# Fecal Microbiota Transplantation
# Clinical Coverage Criteria

## Overview

*Clostridium difficile* (*C. difficile*) infection causes intestinal inflammation, diarrhea, and cell death. These infections range in severity from mild symptoms to life threating colitis. Recurrent *C. difficile* infection is defined as an episode of *C. difficile* infection that occurs eight weeks or less after the initial episode that resolved with or without therapy. Initial treatment for *C. difficile* is oral antibiotics inclusive of metronidazole and vancomycin.

Fecal microbiota transplantation (FMT) is a non-pharmalogical approach for those who failed to respond to oral antibiotic therapies after multiple recurrent infections. FMT refers to the transfer of stool from a healthy donor into the patient's gastrointestinal tract. This is done in order to replace damaged microbiota thus recreating normal and functional microbiota which establishes resistance to further infections. Patient selection, proximity to recurrent CDI episode, and antibiotic treatment prior to FMT all likely influence response to FMT.

The FDA has developed guidance to ensure that patients with *C. difficile* infection not responding to standard therapies have access to this treatment, while addressing and controlling the risks that centralized manufacturing in stool banks presents to subjects. FDA is exercising enforcement discretion regarding the investigational new drug requirements for the use of FMT to treat *C. difficile* infection, provided that: 1) the licensed health care provider treating the patient obtains adequate consent from the patient or his or her legally authorized representative for the use of FMT products. The consent should include, at a minimum, a statement that the use of FMT products to treat *C. difficile* is investigational and a discussion of its reasonably foreseeable risks; 2) the FMT product is not obtained from a stool bank; and 3) the stool donor and stool are qualified by screening and testing performed under the direction of the licensed health care provider for the purpose of providing the FMT product for treatment of the patient. While current FDA guidance permits use of FMT for treating *C. difficile* infections that have not responded to standard antibiotic therapy, use of FMT for any other indication requires submittal and approval of an IND (investigational new drug) application to the FDA.

## Policy

This Policy applies to the following Fallon Health products:

☒ Commercial

☒ Medicare Advantage

☒ MassHealth ACO

☒ NaviCare

☐ PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare does not have an NCD for fecal microbiota transplantation. National Government Services, Inc., the Part A/B Medicare Administrative Contractor (MAC) with jurisdiction in our service area, does not have an LCD or LCA for fecal microbiota transplantation (MCD search 03/21/2022).

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. Unless otherwise noted, in the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Unless otherwise noted, Fallon Health Clinical Coverage Criteria are used to determine medical necessity for MassHealth ACO-covered services for MassHealth ACO members. Fallon Health Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204.

### Fallon Health Clinical Coverage Criteria

Effective for dates of service on or after June 1, 2022, fecal microbiota transplantation (G0455) does not require prior authorization.

Fallon Health considers fecal microbiota transplantation (G0455) using donor stool medically necessary when the following criteria are met:

1. The member has had 3 or more recurrent episodes of Clostridium difficile infection as confirmed by positive stool tests, AND
2. The episodes are refractory to appropriate antibiotic therapy regimens, including at least one regimen of tapered and pulsed vancomycin.

A second fecal microbiota transplantation with donor stool is covered for those plan member's who relapse after initial FMT provided the member completes at least a 10-day course of vancomycin before repeating the procedure (Kelly et al., 2016).

## Exclusions

- Fecal microbiota transplantation is considered investigational for all other indications, including but not limited to Crohn's disease and Inflammatory Bowel Disease.

## Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

### CPT/HCPCS Codes

| Code | Description |
|---|---|
| 44705 | Preparation of fecal microbiota for instillation, including assessment of donor specimen |
| G0455 | Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen |

CPT 44705 is not valid for Medicare purposes and should not be used to report preparation of fecal microbiota for instillation. CMS created HCPCS code G0455 to be used for preparation **and**

instillation of fecal microbiota (by any method) effective January 1, 2013 (CMS-1600-FC). Instillation of fecal microbiota is not separately reimbursed.

CPT 44705 is nonpayable per MassHealth (Transmittal Letter AOH-49, effective 01/01/2021; Transmittal Letter PHY-162; effective 11/01/2021). Consistent with Medicare, MassHealth covers HCPCS code G0455 for preparation and instillation of fecal microbiota by any method.

Effective for dates of service on or after September 1, 2022, CPT 44705 will deny vendor liable for all plan members. HCPCS code G0455 should be used to report fecal microbiota preparation and instillation by any method for all plan members. Effective for dates of service on or after June 1, 2022, G0455 will not require prior authorization.

ICD10 A04.71 (Enterocolitis due to Clostridium difficile, recurrent) or A04.72 (Enterocolitis due to Clostridium difficile, not specified as recurrent) are the only diagnosis codes that will be considered for coverage.

**ICD-10 Diagnosis Codes**

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

## References


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## Policy history

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| Origination date: | 09/01/2017 |
| Approval(s): | Technology Assessment Committee: 05/24/2017 (approved new policy), 05/15/2018 (updated references), 05/22/2019 (updated references); 07/22/2020 (updated coverage criteria to require at least one regimen of tapered and pulsed vancomycin; updated coding and references), 06/25/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section), 07/28/2021 (annual review), 03/22/2022 (annual review; updated Coding section) |