MEDICAL POLICY

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Medical Policy Title	**Fecal Microbiota Transplantation**
Policy Number	**2.01.48**
Current Effective Date	**September 17, 2026**
Next Review Date	**September 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Fecal microbiota transplantation (FMT) is considered **medically appropriate** for the treatment of adults with recurrent Clostridioides difficile infection (CDI), when **BOTH** the following criteria have been met:

   A. The individual has a history of two (2) or more recurrences after the initial episode, despite standard antibiotic treatment (total of three [3] or more episodes);

   B. The appropriate donor stool screening has been completed.

II. Fecal microbiota transplantation (FMT) 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.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

Pharmacy Policy

-09 Clinical Review Prior Authorization (CRPA) Rx, for Vowst - fecal microbiota spores, live-brpk.

-63 Clinical Review Prior Authorization (CRPA) Medical, for Rebyota - fecal microbiota, live-jslm

POLICY GUIDELINE(S)

I. FMT should be performed with appropriately screened donor stool. Rigorous evaluation of all candidate stool donors is important to minimize the risk for transmitting infection and to maximize the likelihood of successful treatment outcome.

DESCRIPTION

Fecal microbiota transplantation (FMT), also called fecal bacteriotherapy or intestinal microbiota transplantation, involves the administration of intestinal microorganisms from a healthy, screened donor into a patient's gastrointestinal tract to restore normal colonic flora. FMT can be delivered via colonoscopy, oral capsules, nasogastric or nasoduodenal tube, or rectal enema. The goal is to replace

disordered native microbiota (dysbiosis) with a stable donor microbial community.

The primary clinical application of FMT is recurrent Clostridioides difficile infection (CDI). C. difficile is a major cause of clinically significant diarrhea and colitis, most commonly following disruption of normal colonic flora by antibiotics and often becomes recurrent. When severe or fulminant, CDI can cause life-threatening complications including toxic megacolon and colonic perforation. Recurrent CDI, defined as reappearance of symptoms after resolution on appropriate therapy, typically within 8 weeks of treatment completion. Risk factors for recurrence include advancing age, concomitant antibiotic exposure, defective humoral immune response to C. difficile toxins, severe underlying disease, and proton pump inhibitor use. Standard first-line treatment for initial and recurrent CDI is antibiotic therapy.

The principal potential risk associated with FMT is transmission of contagious agents contained in the donor stool. There are risks of transmitting agents that do not cause a disease immediately after transplantation but may complicate the treatment of the patient in the future. The fecal transplant material (donor stool) must be appropriately screened for infectious diseases and pathogens.

SUPPORTIVE LITERATURE

Recurrent CDI

Based on published outcomes from case series/case reports and randomized controlled trials (RCT), FMT is a highly effective therapy for recurrent CDI when standard treatments have failed.

A Cochrane systematic review (Minkoff 2023) of 6 RCTs (320 participants) found moderate-certainty evidence that FMT leads to a large increase in resolution of recurrent CDI compared with alternative treatments such as antibiotics, with an approximately 77% cure rate.

First-Line FMT for CDI

The evidence for FMT as a first-line therapy for CDI is insufficient to determine that first-line FMT therapy results in an improvement in the net health outcome. The American Gastroenterological Association's clinical practice guidelines indicate that trials are needed to assess FMT therapies as primary prevention in patients at high risk of CDI and as first-line treatment after short course of anti-CDI therapy (Peery 2024).

Baunwall et al (2022) conducted the EarlyFMT trial, a small randomized, double-blind, placebo-trial to compare the efficacy and safety of FMT compared with placebo after vancomycin for first or second C difficile infection. Eligible patients were aged 18 years or older with first or second C difficile infection. Patients were randomly assigned (1:1) to FMT (n=21) or placebo (n=21) administered on day 1 and between day 3 and 7, after they had received 125 mg oral vancomycin four times daily for 10 days. The trial was stopped early after interim analysis showed significantly higher resolution in the FMT group (19/21) versus placebo (7/21; p=0.00031). The absolute risk reduction for recurrence following FMT compared with placebo was 57%. The authors indicated that the results should not be interpreted as evidence for FMT alone, but for its use in combination with antibiotics. The authors concluded that FMT after vancomycin is superior to standard-of-care vancomycin alone in achieving sustained cure of first or second C difficile infection.

