

Non-Invasive Prenatal Testing

Effective for dates of service on or after May 1, 2016, benefit criteria for noninvasive prenatal testing procedure codes 81420 and 81507 will change for Texas Medicaid.

Noninvasive prenatal testing (NIPT) is a benefit of Texas Medicaid when medically necessary for the advanced screening of fetal chromosomal abnormalities in pregnant women who meet specific screening criteria. Genetic screening results, when informative, may influence clinical management decisions.

NIPT may be performed as early as ten weeks gestation for specific fetal aneuploidy screening, restricted to Trisomy 13, Trisomy 18, Trisomy 21, and fetal sex chromosome aneuploidy (SCA). To determine NIPT appropriateness, a baseline ultrasound, if not previously performed, is strongly recommended to confirm viability, the number of fetuses, and gestational dating.

If NIPT provides an abnormal screening result, invasive prenatal confirmatory diagnostic testing is strongly encouraged due to the potential risk of a false-positive result from NIPT. Confirmatory diagnostic tests include chorionic villus sampling (CVS) or amniocentesis.

It is recommended that clients who receive an indeterminate result be offered further genetic counseling, comprehensive evaluation with ultrasound, and diagnostic testing due to the increased risk of aneuploidy. Higher body mass index (BMI) may affect NIPT results. Clients weighing more than 250 pounds are at risk of having an inconclusive result from NIPT.

NIPT does not assess the risk for fetal anomalies such as neural tube defects or ventral wall defects. Ultrasound evaluation and maternal serum alpha-fetoprotein screening should be offered for these risk assessments.

NIPT must be ordered by the medical provider rendering direct care to the client. The provider must order the most appropriate test based on the client's medical history and the results of previous screenings, if available. The provider must clarify for the client the option to decline, and the provider must document that the option to decline was clearly provided in the client's medical record.

Note: Some noninvasive prenatal tests include an extended panel that screens for microdeletions and additional trisomies, such as T16 and T22. However, this use has not been validated, and the "opt-out" box on the requisition form should be checked.

Screening for Fetal Sex Chromosome Aneuploidy

In addition to trisomy (e.g., T13, T18, T21), NIPT procedure code 81420 may also screen for fetal SCA (e.g., 45,X; 47,XXX; 47,XXY; 47,XYY). It is recommended that diagnostic testing be offered rather than NIPT if a fetal structural anomaly (e.g., hydrops, cystic hygroma, cardiac malformations, abdominal wall defects, or skeletal abnormalities) is identified upon ultrasound examination.

Sex chromosome aneuploidy of maternal origin should be considered when NIPT results suggest fetal sex chromosome aneuploidy (e.g., 45,X; 47,XXX; 47,XXY; 47,XYY). Other considerations include the risk for incidental findings with NIPT. Appropriate client counseling is encouraged.

Screening Criteria

NIPT is a benefit for singleton pregnancies. At least one of the following criteria must be met for a client to be eligible for NIPT:

- Maternal age of 35 years or older at time of delivery
- Fetal ultrasound indicates risk of aneuploidy

- Fetal ultrasound indicates structural anomalies associated with aneuploidy, and the mother wishes to postpone invasive diagnostic testing
- History of pregnancy with aneuploidy
- Parental balanced Robertsonian translocation of chromosome 13 or 21
- Abnormal serum screening results for the current pregnancy:
 - First trimester screen
 - Sequential screen
 - Integrated screen
 - Quadruple screen

Genetic Counseling Requirements

Genetic counseling must be provided by a trained genetic counselor, nurse specialist in genetics, maternal-fetal medicine specialist, or other medical provider possessing expertise in genetic counseling who is not affiliated with the genetic testing laboratory. Both pre- and post-test counseling must provide the depth of content and time for the client to make an informed testing decision.

