Fecal Microbiota Transplantation (FMT)

Published: 02/01/2017

Next Review: 12/2017
Last Review: 01/2017

IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured’s benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

Fecal microbiota transplantation (FMT) - also known as stool transplant, donor feces infusion, intestinal microbiota transplantation, and fecal bacteriotherapy - is the transfer of fecal bacteria, taking a stool specimen from a healthy individual and transplanting it into a diseased individual. FMT is generally used as a treatment of recurrent Clostridium difficile infection (CDI) unresponsive to standard therapy, as well as other conditions that may be associated with disruption of normal intestinal flora.

MEDICARE ADVANTAGE POLICY CRITERIA

<table>
<thead>
<tr>
<th>CMS Coverage Manuals*</th>
<th>None</th>
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<tr>
<td>National Coverage Determinations (NCDs)*</td>
<td>None</td>
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<tr>
<td>Noridian Healthcare Solutions (Noridian) Local</td>
<td>None</td>
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Medicare coverage guidance is not available for FMT. Therefore, the health plan’s medical policy is applicable.

Fecal Microbiota Transplantation, Medicine, Policy No. 154
(see “NOTE” below)

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (Medicare IOM Pub. No. 100-04, Ch. 23, §30 A). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an objective, evidence-based process, based on authoritative evidence. (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan’s evidence-assessment process (see Cross References).

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below must be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- Medical records and clinical documentation detailing the proposed treatment plan and the condition being treated.

REGULATORY STATUS

In July 2013, the U.S. Food and Drug Administration (FDA) issued guidance regarding investigational new drug (IND) requirements for the use of fecal microbiota transplantation (FMT) to treat CDI unresponsive to medication therapy.[1] This guidance states the FDA will use enforcement discretion regarding use of fecal transplant to treat treatment-resistant CDI infections. FDA requires physicians to obtain adequate informed consent from patients or their legal representative before performing the procedure. This informed consent should include, at a minimum, a statement advising the use of MFT to treat CDI is investigational and its potential risks. This FDA policy concludes by stating it does not extend to other uses of FMT.

CROSS REFERENCES

Investigational (Experimental) Services and New and Emerging Medical Technologies and Procedures, Medicine, Policy No. M-149

REFERENCES

**CODING**

**NOTE:** CPT code 44705 is a Medicare Status I code, and therefore, is not recognized by Medicare or for Medicare Advantage plans.

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<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td>44705</td>
<td>Preparation of fecal microbiota for instillation, including assessment of donor specimen <em>(Not valid for Medicare purposes)</em></td>
</tr>
<tr>
<td>HCPCS</td>
<td>G0455</td>
<td>Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen</td>
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*IMPORTANT NOTE: Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*