Irritable Bowel Syndrome (IBS)

Ianiro et al (2019) conducted a systematic review with meta-analysis reviewed 5 randomized controlled trials (RCTs) and reported mixed outcomes for FMT in patients with IBS. When all studies were pooled, no net benefit was found for active FMT.

Lahtinen et al (2020) reported the results of a double-blind RCT evaluating the efficacy of FMT in patients with IBS. The intervention group (n=23) received donor FMT via colonoscopy and the control group (n=26) received autologous FMT placebo via the same route. Approximately 35% of patients experienced adverse events, with no significant difference between groups.

Holvoet et al (2021) reported the results of a double-blind RCT evaluating the efficacy of FMT in patients with refractory IBS, defined as failure of ≥3 conventional therapies. The intervention group (n=43) received donor FMT via the nasojejunal route and the control group (n=19) received autologous FMT placebo via the same route. A daily symptom diary was used to assess IBS-related symptoms and improvement in IBS symptoms at 12 weeks was the primary outcome of the trial. After a single FMT, more patients in the treatment group versus placebo reported efficacy for more than 1 year (21% vs. 5%). A second FMT reduced symptoms in 67% of patients with an initial response to donor stool, but not in patients with a prior non-response.

Madsen et al (2021) reported the results of a double-blind RCT evaluating the efficacy of FMT capsules (n=26) versus placebo capsules (n=25) in patients with moderate-to-severe IBS (IBS-SSS score ≥175 points). Both groups administered capsules for 12 days and patients were allowed to continue any concomitant IBS medications, including laxatives or agents for constipation. Patients tracked their symptoms in a diary and were followed for 6 months. The primary outcome was not specified, but investigators evaluated abdominal pain, stool frequency, and stool form. Subgroup analyses by IBS subtype were not performed.

El-Salhy et al (2022) published 3-year follow-up results of a double-blind, placebo-controlled study that randomized 165 patients with IBS, published in 2020 by the same researcher. The current study included 125 patients (n=38 placebo group; n=42 received 30 grams (g) of donor feces; n=45 received 60 g of donor feces). Two years after FMT, response rates were 26.3%, 69.1%, and 77.8% in the placebo, 30 g, and 60 g groups, respectively. Three years after FMT, response rates were 27.0%, 64.9%, and 71.8%, respectively. The response rates were significantly higher in the 30-g and 60-g groups than in the placebo group. Patients in the 30-g and 60-g groups had significantly fewer IBS symptoms and fatigue, and a greater quality of life both at 2 and 3 years after FMT. No long-term adverse events were recorded.

Wang et al (2023) performed a meta-analysis of 9 RCTs (n=516) and found that a single FMT significantly decreased IBS-SSS scores at months 1, 3, 6, 24, and 36 compared with placebo, with improved clinical response rates and quality of life at months 3, 24, and 36. FMT did not increase adverse event risk. The authors conclude that a single FMT is effective and safe for patients with IBS, however, the authors noted that the relationship between the gut microbiome and FMT efficacy in IBS remains unclear.

Inflammatory Bowel Disease (IBD) – Crohn's Disease

Sokol et al (2020) conducted a pilot RCT investigating endoscopic delivery of FMT in patients with Crohn's disease (CD). This small, multicenter, single-blind, placebo-controlled RCT was conducted in France and randomized patients to FMT (n=8) and sham transplantation (n=9). The primary endpoint was the colonization of donor microbiota at week 6, which was not reached by any patient. The rate of clinical flares in the 24 weeks following FMT was a secondary endpoint in the study. Only those patients who achieved clinical remission within the 3 weeks following the commencement of corticosteroids were randomized to treatment or placebo. The treatment group received FMT after colon cleansing with polyethylene glycol. The steroid-free clinical remission rate at 10 and 24 weeks was 44.4% (4/9) and 33.3% (3/9) in the sham transplantation group and 87.5% (7/8) and 50.0% (4/8; one patient loss of follow-up while in remission at week 12 and considered in flare at week 24) in the FMT group. Crohn's Disease Endoscopic Index of Severity decreased 6 weeks after FMT ($p = 0.03$) but not after sham transplantation ($p = 0.8$). Conversely, the CRP level increased 6 weeks after sham transplantation ($p = 0.008$) but not after FMT ($p = 0.5$). None of the adverse events observed in the trial was related to FMT. These results must be confirmed in larger studies.

