Medical Necessity Guidelines:
Fecal Microbial Transplant (FMT) for Clostridium Difficile Infection

Effective: October 21, 2020

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

- CareLink[SM] – 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: 857.304.6304

*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 (one initial and at least 2 recurrences) of 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 guidance[2].

LIMITATIONS

Tufts Health Plan covers FMT for recurrent CDI only.

CODES

Table 1: Covered CPT and HCPCS Codes

CPT/HCPCS Code	Description
G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen
44705	Preparation of fecal microbiota for instillation, including assessment of donor specimen

ICD-10 diagnosis codes associated with the above procedure code(s) include:

Table 2: ICD-10 Codes

ICD-10 Code	Description
A04.71	Enterocolitis due to Clostridium difficile, recurrent
A04.72	Enterocolitis due to Clostridium difficile, not specified as recurrent

REFERENCES

1. Borody, TJ., Leis, S., Pang, G., Wettstein, AR. Fecal microbiota transplantation in the treatment of recurrent Clostridium difficile infection. UpToDate®, August 2014. Uptodate literature review search current through September 2017.
2. Food and Drug Administration (FDA). Enforcement policy regarding investigational new drug requirements for use of fecal microbiota for transplantation to treat Clostridium difficile infection not responsive to standard therapies. July 2013. Superseded guidance March 2016.
3. van Nood E, Vrieze A, Nieuwdorp M, et al. Duodenal infusion of donor feces for recurrent Clostridium difficile. N Engl J Med. 2013;368(5):407-415.
4. Hayes, Inc. Health Technology Brief. Fecal microbiota transplant for refractory or recurrent Clostridium Difficile Infection in adults. August 11, 2016. Update search July 27, 2017.
5. L Clifford McDonald, Dale N Gerding, Stuart Johnson, Johan S Bakken, Karen C Carroll, Susan E Coffin, Erik R Dubberke, Kevin W Garey, Carolyn V Gould, Ciaran Kelly, Vivian Loo, Julia Shaklee Sammons, Thomas J Sandora, Mark H Wilcox, Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA), Clinical Infectious Diseases, Volume 66, Issue 7, 1 April 2018, Pages e1–e48, doi.org/10.1093/cid/cix1085. Accessed September 16, 2020.

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
- September 27, 2017: Annual ICD-10-CM coding update, added ICD-10-CM codes A04.71 and A04.72; removed ICD-10-CM code A04.7 effective October 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
- September 18, 2019: Reviewed by IMPAC, renewed without changes
- October 21, 2020: Reviewed and approved by IMPAC. Change to clarify first bullet in Clinical Coverage Criteria regarding initial and subsequent episode of recurrence.
- October 26, 2020: Fax number for Unify 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.

Provider Services