Medical Necessity Guidelines:
Genetic Testing: Prenatal, Preconception

Effective: September 12, 2018

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>Yes ☒ No ☐</th>
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<tr>
<td>If REQUIRED, submit supporting clinical documentation pertinent to service request.</td>
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Applies to:

- **COMMERCIAL Products**
  - ☒ Tufts Health Plan Commercial products; Fax: 617.972.9409
  - ☒ Tufts Health Freedom Plan products; Fax: 617.972.9409
  - ☒ CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

- **TUFTS HEALTH PUBLIC PLANS Products**
  - ☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 888.415.9055
  - ☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055
  - ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404
  - ☒ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 781.393.2607

  *The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

- **SENIOR Products**
  - ☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List
  - ☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

**OVERVIEW**

There are two types of genetic testing that are performed in the preconception and/or prenatal period:

- Carrier testing is used to identify people who carry a gene mutation that can increase the risk of having a child with a genetic disorder. This type of testing is offered to individuals who have a family history of a genetic disorder and to people in certain ethnic groups with an increased risk of specific genetic disorders. For these genetic disorders to be present in a child two copies of the abnormal gene are needed, therefore each partner to the pregnancy must be a carrier for the child to inherit the disorder.

- Prenatal testing is used to detect changes in a fetus’s genes or chromosomes before birth. This type of testing is offered during pregnancy if there is an increased risk that the baby will have a genetic or chromosomal disorder. In some cases, prenatal testing can lessen the uncertainty or guide decisions regarding a pregnancy. It cannot identify all possible inherited disorders and birth defects.

**CLINICAL COVERAGE CRITERIA**

- Tufts Health Plan will cover the following genetic testing without prior authorization:
  - Ashkenazi panel (which includes Tay-Sachs Disease, Gaucher Disease, cystic fibrosis, Canavan Disease, Bloom Syndrome, Familial Dysautonomia, Mucolipidosis Type IV, Fanconi Anemia Type C, Nieman-Pick Disease Type A, and Glycogen Storage Disease type 1a).
  - Cystic fibrosis
  - Spinal muscular atrophy
  - First trimester screening combination of ultrasound for nuchal cord translucency and maternal blood testing for free beta subunit of human chorionic gonadotropin (ß-hCG), and pregnancy-associated plasma protein-A (PAPP-A). This testing is also known as Early Risk Assessment, First Screen, or Ultrascreen.
Second trimester screening combination second-trimester screening using four serum markers (alpha-fetoprotein, β-hCG, unconjugated estriol, inhibin-A).

Refer to **Genetic and Molecular Diagnostic Testing Medical Necessity Guidelines**

- Tufts Health Plan may authorize coverage for prenatal genetic testing, not listed above, if the Member meets **ALL** of the following criteria (documentation, including a letter of medical necessity is required):
  - The request is for a Member who is currently pregnant, is partner to a pregnancy, or is planning a pregnancy and who falls within a high-risk group for a particular disease(s) based on personal history, family history, documentation of a genetic mutation, and/or ethnic background.
  - The results of the test will significantly alter the medical management of the pregnancy and/or the reproductive choices of the Member.
  - Documentation is provided by a licensed genetic counselor or physician with expertise in genetic counseling that supports the recommendation for testing based on a review of risk factors, clinical scenario and family history.
  - Testing of partner has not been done or partner’s test results alone are insufficient to inform an appropriate treatment decision.
  - The testing method is considered a proven method for the identification of a genetically linked inheritable disease (i.e., the genotypes to be detected by a genetic test must be shown by scientifically valid methods to be associated with the occurrence of a disease, and the observations must be independently replicated and subject to peer review).

**Note:** For maternal laboratory genetic testing for trisomy please refer to: **Genetic Testing: Maternal Tests for Fetal Trisomy Medical Necessity Guidelines**

**LIMITATIONS**

- Tufts Health Plan will initially cover testing of only the female parent or potential female parent for autosomal recessive or X-linked recessive conditions.
- Testing of the male partner to a pregnancy will be covered for an autosomal recessive condition only if the female partner has been found to be a carrier for the disorder, OR if the couple is felt to be at high risk and the pregnancy is beyond 15 weeks gestation.

**REFERENCES**


**APPROVAL HISTORY**

February 1, 2007: Reviewed by the Clinical Coverage Criteria Committee

Subsequent endorsement date(s) and changes made:

- January 30, 2008: Preimplantation Genetic Determination limitation removed from guideline
- March 16, 2009: Reviewed and renewed without changes
- December 16, 2009: Reviewed and no changes made
- February 1, 2010: Reviewed by Medical Policy Advisory Group Committee (MSPAC), no changes
- March 2011: Reviewed by MSPAC. Preconception added to title. Cystic fibrosis and spinal muscular atrophy added to covered without prior authorization section
- March 7, 2012: Reviewed by Integrated Medical Policy Advisory Committee (IMPAC), no changes
- November 28, 2012: Reviewed at IMPAC. A link was added for access to the Medical Necessity Guideline ‘Genetic Testing: Maternal Tests for Fetal Trisomy’.
October 9, 2013: Reviewed by IMPAC, renewed without changes.
October 8, 2014: Reviewed by IMPAC, renewed without changes.
November 19, 2014: Reviewed by IMPAC, renewed without changes.
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 16, 2015: Reviewed by IMPAC, renewed without changes
November 9, 2016: Reviewed by IMPAC, renewed without changes
December 14, 2016: Reviewed by IMPAC, renewed without changes
July 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
October 11, 2017: Reviewed by IMPAC, renewed without changes
December 13, 2017: Reviewed by IMPAC, renewed without changes
July 25, 2018: Reviewed by IMPAC, renewed without changes
September 12, 2018: Reviewed by IMPAC, renewed without changes
October 2018: Template and disclaimer updated

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.

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.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline 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.