Zhou et al (2023) conducted a systematic review and meta-analysis to examine the safety and effectiveness of FMT in patients with CD. Eleven cohort studies and one RCT involving 228 patients were included. In a meta-analysis, the pooled proportion of adult patients with active CD that achieved clinical remission 2 to 4 weeks after FMT was 57%. Results showed that FMT reduced Crohn's disease activity index scores 4 to 8 weeks after FMT. Subgroup analyses showed no difference between FMT methodologies, except for pre-FMT treatment with antibiotics ($P = 0.02$). Most adverse events were self-limiting and disappeared spontaneously within hours or days after FMT. The authors concluded that FMT could be a promising therapy in the short-term treatment of active CD; however, more placebo-controlled RCTs, with long-term-up follow-up, are necessary.

Kao et al (2024) conducted the first placebo-controlled multicenter RCT of FMT in active Crohn's disease (CD). Patients with mild-to-moderate CD were randomized 1:1 and received FMT (n=17) or placebo (n=12). The first treatment was administered by colonoscopy followed by weekly oral capsules for 7 weeks. Primary end point was clinical and endoscopic remission at week 8. Secondary outcomes included clinical and endoscopic response, adverse events, and health-related quality of life using generic and disease-specific instruments. At week 8, 0% (0/15) of patients in the FMT group versus 8.3% (1/11) in the placebo group reached the primary end point of combined clinical and endoscopic remission as per protocol analysis. There were no differences between the groups in clinical or endoscopic responses. One patient in each group had worsening of CD. Although both groups experienced statistically significant improvements in health-related quality of life, only the FMT group had a significant decrease in activity impairment. FMT was not effective at inducing clinical and endoscopic remission in CD using the FMT regimen in this study. Future studies should use an adequately powered multicenter trial and use a longer intervention period to improve clinical efficacy.

Inflammatory Bowel Disease (IBD) – Ulcerative Colitis

A Cochrane review (Imdad 2023) of 12 studies (N=550 participants) evaluated the efficacy and safety of FMT for the treatment of IBD. The follow-up duration across studies ranged from 6 to 12 weeks for the evaluation of induction and from 48 to 56 weeks for the evaluation of remission.

Comparators included autologous FMT, placebo, standard medication, and no intervention. The results showed that FMT may increase rates of clinical remission induction in UC compared with controls (risk ratio, 1.79; 95% CI, 1.13 to 2.84; low certainty), but FMT did not significantly improve the likelihood of induction of endoscopic remission. FMT did not significantly improve the maintenance of clinical or endoscopic remission of UC. There were no statistically significant differences in the rates of adverse events or serious adverse events. Evidence was very uncertain regarding serious adverse events, quality of life, and maintenance of remission.

Caenepeel et al (2025) conducted a multi-centric, double-blind, sham-controlled, randomized trial with repeated FMTs to induce clinical remission in patients with active UC through rigorous donor screening and by applying an anerobic workflow to create cell-density-standardized FMT preparations. Thereby, targeting the identification and characterization of potentially highly effective donors (also referred to as 'superdonors') for treatment of UC. Patients (n=66) were randomized to receive 4 infusions of allogenic donor or autologous FMT (allogenic FMT, n=30; and autologous FMT, n=36). At week 8, respectively, 3 and 5 patients reached the primary endpoint of steroid-free clinical remission (P= .72), indicating no treatment difference of at least 5% in favor of allogenic FMT. The trial did not meet its primary endpoint of increased steroid-free clinical remission and was halted at 66% of intended inclusions due to futility. The authors concluded that strict allogenic donor selection could not increase the efficacy of FMT in active UC. Nevertheless, key lessons for future research were learned.

Gefen et al (2025) indicated that FMT has been shown to restore gut microbiome composition with an acceptable safety profile. A systematic review and meta-analysis of randomized controlled trials was conducted to assess the efficacy of FMT in inducing UC remission. A total of 14 studies (n= 600 patients with a median age of 40.7 years) were assessed. FMT was used in 299 patients and associated with significantly higher odds of combined clinical and endoscopic remission ($p<0.0001$), clinical remission ($p=0.0002$), and endoscopic remission ($p=0.011$). Compared with baseline, FMT was more effective when biologics, steroids, or methotrexate were used as pre-FMT treatment. Oral delivery of FMT and pooled donors led to higher odds of remission. On meta-regression, pooled donors and methotrexate pre-treatment were associated with an increased likelihood of remission. Current evidence shows that oral delivery of FMT and multi-donor FMT may confer better results than transanal delivery and single-donor FMT. Standardization of the administration method, dosage, donors, and pre-FMT treatment is needed.

