



MASSACHUSETTS

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Medical Policy Fecal Microbiota Transplantation

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Policy Number: 682

BCBSA Reference Number: 2.01.92

NCD/LCD: N/A

Related Policies

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

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Fecal microbiota transplantation may be considered **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 considered **INVESTIGATIONAL** in all other situations.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO Blue SM	Prior authorization is not required .
Medicare PPO Blue SM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

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.

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

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above **medical necessity criteria MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

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

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and HCPCS codes above if **medical necessity criteria** are met:

ICD-10 Diagnosis Codes

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

DESCRIPTION

Fecal Microbiota

Fecal microbiota transplantation (FMT), also called donor feces infusion, intestinal microbiota transplantation, and fecal bacteriotherapy involves the infusion of intestinal microorganisms via the 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 the stool can be infused 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 performs a variety of useful functions including aiding in

the digestion of carbohydrates, mediating the synthesis of certain vitamins, repressing the growth of pathogenic microbes, and stimulating the lymphoid tissue to produce antibodies to pathogens.

Applications

***Clostridium difficile* Infection**

To date, the major potential clinical application of FMT is the treatment of *Clostridium difficile* infection (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 the intestinal flora. The incidence of CDI in North America has increased substantially. For example, according to hospital discharge diagnosis data, there were more than 300000 cases of CDI in 2006 compared with fewer than 150000 cases in 2000. Moreover, CDI causes an estimated 15000 to 20000 deaths per year in U.S. hospitals.^{1,2}

It is unclear what causes *C. difficile* overgrowth, but disruption of the normal colonic flora and colonization by *C. difficile* are major components. Disruption of the normal colonic flora occurs most commonly following the 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 Applications

Other potential uses of FMT include treatment of conditions in which altered colonic flora may play a role. They include inflammatory bowel disease, irritable bowel syndrome, idiopathic constipation, and non-gastrointestinal diseases 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. In a proof of principle study, Petrof et al (2013) evaluated a synthetic stool product in 2 patients with recurrent CDI.⁴ The product is made from 33 bacterial isolates developed from culturing stool from a healthy donor.

Summary

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

For individuals who have recurrent CDI refractory to antibiotic therapy who receive FMT, the evidence includes randomized controlled trials (RCTs), multiple systematic reviews, and observational studies. The relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. The RCTs found that FMT was more effective than standard treatment or placebo for patients with recurrent CDI. Other RCTs did not find the superiority of any route of administration over another or the superiority of fresh vs frozen feces. Case reports and case series have reported high rates of resolution of recurrent CDI following treatment with FMT. Few treatment-related adverse events have been reported. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have inflammatory bowel disease who receive FMT, the evidence includes a large-scale systematic review and meta-analysis, two RCTs in patients with ulcerative colitis, as well as observational studies. The relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. Two small RCTs on FMT for treatment of ulcerative colitis were discontinued due to futility, which restricted data analysis to patients already enrolled. Of the 2small RCTs, one found a statistically significant higher remission rate after active FMT than after a control intervention, but this trial had few patients in remission (n=11) and short follow-up (7 weeks); the other trial reported no difference in remission rates. Data on a small number of patients with Crohn disease are available; however, there

are no controlled studies of FMT in this population. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have irritable bowel syndrome who receive FMT, the evidence includes a systematic review and RCTs. The relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. The systematic review found mixed outcomes; in a pooled analysis of three RCTs utilizing autologous FMT as a placebo, the relative risk of irritable bowel syndrome symptoms not improving decreased and was statistically superior compared to donor FMT. Few treatment-related adverse events have been reported. Data are limited by small study sizes and heterogeneity in utilized outcome measurement scales and definitions of treatment response. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have pouchitis, constipation, multi-drug resistant organism infection, or metabolic syndrome who receive FMT, the evidence includes a small number of case series and RCTs. The relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. Data are available for only a limited number of patients and there is a lack of comparative studies. Current comparative studies are small and either do not report clinical outcomes or fail to demonstrate a significant benefit. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
1/2020	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
1/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
1/2018	New references added from BCBSA National medical policy.
10/2017	Clarified coding information.
12/2016	New references added from BCBSA National medical policy.
1/2016	New references added from BCBSA National medical policy.
6/2015	New references added from BCBSA National medical policy.
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](#)

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