MEDICAL POLICY

SUBJECT: FECAL BACTERIOTHERAPY
POLICY NUMBER: 2.01.48
CATEGORY: Technology Assessment

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<thead>
<tr>
<th>EFFECTIVE DATE: 08/16/12</th>
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</thead>
<tbody>
<tr>
<td>REVISED DATE: 08/15/13, 07/17/14, 07/16/15, 06/16/16, 06/15/17</td>
</tr>
<tr>
<td>PAGE: 1 OF: 7</td>
</tr>
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- If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.
- If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY STATEMENT:

I. Based upon our criteria and assessment of peer-reviewed literature, fecal bacteriotherapy has been medically proven to be effective and is considered medically appropriate for the treatment of recurrent clostridium difficile infection (CDI) when ALL of the following have been met:
   A. Patient has had at least three episodes of recurrent CDI despite the standard antibiotic therapy;
   B. Patient is not immunocompromised; AND
   C. The appropriate donor stool screening has been completed (see guidelines below).

II. Based upon our criteria and assessment of the peer-reviewed literature, fecal bacteriotherapy has not been medically proven to be effective and is considered investigational for all other indications, including but not limited to, the first line treatment for CDI or the treatment of inflammatory bowel disease.

POLICY GUIDELINES:

I. The most appropriate donor is a spouse, significant other, or first degree relative if possible. Donor stool screening should follow the FDA guidelines for biologic donors and include at least the following:
   A. Screening for transmissible bloodborne diseases or other diseases associated with microflora changes (e.g., irritable bowel syndrome, constipation);
   B. Screening for transmissible pathogens;
   C. Donor has not had antibiotic therapy for at least three months previous to donation; and
   D. Donor should not ingest foods that the patient is allergic to.

II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

The recurrence of Clostridium difficile infection (CDI) is one of the most difficult and increasingly common challenges associated with the infection. An initial incidence of CDI is followed by a relapse within 30 days in about 20 – 30% of cases, and the risk of recurrence doubles after two or more occurrences. Older age, intercurrent antibiotic use for non-C. difficile indications, renal insufficiency, immune deficiency and antacid medications are some of the known risk factors for recurrence. The presence of just three clinical criteria: age greater than 65 years, severe disease, and continued use of antibiotics after treating the initial CDI episode, are predictive of an almost 90% relapse rate. It is now recognized that the presence of normal, healthy, intestinal microbiota offers protection against CDI. Conversely, severe disruption of normal intestinal microbiota by repeated cycles of antibiotics, including metronidazole and vancomycin that are used to treat CDI, is likely one of the major reason for its recurrence.

The American College of Gastroenterology published guidelines for the diagnosis, treatment, and prevention of CDI in 2013. Highlights of the guidelines for the treatment of CDI are as follows: Patients with mild-to-moderate CDI should be treated with metronidazole 500 mg orally three times per day for 10 days (Strong recommendation, high-quality evidence); Patients with severe CDI should be treated with vancomycin 125 mg four times daily for 10 days (Conditional recommendation, moderate-quality evidence); Failure to respond to metronidazole therapy within 5 – 7 days should prompt consideration of a change in therapy to vancomycin at standard dosing (Strong recommendation, moderate-quality evidence); For mild-to-moderate CDI in patients who are intolerant/allergic to metronidazole and for pregnant
Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

CODES:
- Number
- Description

Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.
CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

**CPT:**
44705 Preparation of fecal microbiota for instillation, including assessment of donor specimen

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

**ICD9:**
008.45 Clostridium difficile

**ICD10:**
A04.7 Enterocolitis due to Clostridium

**REFERENCES:**


* key article

KEY WORDS:
Fecal microbiota therapy (FMT), Fecal transfusion, Fecal transplant, Human probiotic infusion (HPI), Intestinal microbiota Transplantation (IMT), Microbiome, Stool transplant

**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

Based upon our review, fecal bacteriotherapy is not addressed in National or regional CMS coverage determinations or policies.