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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.

DESCRIPTION:

Fecal microbiota transplantation (FMT), also called donor feces infusion, intestinal microbiota transplantation, and fecal bacteriotherapy involves the duodenal infusion of intestinal microorganisms via the 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 the upper gastrointestinal tract through a nasogastric tube or gastroscopy, into the colon through a colonoscope or rectal catheter, or administered orally via capsules (ie, encapsulated FMT).

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.

Summary and Analysis of Evidence: Rokkas et al (2019) performed a systematic review and meta-analysis to assess the efficacy of fecal microbiota transplantation (FMT) for the treatment of recurrent Clostridium difficile (CDI). Six RCTs were included in the analysis (N=348), and 7 interventions were compared: dFMT, aFMT, vancomycin, vancomycin plus dFMT, vancomycin plus bowel lavage, fidaxomicin, and placebo). The primary outcome was the resolution of CDI-related symptoms. The network meta-analysis demonstrated that dFMT was superior to vancomycin, vancomycin plus dFMT,

vancomycin plus bowel lavage, and fidaxomicin groups. Tariq et al (2019) performed a systematic review and meta-analysis to assess the efficacy of FMT as a treatment option for recurrent CDI on the basis of results from open-label studies and placebo-controlled clinical trials. The authors were motivated to perform this analysis based on observations that FMT cure rates for CDI are high in observational studies (eg, >90%) but appear to be consistently lower in open-label studies and clinical trials. Thirteen studies were included for evaluation, including 6 placebo-controlled RCTs and 7 open-label studies. Out of 610 patients receiving FMT, 439 patients achieved clinical cure; study heterogeneity was significant (I2 =91.35%). Cure rates were found to be lower in randomized trials versus open-label studies. Subgroup meta-analysis by FMT route of administration indicated lower cure rates with enema than colonoscopy. However, no differences between colonoscopy and oral delivery routes were detected. Lower cure rates were observed for studies that included both recurrent and refractory CDI than those that only included patients with recurrent CDI. To investigate the long-term clinical outcomes of FMT in patients with CDI, Mamo et al (2018) conducted a retrospective study using a follow-up survey of 137 patients who had received FMT for recurrent CDI at a single-center between January 2012 and December 2016. Median time from last FMT to follow-up was 22 months. Overall at follow-up, 82% (113/137) of patients had no recurrence of CDI (nonrecurrent CDI group) and 18% (24/137) of patients had CDI (recurrent CDI group). The survey results suggested that antibiotic exposure for non-CDI infections after FMT were more common in the recurrent CDI group (75%) than in the nonrecurrent CDI group (38%). Overall, 82% of patients reported being symptom-free. Tun et al (2022) performed a systematic review and meta-analysis to assess the efficacy of FMT for the treatment of CDI in children. The analysis included 904 children across 14 observational studies (5 prospective, 5 retrospective, and 4 case series); 12 studies included children with recurrent CDI and 2 studies included children with recurrent CDI or first episode of CDI. The most common route of FMT administration was colonoscopy (49.79%). The primary outcome was the efficacy of FMT in treating CDI or recurrent CDI. Results demonstrated a rate of success ranging between 66% and 100%, the latter of which was found in 7 studies. The pooled rate of clinical success in the overall cohort was 86%. There were 47 adverse events in 45 patients and 38 serious adverse events in 36 patients; the causes of serious adverse events were variable and there was no single predominant cause. A systematic review and meta-analysis by Du et al (2021) evaluated the efficacy of FMT delivery via oral capsules for the treatment of recurrent CDI. The analysis included 12 case series and 3 RCTs (N=763 patients). Encapsulated delivery of FMT demonstrated an overall efficacy rate of 82.1%. There was no statistically significant difference in the efficacy of FMT capsules that used lyophilized stool versus frozen stool. There was also no statistically significant difference in the efficacy of FMT capsules compared with colonoscopy. No serious adverse events attributable to oral FMT capsules were reported, other than those associated with treatment failure. Gangwani et al (2023) published a systematic review comparing fresh vs frozen vs lyophilized FMT for recurrent CDI. A total of 616 patients were included across 8 studies (4 RCT and 4 cohort); all 8 studies evaluated fresh FMT, 6 also assessed frozen FMT, and 3 assessed lyophilized FMT. Fresh FMT was determined to be most successful for the resolution of symptoms with 93% efficacy, followed by frozen at 88% efficacy and lyophilized at 83% efficacy. There were no significant differences in efficacy between frozen vs fresh FMT groups or frozen vs lyophilized groups. A double-blind RCT by Lee et al (2016) compared fresh with frozen stool used in FMT to treat patients with recurrent CDI. A total of 232 patients were included, with 114 assigned to frozen FMT and 118 to fresh FMT. The primary endpoint was the proportion of patients with no recurrence of CDI-related diarrhea 13 weeks after FMT. The trial was designed as a noninferiority trial, with a margin of 15%. In the per-protocol population (n=178),

