The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is required. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Description

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 the treatment of treatment-refractory Clostridium difficile infection (CDI), as well as for other conditions including inflammatory bowel disease (IBD).

Background

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 (i.e., 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. 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 in conjunction with 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 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.

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 two patients with recurrent CDI. (4) The product is made from 33 bacterial isolates that were developed from culturing stool from a healthy donor.

Regulatory Status

In July 2013, the U.S. Food and Drug Administration (FDA) issued guidance regarding investigational new drug requirements for use of fecal microbiota transplant to treat CDI not responsive to medication therapy. (5) The document states that FDA is continuing to consider how to regulate fecal microbiota transplant and that, during this interim period, the agency will use enforcement discretion regarding use of fecal transplant to treat treatment-resistant CDI infections. FDA requires that physicians obtain adequate informed consent from patients or their legal representative before performing the intervention. The document also states that selective enforcement does not apply to use of fecal transplant for treating conditions other than treatment-resistant CDI.

Related Protocol

Fecal Analysis in the Diagnosis of Intestinal Dysbiosis

Policy (Formerly Corporate Medical Guideline)

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 three episodes of recurrent infection; AND
- Episodes are refractory to appropriate antibiotic regimens, including at least one regimen of pulsed vancomycin.

Fecal microbiota transplantation is considered investigational in all other situations.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.
References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