Other Indications

FMT has been shown to have some effect in alleviating symptoms in patients with other difficult-to-treat conditions (e.g., diabetes, obesity and metabolic syndrome, neurological disorders); however, most studies of these diseases consist of case series, case reports, and cohort studies. While outcome data are promising, there is insufficient evidence currently to implement FMT as a treatment regimen. Additional RCTs and longer-term studies are still needed to determine efficacy and safety profiles.

Pediatric Population

Ulcerative colitis (UC) and FMT in children was studied in the first pilot RCT, the Pediatric FEcal microbiota Transplant in ulcerative Colitis (PediFETCh) (Pai 2021). During a 36-month study period, patients aged 4 to 17 years with active UC for less than 1-year were randomized to FMT (n=13) or placebo (n=12) arms. Seven patients randomized to the placebo arm crossed over to the open-label arm, and six patients completed the 30-week arm. The study did not reach the primary feasibility outcome of achieving recruitment targets (50 patients over 2 years), which suggests that recruitment remains the most significant challenge. There were several study limitations, however, the authors indicated that this pilot RCT offers evidence that FMT may have an important role in improving symptoms and inflammatory indices in the pediatric UC.

Tun et al (2022) performed a systematic review and meta-analysis of 14 observational studies (n=904 children) assessing FMT for CDI in patients ≤21 years. The pooled clinical success rate was 86% (p<0.001). There were 47 adverse events and 38 serious adverse events with no single predominant cause. No RCTs were available. The authors concluded FMT is effective and safe in pediatric patients with CDI but remains poorly regulated and standardized.

Gu et al (2024) conducted a double-blind RCT to determine the safety and efficacy of retrograde colonic enema (RCE)-based FMT in the treatment of intractable constipation in children. A total of 110 children were randomized to the FMT with RCE group or the placebo with RCE group. All participants received a daily RCE, followed by a 4-week FMT treatment (twice a week) and a 12-week follow-up period. Spontaneous bowel movements ≥ 3 per week were the main outcome. At the end of the follow-up period, 22 patients (40.0%) in the FMT with RCE group and 10 patients (18.2%) in the placebo with RCE group had ≥ 3 spontaneous bowel movements per week (P < 0.05). Both RCE and FMT enriched the intestinal bacterial diversity of patients with constipation. The adverse events were all mild self-limiting gastrointestinal symptoms. The authors concluded that FMT enhances the efficacy of RCE, and the use of RCE-based FMT is a safe and effective method in the treatment of intractable constipation in children.

PROFESSIONAL GUIDELINE(S)

Adult Population

American Gastroenterological Association (AGA) In 2024, the AGA published a clinical practice guideline on fecal microbiota–based therapies for select gastrointestinal diseases (Peery 2024). The AGA:

- Suggests the use of fecal microbiota-based therapies upon completion of standard of care antibiotics over no fecal microbiota–based therapies in immunocompetent adults with recurrent C difficile infection, and mildly or moderately immunocompromised adults with recurrent C difficile infection. (Conditional recommendation, low certainty evidence)
- Suggests against the use of fecal microbiota–based therapies upon completion of standard of care antibiotics over no fecal microbiota–based therapies for severely immunocompromised adults with recurrent C difficile infection. (Conditional recommendation, very low certainty of evidence)

- Suggests the use of conventional FMT over no FMT in adults hospitalized with severe or fulminant C difficile infection not responding to antimicrobial therapy. (Conditional recommendation, low certainty of evidence)
- Suggests against the use of conventional FMT except in the context of clinical trial in adults with ulcerative colitis, Crohn's disease, pouchitis, and irritable bowel syndrome. (Conditional recommendation, very low certainty of evidence)

The AGA defines severely immunocompromised patients as those receiving active cytotoxic therapy for solid tumors and hematologic malignancies, patients who have received chimeric antigen receptor T-cell therapy or hematopoietic cell transplant (only when neutropenic), any neutropenia, patients with severe primary immunodeficiency, and patients with advanced or untreated HIV infection (CD4 counts <200/mm^3, AIDS-defining illness without immune reconstitution, or symptomatic HIV). Mildly or moderately immunocompromised patients are those who are immunocompromised but do not meet the definition of severe.

