FUFTS
Health Plan

Medical Necessity Guidelines:
Fecal Microbial Transplant (FMT) for CDI

Effective: September 12, 2018

Prior Authorization Required
If REQUIRED, submit supporting clinical documentation pertinent to service request.  ❌ Yes ☐ No ❌

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

OVERVIEW
Fecal microbiota transplantation (FMT) involves the infusion of intestinal microorganisms via transfer of stool from a healthy person into a diseased patient. The intent is to restore normal intestinal flora. For the purposes of this coverage guideline, fecal transplant may be covered for the treatment of clostridium difficile infection (CDI) that has not responded to standard therapies.

CLINICAL COVERAGE CRITERIA
Tufts Health Plan may cover FMT when medically necessary for the treatment of Members with CDI under the following conditions:

• There have been at least 3 episodes of recurrent infection confirmed by positive stool cultures; OR
• A persistent episode that is refractory to appropriate antibiotic treatment protocol, including at least one regimen of pulsed vancomycin.

Documentation should include the following:

• If requested for review, the submitted medical record should support the use of the selected ICD-CM and CPT/HCPCS code(s) used to describe the service performed.
• Documentation maintained by the ordering physician/treating physician must indicate the medical necessity for performing this procedure.
• Informed consent should include, at a minimum, a statement that the use of FMT products to treat C. difficile is investigational with a discussion of its potential risks, per FDA suggested guidance2.

LIMITATIONS
Tufts Health Plan covers FMT for recurrent CDI only.
Table 1: Covered CPT and HCPCS Codes

<table>
<thead>
<tr>
<th>CPT/HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>G0455</td>
<td>Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen</td>
</tr>
<tr>
<td>44705</td>
<td>Preparation of fecal microbiota for instillation, including assessment of donor specimen</td>
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ICD-10 diagnosis codes associated with the above procedure code(s) include:

Table 2: ICD-10 Codes

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>A04.71</td>
<td>Enterocolitis due to Clostridium difficile, recurrent</td>
</tr>
<tr>
<td>A04.72</td>
<td>Enterocolitis due to Clostridium difficile, not specified as recurrent</td>
</tr>
</tbody>
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REFERENCES


APPROVAL HISTORY

April 9, 2015: Reviewed and approved by Integrated Medical Policy Advisory Committee (IMPAC) for a June 1, 2015 effective date.

Subsequent endorsement date(s) and changes made:
- September 9, 2015: 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.
- March 17, 2016: Coding updated; ICD-9-CM codes removed
- October 24, 2016: Reviewed by IMPAC; minor wording change clarifications
- April 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
- 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.