Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Fecal Microbial Transplant (FMT) for Clostridium Difficile Infection

Effective: October 1, 2024

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below	Yes ☐ No ☒
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; 800-232-0816

☒ Tufts Health Plan Commercial products; 617-972-9409

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055

☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404

☒ Tufts Health One Care – A dual-eligible product; 857-304-6304

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; 866-874-0857

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

Fecal microbiota transplantation (FMT) involves the infusion of intestinal microorganisms via transfer of stool from a healthy person to 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 the clostridium difficile infection (CDI) that has not responded to standard therapies.

Clinical Guideline Coverage Criteria

The Plan considers FMT as reasonable and medically necessary for the treatment of CDI when **ONE** of the following are met:

1. There have been at least three(3) episodes (one initial and at least two recurrences) of infection confirmed by positive stool cultures; **or**
2. A persistent episode that is refractory to appropriate antibiotic treatment protocol, including **one** of the following:
    a. At least one regimen of tapered or pulsed vancomycin; **or**
    b. Vancomycin followed by Rifaximin; **or**

c. A regimen of Fidaxomicin (standard or extended-pulsed)

Documentation should include the following:

1. If requested for review, the submitted medical record should support the use of the selected ICD-10 CM and CPT/HCPCS code(s) used to describe the service performed
2. Documentation maintained by the ordering physician/treating physician must indicate the medical necessity for performing this procedure
3. Informed consent should include, at a minimum, a statement that the use of FMT products to treatment C. difficile is investigation with a discussion of its potential risks, per FDA suggested guidance[2]

Limitations

The Plan covers FMT for recurrent CDI only

Codes

The following code(s) are associated with this service:

Table 1: CPT/HCPCS Codes

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

Table 2: ICD-10 Codes

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.
6. Stuart Johnson, Valéry Lavergne, Andrew M Skinner, Anne J Gonzales-Luna, Kevin W Garey, Ciaran P Kelly, Mark H Wilcox, Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of Clostridioides difficile Infection in Adults, Clinical Infectious Diseases, Volume 73, Issue 5, 1 September 2021, Pages e1029–e1044, doi.org/10.1093/cid/ciab549

Approval And Revision History

October 21, 2020: Reviewed by the Medical Policy Approval Committee (MPAC), change to clarify criteria regarding initial and subsequent episode recurrence

Subsequent endorsement date(s) and changes made:

- November 17, 2021: Reviewed and approved by IMPAC, updated to clinical criteria to include “Vancomycin followed by Rifaximin and a regimen of Fidaxomicin (standard or extended-pulsed)” effective November 17, 2021; policy updated for integration purposes between Harvard Pilgrim Health Care and Tufts Health Plan effective 1/1/22
- February 17, 2022: Freedom plans removed from the template
- August 17, 2022: Reviewed by Medical Policy Approval Committee (MPAC), renewed without changes
- September 20, 2023: Reviewed by MPAC, renewed without changes
- November 2023: Unify name changed to One Care effective January 1, 2024
- August 30, 2024: Reviewed by MPAC, renewed without changes, effective October 1, 2024

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. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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.