Driscoll Health Plan
Medical Necessity Guideline

Medical Necessity Guideline: Non-Invasive Prenatal Screening (NIPS)	**Creation Date:** 09/24/2018	**Review Date:** 05/12/2022	**Effective Date:** 11/21/2018

PURPOSE:
To outline the prior authorization requirements and process for Non-Invasive Prenatal Screening (NIPS) CPT codes: (81243, 81420, and 81507).

DEFINITIONS:

Non-invasive prenatal screening (NIPS), sometimes called non-invasive prenatal testing (NIPT), is a method of determining the fetus's risk of being born with certain genetic abnormalities.

GUIDELINE:

Documentation Requirements:

DHP requires provider attestation that (see Attachment A):

1. **At least ONE** of the following criteria must be met for a client to be eligible for NIPS.
   - ☐ Fetal ultrasound indicates a 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
   - ☐ Maternal age of 35 years or older at time of delivery
   - ☐ Parental balanced Robertsonian translocation of chromosome 13 or 21
   - ☐ Abnormal serum screening results for the current pregnancy:
     a. First-trimester screen
     b. Sequential screen
     c. Integrated screen
     d. Quadruple screen
2. In addition to at least one of the above, the client was provided counseling regarding potential outcomes of aneuploidy screening and potential consequences of fetal sex chromosome aneuploidy screening when included. As a result, she understands the implications associated with each possible aneuploidy result.
3. If not performed by an in-network lab, there is medical necessity, unavailability, or other impediments to access to justify referral to another national laboratory.
4. Prior authorization is required for NIPS procedure codes 81420 and 81507.

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BACKGROUND:

1. NIPS is medically necessary for the advanced screening of fetal chromosomal abnormalities in pregnant women between 10 and 55 who have a single fetus and meet the specific screening criteria listed below. Genetic screening results, when informative, may influence clinical management decisions.
2. NIPS (CPT 81420 and 81507) is a benefit and payable under Texas Medicaid [1] for pregnant women who meet specific screening criteria and is limited to Trisomies 13, 18, 21, and fetal sex chromosome aneuploidy (SCA) (e.g., 45, X; 47, XXX,; 47, XXY; 47, XXY).
3. Genetic counseling must be provided by a trained genetic counselor, nurse specialist in genetics, maternal-fetal medicine specialist, or other medical provider (e.g., obstetrician) possessing genetic counseling who is not affiliated with the genetic screening laboratory. Both pre- and post-counseling must be performed with the depth of content and time for the client to make an informed decision. Documentation requirements of the pre- and post-screening genetic counseling must be reflected in the medical record according to Texas Medicaid Provider Procedures Manual (TMPPM) (1)
4. NIPS must be ordered by the medical provider rendering direct care to the client.
5. Some non-invasive prenatal screenings include an extended panel that screens for microdeletions, additional trisomies (such as T16 and T22), and other conditions. These uses have not been validated and the "opt-out" box on the requisitions form should be checked according to the TMPPM. (1)
6. In-network laboratories are preferred. Medical necessity or other circumstances precluding the use of in-network labs must be documented in the medical record and attested.
7. Specific Exclusions as Non-Covered Services
    - NIPS as part of a routine prenatal laboratory assessment
    - NIPS if performed without informed patient choice and pre- and post-screen genetic counseling from a qualified professional
    - NIPS for women who do not meet the criteria outlined above
    - NIPS for women with multiple gestations (e.g., twins, triplets, etc.)
    - NIPS for screening of chromosomal microdeletion syndromes
    - NIPS for screening of trisomy other than T13, T18, or T21
    - NIPS for sex determination, paternity determination, or non-medical reasons
    - NIPS is not reimbursed with procedure code 81599

PROVIDER CLAIMS CODES:

CPT CODES		
81243	81420	81507

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REFERENCES:

1. Rose, Nancy C. MD; Kaimal, Anjali J. MD, MAS; Dugoff, Lorraine MD; Norton, Mary E. MD; American College of Obstetricians and Gynecologists' Committee on Practice Bulletins - Obstetrics Committee on Genetics Society for Maternal-Fetal Medicine Screening for Fetal Chromosomal Abnormalities, Obstetrics & Gynecology: October 2020 - Volume 136 - Issue 4 - p e48-e69 doi: 10.1097/AOG.0000000000004084
2. Texas Medicaid Provider Procedures Manual - Gynecological, Obstetrics, and Family Planning Title XIX Services Handbook, 5 Non-invasive Prenatal Screening (NIPS), May 2022.

