Subject: Fecal Microbial Transplant (FMT) for Clostridium Difficile Infection

Background: Fecal microbiota transplantation (FMT) involves the infusion of intestinal microorganisms via transfer of stool from a healthy person into a diseased patient. The intent is to restore normal intestinal flora. For the purposes of this coverage guideline, fecal transplant may be covered for the treatment of clostridium difficile infection (CDI) that has not responded to standard therapies.

Policy and Coverage Criteria:

Harvard Pilgrim Health Care (HPHC) considers fecal microbial transplant (FMT) as reasonable and medically necessary for the treatment of members with Clostridium Difficile Infection (CDI) when documentation confirms ANY of the following conditions:

- There have been at least 3 episodes (one initial and at least 2 recurrences) of infection confirmed by positive stool cultures; OR
- A persistent episode that is refractory to appropriate antibiotic treatment protocol, including one of the following:
  - At least one regiment of tapered or pulsed vancomycin
  - Vancomycin followed by Rifaximin
  - A regimen of Fidaxomicin (standard or extended-pulsed)

Documentation should include the following:

- If requested for review, the submitted medical record should support the use of the selected ICD-CM and CPT/HCPCS code(s) used to describe the service performed.
- Documentation maintained by the ordering physician/treating physician must indicate the medical necessity for performing this procedure.
- Informed consent should include, at a minimum, a statement that the use of FMT products to treat C. difficile is investigational with a discussion of its potential risks, per FDA suggested guidance.

NOTE: FMT is considered medically necessary for recurrent CDI only.

Exclusions: Harvard Pilgrim Health Care (HPHC) considers urine drug testing as not medically necessary for all other indications.

Coding:

Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>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>
</tr>
<tr>
<td>44705</td>
<td>Preparation of fecal microbiota for instillation, including assessment of donor specimen</td>
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</table>
HPHC Medical Policy

Fecal Microbial Transplant (FMT) for Clostridium Difficile Infection

HPHC policies are based on medical science, and written for the majority of people with a given condition.

Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g. Benefit Handbook, Certificate of Coverage) for member-specific benefit information.

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>A04.71</td>
<td>Enterocolitis due to Clostridium difficile, recurrent</td>
</tr>
<tr>
<td>A04.72</td>
<td>Enterocolitis due to Clostridium difficile, not specified as recurrent</td>
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</table>

Billing Guidelines:
Member’s medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

References:

Summary of Changes:

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>8/22</td>
<td>Annual review; no changes</td>
</tr>
<tr>
<td>11/21</td>
<td>New policy for integration purposes with Tufts Health Plan (THP)</td>
</tr>
</tbody>
</table>

Approved by Medical Policy Committee: 8/17/22
Approved by Clinical Policy Operational Committee: 12/21
Policy Effective Date: 8/17/22
Initiated: 11/21