

	Noninvasive prenatal testing (NIPT) Genetic Testing Guidelines	
Guideline # 6188	Categories Clinical → Care Management CM, TCHP Guidelines, Utilization Management UM	This Guideline Applies To: Texas Children's Health Plan
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GUIDELINE STATEMENT:

Texas Children's Health Plan (TCHP) performs authorization of all noninvasive prenatal testing requests.

PRIOR AUTHORIZATION GUIDELINES

1. Noninvasive prenatal testing requests conducted by out-of-network providers will be treated as out-of-network requests and will comply with the out-of-network authorization Guidelines.
2. All requests for prior authorization for noninvasive prenatal testing are received via online submission, fax, phone or mail by the Utilization Management Department and processed during normal business hours.
3. The Utilization Management professional receiving the request evaluates the submitted information to determine if the documentation supports the noninvasive prenatal testing as an eligible service.
4. To request prior authorization for noninvasive prenatal testing, the following documentation must be submitted by the provider rendering direct care to the member:
 - 4.1. Description of the medical necessity of the procedure requested
 - 4.2. Documentation that member meets criteria for testing
 - 4.3. Documentation that the member was provided counseling regarding potential outcomes of aneuploidy screening and member understanding of the implications associated with each possible aneuploidy result.
 - 4.4. A Baseline ultrasound with number of fetuses, gestational age and viability.
5. Noninvasive Genetic testing of pregnant women is considered medically necessary for women with a current single gestation pregnancy at greater than 10 weeks gestation that meet any of the following criteria:
 - 5.1. Maternal age of 35 years or older at expected date of delivery;
 - 5.2. Fetal ultrasound findings indicating an increased risk of aneuploidy.
 - 5.3. A previous pregnancy with aneuploidy;
 - 5.4. Fetal ultrasound that shows structural anomalies associated with aneuploidy and member is not yet ready for invasive diagnostic test.

- 5.5. A known balanced Robertsonian translocation in a parent or the parent of the partner.
 - 5.6. Abnormal serum screening results for the current pregnancy such as:
 - 5.6.1. First trimester screen
 - 5.6.2. Sequential screen
 - 5.6.3. Integrated screen
 - 5.6.4. Quadruple or Penta screen
 - 5.7. Clinical risk verified by TCHP Medical Director/Physician Reviewer
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6. The following noninvasive prenatal testing (NIPT) services are not a benefit:
 - 6.1. NIPT as part of a routine prenatal laboratory assessment
 - 6.2. NIPT if performed without informed patient choice and pre- and post-test genetic counseling from a qualified professional
 - 6.3. NIPT for women who do not meet the criteria outlined above
 - 6.4. NIPT for women with multiple gestations (e.g., twins, triplets, etc.)
 - 6.5. NIPT for screening of chromosomal microdeletion syndromes
 - 6.6. NIPT for screening of trisomy other than T13, T18, or T21
 - 6.7. NIPT for sex determination, paternity determination, or non-medical reasons
 - 6.8. NIPT using procedure code 81599
 7. NIPT procedure codes 81420 or 81507 are limited to once per pregnancy. Additional tests will not be authorized.
 8. Requests that do not meet the criteria established by this procedure will be referred to a TCHP Medical Director/Physician Reviewer for review and the Denial Policy will be followed.
 9. Preauthorization is based on medical necessity and not a guarantee of benefits or eligibility. Even if preauthorization is approved for treatment or a particular service, that authorization applies only to the medical necessity of treatment or service. All services are subject to benefit limitations and exclusions. Providers are subject to State and Federal Regulatory compliance and failure to comply may result in retrospective audit and potential financial recoupment.

REFERENCES:**Peer Reviewed Publications:**

- Palomaki GE, Deciu C, Kloza EM, Lambert-Messerlian GM et al. DNA sequencing of maternal plasma reliably identifies trisomy 18 and trisomy 13 as well as Down syndrome: an international collaborative study. *Genetics in Medicine*. 2012 Mar; 14(3):296-305.
- Palomaki GE, Kloza EM, Lambert-Messerlian GM et al. DNA sequencing of maternal plasma to detect Down syndrome: an international clinical validation study. *Genetics in Medicine*. 2011 Nov, 13(11):913-20.

Luo Y, Hu H, Jiang L, et al. A retrospective analysis the clinic data and follow-up of non-invasive prenatal test in detection of fetal chromosomal aneuploidy in more than 40,000 cases in a single prenatal diagnosis center. Eur J Med Genet. 2020;63(9):104001.

Government Agency, Medical Society, and Other Publications:

Error! Hyperlink reference not valid. Texas Medicaid Provider Procedure Manual Accessed September 2020

http://www.tmhp.com/sites/default/files/file-library/resources/provider-manuals/tmpm/pdf-full/2020/Sept_2020%20TMPPM.pdf

American College of Obstetricians and Gynecologists (ACOG). ACOG Committee on Practice Bulletins. ACOG Practice Bulletin No. 77: Screening for fetal chromosomal abnormalities. Obstet Gynecol. 2007a; 109(1):217-227.

- American College of Obstetricians and Gynecologists (ACOG). Committee opinion no. 545: Noninvasive prenatal testing for fetal aneuploidy. Obstet Gynecol. 2012; 120(6):1532-1534.
- American College of Obstetricians and Gynecologists (ACOG). Committee Opinion No. 640: Cell-free DNA Screening for Fetal Aneuploidy. 2015; 126(3):e31-37.
- American College of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin No. 88: Invasive prenatal testing for aneuploidy. Obstet Gynecol. 2007b; 110(6):1459-1467.
- Benn P, Borell A, Chiu R, et al. Position statement from the Aneuploidy Screening Committee on behalf of the Board of the International Society for Prenatal Diagnosis. Prenat Diagn. 2013; 33(7):622-629.
- Benn P, Borell A, Chiu R, 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.
- Devers PL, Cronister A, Ormond KE, et al. Noninvasive prenatal testing/noninvasive prenatal diagnosis: the position of the National Society of Genetic Counselors. J Genet Couns. 2013; 22(3):291-295.
- Society for Maternal and Fetal Medicine (SMFM). SMFM Statement: Maternal serum cell-free DNA screening in low risk women. 2014. Available at: <https://www.smfm.org/publications/157-smfm-statement-maternal-serum-cell-free-dna-screening-in-low-risk-women>. Accessed on September 4, 2015.
- American College of Medical Genetics and Genomics. Position Statement. Points to consider in the clinical application of genomic sequencing. 2012. Approved May 15, 2012. Available at: <https://www.acmg.net/PDFLibrary/Genomic-Sequencing-Clinical-Application.pdf> Accessed on September 28, 2020

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