DOCUMENT HISTORY:

DHP Committee that Approved	*Review Approval Date (last 5 years)*				
Medical Director	11/21/2018	6/13/2019	6/22/2020	6/10/2021 8/3/2021	5/24/2022
CMO	11/21/2018	6/13/2019	6/22/2020	6/10/2021 8/3/2021	6/7/2022
Medical Policy Workgroup *Effective 2022*					6/7/2022
Medical Management *Retired December 2020*	11/21/2018	6/13/2019	6/22/2020		
Utilization Management & Appeals *Effective January 2021*				6/10/2021 8/3/2021	6/21/2022
Utilization Management Behavioral Health *Retired December 2020*	11/21/2018	8/22/2019	6/22/2020		
Provider Advisory					6/17/2022

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Committee (PAC) *Effective 2022*					
Clinical Management Committee *Effective March 2021*				6/17/2021 9/2/2021	
Quality Management *Retired 2020*	4/16/2019	10/22/2019	6/26/2020		
Executive Quality Committee *Effective 2021*				8/4/2021 Minor ad hoc revisions only - NA	6/28/2022

Document Owner	***Organization***	***Department***
Dr. Fred McCurdy, Medical Director	Driscoll Health Plan	Utilization Management

Review/Revision Date	***Review/Revision Information, etc.***
10/04/2019	Added reference to checklist and updated references.
11/30/2019	Review, updated TMPPM reference
05/08/2020	Update format and added CPT codes.
06/04/2020	Minor Modifications in language per Dr. Serrao
06/16/2020	Final format and final review
04/30/2021	Review and Update of TMPPM reference, new reference ACOG Practice Bulletin 226
8/2/2021	Removal of specific laboratories that were named and revised to an in-network lab
05/11/2022	Policy reviewed and updated, Dr. Roxanne Doucet
05/24/2022	Review and final editing by Dr. Fred McCurdy

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ATTACHMENT A: Non-invasive Prenatal (NIPS) Attestation for Obstetrical Providers

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Non-invasive Prenatal Screening (NIPS) Attestation for OB GYN's

Driscoll Health Plan (DHP) requires prior authorization of all requests for Noninvasive Prenatal Screening (CPT codes 81420 and 81507).

Non-invasive prenatal screening (NIPS) 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.

NIPS 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 NIPS appropriateness, a baseline ultrasound, if not previously performed, is strongly recommended to confirm viability, the number of fetuses, and gestational dating.

If NIPS provides an abnormal screening result, invasive prenatal confirmatory diagnostic testing is strongly encouraged due to the potential risk of a false-positive result from NIPS. 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 NIPS results. Clients weighing more than 250 pounds are at risk of having an inconclusive result from NIPS.

NIPS 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.

If a fetal structural anomaly (e.g., hydrops, cystic hygroma, cardiac malformations, abdominal wall defects, or skeletal abnormalities) is identified upon ultrasound examination, it is recommended that diagnostic testing be offered rather than NIPS.

NIPS must be ordered by the medical provider rendering direct care to the client. The provider must order the most appropriate screening 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 non-invasive prenatal screenings 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), NIPS may also screen for fetal SCA (e.g., 45, X; 47, XXX; 47, XXY; 47, XYY).

Note: *Currently, clinical evidence is unclear for concluding the net health benefits when using cell free fetal DNA to screen for fetal sex chromosome aneuploidy (SCA). The potential benefit of early detection for management must be balanced against potential harms, stigmatization, and distorted perceptions of the child.*

Sex chromosome aneuploidy of maternal origin should be considered when NIPS 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 NIPS. Appropriate client counseling is encouraged.

Genetic Counseling Requirement

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

The client must be provided with information about the purpose and nature of the screenings. 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-screening genetic counseling:
  - The date that formal pre-screening 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

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  - The client's ability to understand the risks, benefits, and limitations and the client's informed choice to proceed with NIPS as evidenced by the client's signature on a consent form specific to the NIPS to be performed
  - The client's other prenatal radiological or lab results, if available, to support medical necessity of NIPS
- Post-screening genetic counseling:
  - The client's NIPS results
  - The date that formal post-screening 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 NIPS 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 NIPS result does not ensure an unaffected pregnancy.

Additional Documentation Requirements

In addition to the documentation of pre and post genetic counseling, and the option to decline NIPS provided to the client, the following NIPS documentation must also be maintained in the client's medical record and is subject to retrospective review:

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

NIPS Limitations

Procedure codes 81507 and 81420 are restricted to female clients only who are 10 through 55 years of age. 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 later for the same pregnancy.

Non-Covered Services

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

- NIPS as part of a routine prenatal laboratory assessment
- NIPS if performed without informed patient choice and pre- and post-screen genetic counseling from a qualified professional
- NIPS for women who do not meet the criteria outlined above
- NIPS for women with multiple gestations (e.g., twins, triplets, etc.)
- NIPS for screening of chromosomal microdeletion syndromes
- NIPS for screening of trisomy other than T13, T18, or T21
- NIPS for sex determination, paternity determination, or non-medical reasons
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Member Name: _____
Member DOB: _____
Member ID: _____

DHP requires the ordering physician to attest to the following for NIPS:
Prior authorization is required for NIPS procedures codes 81420 and 81507 and limited to once per pregnancy. NIPS is a benefit for singleton pregnancies.
At least ONE of the following criteria must be met for a client to be eligible for NIPS. Please select those that apply:

- ☐ 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
- ☐ Maternal age of 35 years or older at time of delivery
- ☐ 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
- ☐ In addition to at least one of the above, the client was provided counseling regarding potential outcomes of aneuploidy screening, as well as potential outcomes of fetal sex chromosome aneuploidy screening when included, and that she understands the implications associated with each possible aneuploidy result.
- ☐ If not performed by an in network lab, there is medical necessity, unavailability, or other impediment to access to justify referral to another laboratory.

_____ _____
PHYSICIAN SIGNATURE DATE

_____
PHYSICIAN NAME (PRINT)

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