD, et al; MatErnal BLood IS Source to Accurately diagnose fetal aneuploidy (MELISSA) Study Group. Genome-wide fetal aneuploidy detection by maternal plasma DNA sequencing. Obstet Gynecol. 2012;119(5):890-901.

Gregg AR, Gross SJ, Best RG, et al. ACMG statement on noninvasive prenatal screening for fetal aneuploidy. Genet Med. 2013;15(5):395-398.

Gregg AR, Skotko BG, Benkendorf JL, et al. Noninvasive prenatal screening for fetal aneuploidy, 2016 update: A position statement of the American College of Medical Genetics and Genomics. Genet Med. 2016;18(10):1056-1065.

Society for Maternal Fetal Medicine (SMFM). Statement on Cell-Free DNA Screening. Washington, DC: SMFM; April 7. 2015

Yaron Y, Jani J, Schmid M, Oepkes D. Current status of testing for microdeletion syndromes and rare autosomal trisomies using cell-free DNA technology. . Obstet Gynecol. 2015;126(5):10951099