



## MASSACHUSETTS

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# Medical Policy

## Fecal Microbiota Transplantation

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### Policy Number: 682

BCBSA Reference Number: 2.01.92

### Related Policies

- Fecal Analysis in the Diagnosis of Intestinal Dysbiosis, #[556](#)

### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

Fecal microbiota transplantation may be **MEDICALLY NECESSARY** for treatment of patients with recurrent *Clostridium difficile* infection under the following conditions:

- There have been at least 3 episodes of recurrent infection; AND
- Episodes are refractory to appropriate antibiotic regimens, including at least 1 regimen of pulsed vancomycin.

Fecal microbiota transplantation is **INVESTIGATIONAL** in all other situations.

### Prior Authorization Information

Pre-service approval is required for all inpatient services for all products.

See below for situations where prior authorization may be required or may not be required for outpatient services.

Yes indicates that prior authorization is required.

No indicates that prior authorization is not required.

#### Outpatient

Commercial Managed Care (HMO and POS)	No
Commercial PPO and Indemnity	No
Medicare HMO Blue <sup>SM</sup>	No
Medicare PPO Blue <sup>SM</sup>	No

### CPT Codes / HCPCS Codes / ICD-9 Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's

contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member. A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

### CPT Codes

CPT codes:	Code Description
44705	Preparation of fecal microbiota for instillation, including assessment of donor specimen

### HCPCS Codes

HCPCS codes:	Code Description
G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen

### ICD-9 Diagnosis Codes

ICD-9 CM diagnosis codes:	Code Description
008.45	Intestinal infections due to clostridium difficile

### ICD-10 Diagnosis Codes

ICD-10 CM diagnosis codes:	Code Description
A04.7	Enterocolitis due to Clostridium difficile

### Description

Fecal microbiota transplantation (FMT) involves the infusion of intestinal microorganisms via transfer of stool from a healthy person into a diseased patient, with the intent of restoring normal intestinal flora. Fecal transplant is proposed for the treatment of treatment-refractory *Clostridium difficile* infection (CDI), as well as for other conditions including inflammatory bowel disease (IBD).

### Background

FMT, also called donor feces infusion, intestinal microbiota transplantation, and fecal bacteriotherapy, involves the infusion of intestinal microorganisms via transfer of stool from a healthy individual into a diseased individual to restore normal intestinal flora. The stool can be infused as a liquid suspension into a patient's upper gastrointestinal tract through a nasogastric tube or gastroscopy, or into the colon through a colonoscope or rectal catheter.

The goal of FMT is to replace damaged and/or disordered native microbiota with a stable community of donor microorganisms. The treatment is based on the premise that an imbalance in the community of microorganisms residing in the gastrointestinal tract (ie, dysbiosis) is associated with specific disease states, including susceptibility to infection.

The human microbiota, defined as the aggregate of microorganisms (bacteria, fungi, archaea) on and in the human body, is believed to consist of approximately 10 to 100 trillion cells, approximately 10 times the number of human cells. Most human microbes reside in the intestinal tract, and most of these are bacteria. In its healthy state, intestinal microbiota perform a variety of useful functions including aiding in the digestion of carbohydrates, mediating the synthesis of certain vitamins, repressing growth of pathogenic microbes, and stimulating the lymphoid tissue to produce antibodies to pathogens.

To date, the major potential clinical application of fecal microbiota transplantation is treatment of CDI. Infection of the colon with *C. difficile* is a major cause of colitis and can cause life-threatening conditions including colonic perforation and toxic megacolon. *C. difficile* occurs naturally in intestinal flora. The incidence of CDI in North America has increased substantially in the past decade. For example, according to hospital discharge diagnosis data, there were more than 300,000 cases of CDI in 2006, compared with fewer than 150,000 cases in 2000. Moreover, CDI causes an estimated 15,000 to 20,000 deaths per year in U.S. hospitals.(1,2)

It is unclear what causes *C. difficile* overgrowth, but disruption of the normal colonic flora in conjunction with colonization by *C. difficile* are major components. Disruption of the normal colonic flora occurs most commonly following administration of oral, parenteral or topical antibiotics. Standard treatment for CDI is antibiotic therapy. However, symptoms recur in up to 35% of patients and up to 65% of patients with recurrences develop a chronic recurrent pattern of CDI.(3)

Other potential uses of fecal microbiota transplant include treatment of conditions in which altered colonic flora may play a role. These include IBD, irritable bowel syndrome, idiopathic constipation and nongastrointestinal disease such as multiple sclerosis, obesity, autism, and chronic fatigue syndrome. However, for these conditions, the contribution of alterations in colonic flora to the disorder is uncertain or controversial.

There is interest in alternatives to human feces that might have the same beneficial effects on intestinal microbiota without the risks of disease transmission. A proof of principle study was published in 2013 that evaluated a synthetic stool product in 2 patients with recurrent CDI.(4) The product is made from 33 bacterial isolates that were developed from culturing stool from a healthy donor.

## Summary

Fecal microbiota transplantation (FMT) is proposed as a treatment of recurrent *C. difficile* infection (CDI) unresponsive to standard therapy and other conditions that are potentially associated with disruption of normal intestinal flora. Two small randomized controlled trials (RCTs) evaluating fecal microbiota transplantation for CDI has been published. Findings of the trial that compared FMT with standard treatment suggest that FMT is more effective than currently used treatments of recurrent CDI. However, the study had limitations including a small sample size and open-label design. The other RCT did not find a significant difference in efficacy when donor feces was administered via colonoscopy or nasogastric tube. Although published evidence is limited and questions remain eg, about safety, patient selection criteria optimal FMT protocol, due to support from the available evidence and clinical reviewers, FMT may be considered medically necessary for treatment of patients with 3 or more recurrences of CDI.

## Policy History

Date	Action
10/2014	New policy describing medically necessary and investigational indications. Effective 10/1/2014.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## References

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