Coverage Guidelines:
Genetic Testing: Maternal Tests for Fetal Trisomy

Effective: December 13, 2017

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Applies to:</td>
<td>√</td>
</tr>
<tr>
<td>☒ Tufts Health Plan Commercial Plans products; Fax: 617.972.9409</td>
<td></td>
</tr>
<tr>
<td>☒ Tufts Health Public Plans products</td>
<td></td>
</tr>
<tr>
<td>☒ Tufts Health Direct – Health Connector; Fax: 888.415.9055</td>
<td></td>
</tr>
<tr>
<td>☒ Tufts Health Together – A MassHealth Plan; Fax: 888.415.9055</td>
<td></td>
</tr>
<tr>
<td>☐ Tufts Health Unify – OneCare Plan; Fax: 781.393.2607</td>
<td></td>
</tr>
<tr>
<td>☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404</td>
<td></td>
</tr>
<tr>
<td>☒ Tufts Health Freedom Plan products; Fax: 617.972.9409</td>
<td></td>
</tr>
</tbody>
</table>

OVERVIEW
The human body has 23 distinct chromosome pairs or copies. Trisomy 21, 18 or 13 means there are three copies of either chromosome 21, 18 or 13, instead of two. Noninvasive prenatal laboratory testing analyzes circulating cell-free DNA from a maternal blood sample which detects increases of chromosome material associated with trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome), or trisomy 13 (Pateau syndrome); and, in some cases may eliminate the need for a more invasive test such as amniocentesis. Currently, these tests may be covered with contracting Laboratories using this Medical Necessity Guideline.

COVERAGE GUIDELINES
Tufts Health Plan will cover maternal blood sampling of cell-free fetal DNA testing for trisomy 21, 18, and 13 when the pregnant Member meets one of the following criteria:

- The Member is of advanced maternal age, defined as age 35 or over at the time of delivery
- The Member has fetal aneuploidy screening test results including maternal serum screening (elevated free beta-hCG) and/or an ultrasound evaluation (nuchal translucency) indicating the possibility of trisomy 21, 18, or 13
- The Member has a family history or prior pregnancy involving fetal aneuploidy
- Documentation of genetic counseling by an MD geneticist or an independent board certified genetic counselor.

CODES
The following CPT codes listed below may be used for this testing.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>81420</td>
<td>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</td>
</tr>
<tr>
<td>81507</td>
<td>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</td>
</tr>
</tbody>
</table>

Note: For other prenatal genetic tests, refer to the Medical Necessity Guidelines for Genetic Testing: Prenatal, Preconception.

LIMITATIONS
Tufts Health Plan will not cover testing that has not been proven to be effective, including:

- Expanded non-invasive prenatal testing (NIPT) panels; refer to the Noncovered Investigational Services list for additional information.
REFERENCES

APPROVAL HISTORY
July 11, 2012: Reviewed by the Integrated Medical Policy Advisory Committee (IMPAC) for effective date of October 1, 2012

Subsequent endorsement date(s) and changes made:
- November 28, 2012: Reviewed by IMPAC. The title of the Medical Necessity Guideline was changed from the former 'MaterniT21™ Plus' to 'Maternal Tests for Fetal Trisomy' as there are other tests such as Verifi™. Both are commercially available laboratory tests with companies Sequenom Center for Molecular Medicine and Verinata Health, Inc. respectively. These are currently contracted with Tufts Health Plan. In addition, a link was added for access to the Medical Necessity Guideline 'Genetic Testing: Prenatal, Preconception'.
- October 9, 2013: Reviewed by IMPAC, renewed without changes.
- December 11, 2013: Reviewed by IMPAC, prior authorization will no longer be required effective April 1, 2014. Coding updated with new CPT code 81507, effective January 1, 2014.
- August 1, 2014: The names of additional tests covered, when the guidelines of this Medical Necessity Guideline are met, were added for reference. Genetic Testing: Maternal Tests for Fetal Trisomy includes guidelines for the following tests: Harmony™ Prenatal Test, Panorama™ Prenatal Test, MaterniT21™ PLUS, and Verifi™Prenatal Test.
- October 8, 2014: Reviewed by IMPAC, renewed without changes.
- November 19, 2014: Reviewed by IMPAC, renewed without changes.
- December 31, 2014: Coding updated. Per AMA CPT®, effective January 1, 2015 the following CPT® code added: 81420.
- September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
- November 9, 2016: Reviewed by IMPAC, renewed without changes.
- December 14, 2016: Reviewed by IMPAC, renewed without changes.
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017.
- May 10, 2017: Reviewed by IMPAC, limitation added for 'Expanded Non-Invasive Prenatal Testing (NIPT)' including a link to the Noncovered Investigational List.
- October 11, 2017: Reviewed by IMPAC, renewed without changes
- December 13, 2017: Reviewed by IMPAC, renewed without changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION
Medical Necessity Guidelines are developed to determine coverage for benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise
and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Medical Necessity Guidelines apply to the fully insured Commercial and Medicaid products when Tufts Health Plan conducts utilization review unless otherwise noted in this guideline or in the Member’s benefit document, and may apply to Tufts Health Unify to the same extent as Tufts Health Together. This guideline does not apply to Tufts Medicare Preferred HMO, Tufts Health Plan Senior Care Options or to certain delegated service arrangements. For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates or other requirements will take precedence. For CareLinkSM Members, Cigna conducts utilization review so Cigna’s medical necessity guidelines, rather than these guidelines, will apply.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of these guidelines is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.