Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Fecal Microbial Transplant (FMT) for Clostridium Difficile Infection

Effective: January 1, 2026

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

Public Plans Products

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

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-972-9409
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-972-9409
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-972-9409

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

Clinical Guideline Coverage Criteria
The Plan considers FMT as reasonable and medically necessary for the treatment of CDI when **either** of the following are met:

1. Recurrent CDI:
   There have been at least three (3) episodes of infection (one initial and at least two recurrences), confirmed by positive stool tests.
2. Refractory CDI:
   A persistent episode that is refractory to appropriate antibiotic treatment, including at least one of the following regimens:

- A tapered or pulsed regimen of vancomycin
- Vancomycin followed by rifaximin
- A regimen of fidaxomicin (standard or extended-pulsed)

Documentation Requirements

1. Medical records must support the use of the selected ICD-10-CM and CPT/HCPCS codes.
2. Documentation must indicate the medical necessity for performing this procedure.
3. Informed consent must include, at a minimum, a statement that the use of FMT products to treat *C. difficile* is investigational, with a discussion of potential risks, per FDA guidance.

Limitations

The Plan covers FMT **only for recurrent or refractory CDI**.

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. American Gastroenterological Association. New guideline: Use FMT for the majority of recurrent *C. difficile* patients. *Gastroenterology*. Published February 21, 2024. https://gastro.org/news/new-guideline-use-fmt-for-recurrent-cdiff-patients,
2. 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.
3. Cymbal M, Chatterjee A, Baggott B. Fecal microbiota transplantation: current evidence and future directions. *Cleveland Clin J Med*. 2025;92(7):421–428. doi:10.3949/ccjm.92a.24107
4. 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.
5. U.S. Food and Drug Administration. Enforcement policy regarding investigational new drug requirements for use of fecal microbiota for transplantation to treat *Clostridioides difficile* infection not responsive to standard therapies. *FDA Guidance for Industry*. November 2022. https://www.fda.gov/media/86440/download
6. 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.
7. 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.
8. Johnson S, Lavergne V, Skinner AM, Gonzales-Luna AJ, Garey KW, Kelly CP, Wilcox MH. 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. *Clin Infect Dis*. 2021;73(5):e1029–e1044. doi:10.1093/cid/ciab549, Accessed September 15, 2025.
9. Khoruts A, Staley C. FMT for recurrent *Clostridioides difficile* infection. *Clin Infect Dis*. Published online April 22, 2025. doi:10.1093/cid/ciaf138.

10. 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
- July 28, 2025: Fax number for Senior Care Options, Tufts Medicare Preferred HMO and Tufts Medicare Preferred PPO updated; language for Carelink removed and Harvard Pilgrim Health Care Stride Medicare Advantage removed as an applicable product from the template
- November 19, 2025: Reviewed by MPAC for annual review, renewed without changes effective January 1, 2026
- December 2025: Administrative updates effective January 1, 2026
- December 8, 2025: Reviewed by UM Committee for annual review, renewed without changes effective January 1, 2026

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.