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
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.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
<th>Commercial Managed Care (HMO and POS)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Commercial PPO and Indemnity</td>
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<td></td>
<td>Medicare HMO BlueSM</td>
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<td></td>
<td>Medicare PPO BlueSM</td>
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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.

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tr>
<td>44705</td>
<td>Preparation of fecal microbiota for instillation, including assessment of donor specimen</td>
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HCPCS Codes

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<th>HCPCS codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>G0455</td>
<td>Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen</td>
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ICD-9 Diagnosis Codes

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<th>ICD-9 CM diagnosis codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>008.45</td>
<td>Intestinal infections due to clostridium difficile</td>
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</table>

ICD-10 Diagnosis Codes

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<th>ICD-10 CM diagnosis codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>A04.7</td>
<td>Enterocolitis due to Clostridium difficile</td>
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Description

Fecal microbiota transplantation (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 though 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 FMT is 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 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 and 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 FMT include treatment of conditions in which altered colonic flora may play a role. These include inflammatory bowel disease, irritable bowel syndrome, idiopathic constipation, and non–gastrointestinal 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) 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 treatment-refractory *Clostridium difficile* infection (CDI), and for other conditions including inflammatory bowel disease (IBD).

The evidence for FMT in patients who have recurrent CDI refractory to antibiotic therapy includes 2 randomized controlled trials (RCTs) and observational studies. Relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. Findings of the trial that compared FMT with standard treatment suggest that FMT is more effective for recurrent CDI. However, the study had a small sample size and open-label design. The other RCT did not find a significant difference in efficacy when donor feces were administered via colonoscopy or nasogastric tube. Case reports and case series report a high rate of resolution of recurrent CDI following treatment with FMT. Few treatment-related adverse events have been reported. The evidence is sufficient to determine qualitatively that the treatment results in meaningful improvements in the net health outcome.

The evidence for FMT in patients who have IBD includes 2 RCTs in patients with ulcerative colitis as well as observational studies. 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, and data from already enrolled patients were analyzed. One trial found a statistically significantly higher remission rate after active FMT compared with 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; there are no controlled studies of FMT in this population. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for FMT in patients who have acute CDI, pouchitis, irritable bowel syndrome, constipation, or metabolic syndrome includes a small number of case series and/or case reports. Relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. Data are available for only
small numbers of patients and there is a lack of comparative studies. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Policy History**

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<thead>
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<td>12/2016</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>1/2016</td>
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**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**