Maryland
DEPARTMENT OF HEALTH

Non-Invasive Prenatal Testing (NIPTs) Clinical Criteria

Cell-free DNA screens for aneuploidies use the analysis of fetal cell-free DNA fragments in the maternal circulation starting at about 9–10 weeks of pregnancy. The American College of Obstetrics and Gynecology (ACOG) has recommended that screening (serum screening with or without Nuchal Translucency (NT) ultrasound or cell-free DNA screening) and diagnostic testing (Chorionic Villus Sampling or Amniocentesis) for chromosomal abnormalities should be discussed and offered to all patients early in pregnancy regardless of maternal age or baseline risk[1].

- NIPTs will be considered for coverage when ALL of the criteria below are met, confirmed with supporting medical documentation.

I. Criteria for Approval

No Preauthorization Required for:
NIPTs will be a covered benefit without the need for preauthorization: Trisomy 21, 18, 13 Screening with Gender Identification (if chosen).

❑ NIPTs is a covered benefit for all pregnant patients, excluding multiple gestation, starting the 10th week of gestation, who elect as their sole option of screening for Trisomy 21, 18, & 13 in pregnancy.*

*ACOG recommends that if a patient chooses NIPTs screening for aneuploidy, only one screening approach should be used. Therefore it is not recommended/covered to also undergo 1st trimester or 2nd trimester serum screening[1].

Preauthorization is Required for:

NIPTs testing for:

- Trisomy screening and Sex Chromosomal Analysis (SCA)
- Trisomy screening , SCA, and microdeletions

Will be considered when the recipient meets one or more of the following conditions:

- ❏ Fetal ultrasound findings for fetuses with ultrasound abnormalities, especially with either ultrasound structural or gonadal anomalies.
- ❏ The recipient must have pre and post-test genetic counseling with a Maternal Fetal Medicine (MFM) physician or certified genetic counselor.

For more information and guidance on ordering please refer to the *NIPTs Ordering Guidelines*.

EXCLUDED FROM COVERAGE: The following indications for NIPTs testing are investigational and are **excluded from coverage**:

- ❏ Testing as a follow-up to an abnormal 1st or 2nd trimester screening.
- ❏ Low Fetal Fraction on initial NIPTs testing (counseling and diagnostic testing recommended[1]).
- ❏ Cases with a known co-twin demise (vanishing twin syndrome).
- ❏ Screening for trisomies other than 21, 18 and 13.
- ❏ Screening for single-gene disorders.
- ❏ Whole genome NIPTs.
- ❏ When used to determine genetic cause of miscarriage or fetal demise (e.g., missed abortion, incomplete abortion).

II. Billing Code/Information

Codes that **do not require** preauthorization:

81420	Fetal chromosomal aneuploidy (e.g., trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21.
81507	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy.

Codes that **require** preauthorization:

81422	Fetal chromosomal microdeletion(s) genomic sequence analysis (e.g., DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood.

81479	Unlisted molecular pathology procedure

Prior authorization of benefits is not the practice of medicine nor the substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or payment. Prior authorization criteria are established based on a collaborative effort using input from the current medical literature and based on evidence available at the time.

Approved by MDH Clinical Criteria Committee: 12/10/2020
Last Reviewed Date: 12/10/2020