Important note:
Unless otherwise indicated, this policy will apply to all lines of business.
Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS’s Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

SERVICE: Medicaid Noninvasive Prenatal Testing

PRIOR AUTHORIZATION: Required.

POLICY: For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid TMPPM.

Noninvasive prenatal testing (NIPT) for common aneuploidies including trisomies 13, 18, and 21, and for fetal sex chromosome aneuploidy (SCA), may be medically necessary when BOTH of the following are met:

- Current pregnancy is beyond 10 weeks
- Pregnancy is singleton

AND, if either

- Maternal screening serum or ultrasound tests are abnormal and suggestive of aneuploidy

OR, if ONE of the following situations apply:

- Maternal age is 35 years or more (at time of delivery)
- There is a prior pregnancy with a chromosomal aneuploidy
- Mother is a known carrier of a Robertsonian translocation

NIPS procedure codes 81420 and 81507 are limited to once per pregnancy.

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 postscreening counseling must provide the depth of content and time for the member to make an informed decision. (See TMPPM Gynecological, Obstetrics, and family Planning Title XIX Services Section 5.2 for details regarding genetic counseling)

Note: Cell-free DNA screening tests for microdeletions (CPT 81422) have NOT been validated and are not deemed medically necessary.
OVERVIEW:

Noninvasive prenatal testing (NIPT) is a sensitive DNA-based test that screens including trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome), and trisomy 13 for common aneuploidies including trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome), and trisomy 13 (Patau syndrome). NIPT uses cell-free fetal DNA (cffDNA) from a maternal blood test. NIPT is a screening test and should not be considered diagnostic. Positive results further diagnostic investigation. False positives do occur.

Genetic counseling should be performed before NIPT testing because the results of testing may guide further decision making regarding the current pregnancy.

According to some experts, NIPT should not be used to identify biological sex or sex chromosome aneuploidies.

MANDATES: The Alberto N Agreement (Section 8.1) states that all DME policies, guidelines, or provider manuals will prominently display the following statement when describing the scope of DME available to beneficiaries:

Medicaid beneficiaries under the age of 21 years are entitled to all medically necessary DME. DME is medical necessary when it is required to correct or ameliorate disabilities or physical or mental illnesses or condition. Any numerical limit on the amount of a particular item of DME can be exceeded for Medicaid beneficiaries under the age of 21 years if medically necessary. Likewise, time period for replacement of DME will not apply to Medicaid beneficiaries under the age of 21 years if the replacement is medically necessary. When prior authorization is required, the information submitted with the request must be sufficient to document the reasons why the requested DME item or quantity is medical necessary.

CODES:

Important note: CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

| CPT Codes: | 81420 - Fetal chromosomal aneuploidy (eg, trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood
81507 - Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT Not Covered:</td>
<td>81422 - Fetal chromosomal microdeletion(s) genomic sequence analysis</td>
</tr>
<tr>
<td>ICD10 codes:</td>
<td></td>
</tr>
</tbody>
</table>

CMS:

POLICY HISTORY:

<table>
<thead>
<tr>
<th>Status</th>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>New</td>
<td>08/27/2020</td>
<td>New policy</td>
</tr>
</tbody>
</table>

REFERENCES:
The following scientific references were utilized in the formulation of this medical policy. The health plan will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution

Medicaid Noninvasive Prenatal Testing Page 2 of 3
of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to the health plan so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Texas Medicaid Provider Procedures Manual:
   http://www.tmhp.com/Pages/Medicaid/Medicaid_Publications_Provider_manual.aspx
2. The Alberto N Agreement (Section 8.1):
   http://www.tmhp.com/Homepage%20File%20Library/Archive/Second%20Partial%20Settlement%20Agreement.pdf