The client must be provided with information about the purpose and nature of the tests. Documentation in the medical record must reflect that the client has been given information on the benefits, risks, and limitations of advanced screening; as well as the nature, inheritance, and implications of genetic disorders. Documentation requirements include all of the following:

- Pre-testing genetic counseling:
 - The date that formal pre-test counseling was provided, with the name and qualifications of the counseling professional
 - The explanation of risks, benefits, and limitations that was discussed with the client
 - The client's ability to understand the risks, benefits, and limitations and the client's informed choice to proceed with NIPT as evidenced by the client's signature on a consent form specific to the NIPT to be performed
 - The client's other prenatal screenings or test results, if available, to support medical necessity of NIPT
 - The client's NIPT results
- Post-testing genetic counseling:
 - The date that formal post-test counseling was provided, with the name and qualifications of the counseling professional
 - The clear, non-directive explanation provided to the client concerning the findings and implications of the NIPT results
 - The client's ability to understand the results and explanation provided

The genetic counseling must be nondirective. The purpose of the provider's information is not to direct the client, but to allow the client to make informed medical and personal decisions.

Clients should be informed that a negative NIPT result does not ensure an unaffected pregnancy.

Prior Authorization Requirements (Fee-For-Service (FFS))

Prior authorization is required in Medicaid FFS for NIPT procedure codes 81420 and 81507. Prior authorization requests must be submitted by the provider rendering direct care to the client. The requesting provider must share the authorization number with the laboratory provider submitting the claim.

A completed Special Medical Prior Authorization (SMPA) Request Form, signed and dated by the referring provider, must be submitted. The provider's signature on a submitted document indicates that the provider certifies, to the best of the provider's knowledge, that the information in the document is true, accurate, and complete. The signature must be handwritten in the provider's own handwriting, and must not be stamped or digitalized.

All documentation must be submitted with a handwritten date next to the handwritten provider's signature, and it must be kept in the client's medical record.

The provider must indicate on the prior authorization request form that the client meets required criteria (as noted above in Screening Criteria) for NIPT.

FFS prior authorization requests for sequencing analysis of fetal sex chromosome aneuploidy (procedure code 81420) must include a description of the medical need for the service on the prior authorization request form. Inadequate documentation for additional fetal sex chromosome aneuploidy screening may result in the denial of procedure code 81420. Providers may resubmit a request for procedure code 81420 without SCA screening, or may submit a request for procedure code 81507.

The request for prior authorization should document that the client was provided counseling regarding potential outcomes of aneuploidy screening, as well as potential outcomes of fetal sex chromosome aneuploidy screening when elected, and that she understands the implications associated with each possible aneuploidy result.

To complete the FFS prior authorization process, the provider must mail or fax the request to the TMHP Special Medical Prior Authorization Unit and include documentation of medical necessity. Medical documentation submitted by the provider must verify any indications the provider included on the form, such as the client's age, history of affected pregnancy or family history, anomalous ultrasound findings, or abnormal maternal serum results. Requisition forms from the laboratory are not sufficient for verification of genetic history.

NIPT procedure codes 81420 and 81507 are limited to once per pregnancy. Additional tests will not be authorized.

Note: Providers may appeal denied claims with documentation of a new pregnancy.

A no-call or inconclusive result is possible and further diagnostic testing is strongly recommended in these cases.

Additional Documentation Requirements

The following additional NIPT documentation must be maintained in the client's medical record and is subject to retrospective review:

- The appropriateness and benefit of NIPT specific to the client
- The client's specific high-risk criteria

Limitations

Procedure code 81420 will be denied when billed during the same pregnancy as procedure code 81507, by any provider. Claims that have been paid for procedure code 81420 are subject to recoupment if procedure code 81507 is submitted for the same pregnancy.

Procedure code 81507 will no longer be a benefit when performed in the office or outpatient hospital settings.

Non-Covered Services

The following NIPT services are not a benefit of Texas Medicaid:

- NIPT as part of a routine prenatal laboratory assessment
- NIPT if performed without informed patient choice and pre- and post-test genetic counseling from a qualified professional
- NIPT for women who do not meet the criteria outlined above
- NIPT for women with multiple gestations (e.g., twins, triplets, etc.)
- NIPT for screening of chromosomal microdeletion syndromes
- NIPT for screening of trisomy other than T13, T18, or T21
- NIPT for sex determination, paternity determination, or non-medical reasons
- NIPT will not be reimbursed using procedure code 81599