clinical resolution of symptoms was reported in 76 (83.5%) of 91 patients in the frozen FMT group and 74 (85.1%) of 87 patients in the fresh FMT group. In the modified intention-to-treat group, clinical resolution with up to 2 FMT treatments was reported in 81 (75.0%) of 108 patients in the frozen FMT group and 78 (70.3%) of 111 patients in the fresh FMT group. The difference between groups was within the 15% noninferiority margin and thus frozen FMT was considered noninferior to fresh FMT. A review by Ramai et al (2020) also included a subgroup analysis of donor relation. Results demonstrated that cure rates were not significantly influenced by whether FMT used unrelated or a mix of related and unrelated donors (94.5% and 95.7%, respectively). Lee et al (2019) performed a prospective study assessing the long-term durability and safety of FMT for patients with recurrent or refractory CDI. Ninety-four patients underwent FMT via retention enema between 2008 to 2012; 32 patients were unreachable and 37 were deceased 4 to 8 years later for a follow-up survey. Twenty-three of the remaining 25 patients completed the questionnaire. No CDI recurrences were reported in patients treated with FMT. Twelve of 23 participants (52.2%) received at least 1 course of antibiotics for treatment of a condition other than CDI. Nine participants (40.9%) received probiotics. Current health was self-reported as "much better" in 17 patients (73.9%) or "somewhat better" in 3 patients (13.0%). The authors concluded that FMT for recurrent or refractory CDI appears to be durable at 4 to 8 years following treatment, even after receiving non-CDI antibiotic therapy.

POSITION STATEMENT:

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

- There have been at least 2 recurrences that are refractory to standard antibiotic treatment

Fecal microbiota transplantation for all other conditions is considered **experimental or investigational.** 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
0780T	Instillation of fecal microbiota suspension via rectal enema into lower gastrointestinal tract

HCPCS Coding:

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

ICD-10 Diagnosis Codes That Support Medical Necessity:

A04.7	Enterocolitis due to Clostridium difficile

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: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

None applicable.

RELATED GUIDELINES:

None applicable.

OTHER:

None applicable.

Florida Statute 765.523 Discrimination in access to anatomical gifts and organ transplants prohibited. (excerpt)

(d) "Organ transplant" means the transplantation or transfusion of a part of a human body into the body of another individual for the purpose of treating or curing a medical condition.

Florida Statute 627.64197 Coverage for organ transplants.—A health insurance policy issued, delivered, or renewed on or after July 1, 2020, in this state by an insurer which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

Florida Statute 627.65736 Coverage for organ transplants.—A group health insurance policy delivered, issued, or renewed on or after July 1, 2020, in this state by an insurer or nonprofit health care services plan which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer or nonprofit health care service plan to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

Florida Statute 641.31075 Coverage for organ transplants.—A health maintenance contract issued or renewed on or after July 1, 2020, in this state by a health maintenance organization which provides coverage for organ transplants may not deny coverage for an organ transplant solely on the basis of a subscriber's disability. This section may not be construed to require such health maintenance organization to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/26/24.

09/15/14	New Medical Coverage Guideline.
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.
07/01/20	Revision: added Florida statute language regarding discrimination in access to anatomical gifts and coverage of organ transplants. Updated references.
12/15/20	Scheduled review. Revised description, maintained position statement and updated references.
02/15/22	Scheduled review. Revised description and position statement. Updated references.
01/01/23	Annual CPT/HCPCS coding update. Added 0780T.
05/25/23	Update to Program Exceptions section.
01/01/24	Position statements maintained.
10/15/24	Scheduled review. Revised description, maintained position statement and updated references.