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**Original Effective Date: 09/15/14**

**Reviewed: 07/25/19**

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## **Subject: Fecal Microbiota Transplantation**

**THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.**

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### **DESCRIPTION:**

Fecal microbiota transplantation (FMT) involves the infusion of intestinal microorganisms via transfer of stool from a healthy person into a diseased person, 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). The stool can be infused as a liquid suspension into an individual'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. *Clostridium difficile* occurs naturally in intestinal flora.

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.

### **POSITION STATEMENT:**

Fecal microbiota transplantation **meets the definition of medical necessity** for treatment of individuals with recurrent *Clostridium difficile* infection when **ALL** of the following are met:

- 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 for all other conditions is considered **experimental or investigational**, including, but not limited to, the following:

- Autism spectrum disorders
- Autoimmune disorders (e.g., multiple sclerosis)
- Chronic fatigue syndrome
- Crohn's disease
- Diabetes
- Fatty liver disease
- First-line therapy for *Clostridium difficile* infection
- Idiopathic constipation
- Idiopathic thrombocytopenic purpura
- Irritable bowel disease (IBS); irritable bowel syndrome (IBS)
- Metabolic syndrome
- Neurological disorders (e.g., Parkinson's disease)
- Obesity
- Ulcerative colitis

There is insufficient published clinical evidence to support the safety and effectiveness of FMT in conditions other than recurrent *Clostridium difficile* infection.

### **BILLING/CODING INFORMATION:**

#### **CPT Coding:**

44705	Preparation of fecal microbiota for instillation, including assessment of donor specimen
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#### **HCPCS Coding:**

G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen
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#### **ICD-10 Diagnosis Codes That Support Medical Necessity:**

A04.7	Enterocolitis due to <i>Clostridium difficile</i>
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## **REIMBURSEMENT INFORMATION:**

Refer to section entitled **POSITION STATEMENT**.

## **PROGRAM EXCEPTIONS:**

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

**Medicare Advantage products:** The following Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Noncovered Services (L33777), located at fcso.com.

## **DEFINITIONS:**

**Pulsed vancomycin regimen:** Vancomycin 125 mg every 2 to 3 days for at least 3 weeks.

## **RELATED GUIDELINES:**

None applicable.

## **OTHER:**

### **Index terms:**

Donor feces infusion

Intestinal microbiota transplantation

Fecal bacteriotherapy

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### **COMMITTEE APPROVAL:**

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 07/25/19.

### **GUIDELINE UPDATE INFORMATION:**

09/15/14	New Medical Coverage Guideline.
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09/15/15	Scheduled review. Maintained position statement and updated references.
11/01/15	Revision: ICD-9 Codes deleted.
08/15/16	Scheduled review. Maintained Position Statement section. Updated references.
08/15/17	Scheduled review. Maintained Position Statement section. Updated references. Reformatted guideline.
08/15/18	Scheduled review. Position statement maintained. Updated references.
08/15/19	Scheduled review. Maintained position statement and updated references.