The AGA intentionally refrains from limiting fecal microbiota–based therapies to patients with ≥2 recurrences, noting that some patients at increased risk of recurrence or morbid recurrence may benefit after the initial CDI episode or first recurrence.

In 2026, the AGA published clinical best practice advice for the management of CDI in adults and in patients with IBD. These documents were developed through expert review of the literature and do not provide formal guideline recommendations or evidence ratings.

- CDI in adults: Conventional FMT should be offered after treatment of a second recurrence (third CDI episode) (Fischer 2026). Microbiota restoration therapy may be considered after treatment of an initial infection or first recurrence in patients who are at high risk for further recurrence or in patients whose initial CDI episode was particularly morbid or difficult to treat.
- CDI in IBD: Microbiome-based therapies (e.g., fecal microbiota) should be offered to patients with IBD with at least one (1) recurrence of CDI to prevent future infection (Khanna 2026).

American College of Gastroenterology (ACG)

In 2021, the ACG published a guideline on the management of Clostridioides difficile infection (Kelly 2021). The ACG considers FMT to be the best treatment option for multiple recurrent CDI, including immunocompromised patients who are seronegative for cytomegalovirus (CMV) and Epstein-Barr virus (EBV). Key recommendations:

- FMT should be considered for patients with severe and fulminant CDI refractory to antibiotic therapy, particularly, when patients are deemed poor surgical candidates (strong recommendation, low quality of evidence).
- Patients experiencing their second or further recurrence of CDI be treated with FMT to prevent further recurrences (strong recommendation, moderate quality of evidence).
- FMT be delivered through colonoscopy (strong recommendation, moderate quality of evidence) or capsules (strong recommendation, moderate quality of evidence) for treatment of CDI; we

suggest delivery by enema if other methods are unavailable (conditional recommendation, low quality of evidence).

- Repeat FMT for patients experiencing a recurrence of CDI within 8 weeks of an initial FMT (conditional recommendation, very low quality of evidence).
- FMT should be considered for recurrent CDI in patients with IBD (strong recommendation, very low quality of evidence).

In 2021, the ACG recommends against the use of fecal transplant for the treatment of global irritable bowel syndrome (IBS) symptoms. (strong recommendation; very low quality of evidence) (Lacy 2021)

In 2019, the ACG recommends against the use of fecal transplant in adults with ulcerative colitis (UC), noting FMT requires more study and clarification of treatment before use as therapy for UC. (Rubin 2019)

American Society of Colon and Rectal Surgeons (ASCRS)

The 2021 ASCRS guideline on the management of CDI recommends (Poylin 2021):

- Patients with recurrent or refractory CDI should typically be considered for fecal bacteriotherapy (e.g., intestinal microbiota transplantation) if conventional measures, including appropriate antibiotic treatment, have failed. (Grade of recommendation: Strong recommendation based on moderate-quality evidence, 1B)
- Patients with three (3) or more CDI episodes can be managed with a vancomycin tapered and pulsed course or fidaxomicin followed by a microbiome-based therapy such as fecal microbiota transplantation.
- In general, conventional antibiotic treatment should be used for at least two (2) recurrences (i.e., 3 CD episodes) before offering fecal microbiota transplantation.

Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA)

In 2021, the IDSA and SHEA published a focused update guideline echoing earlier recommendations for FMT (Johnson 2021). FMT is recommended only for patients with multiple recurrences of CDI who have failed appropriate antibiotic treatments and where appropriate screening of donor and donor fecal specimens have been performed, in accordance with these newer FDA recommendations.

The 2017 updated IDSA and SHEA clinical practice guidelines for the diagnosis and treatment of CDI in children and adults (McDonald 2018) recommendations include:

- Consider fecal microbiota transplantation for pediatric patients with multiple recurrences of CD following standard antibiotic treatments. (Weak recommendation, very low quality of evidence)
- Fecal microbiota transplantation is recommended for patients with multiple recurrences of CDI who have failed appropriate antibiotic treatments. (Strong recommendation, moderate quality of evidence)

- Potential candidates for FMT include patients with multiple recurrences of CDI who have failed to resolve their infection despite treatment attempts with antibiotic agents targeting CDI. Although there is no data to indicate how many antibiotic treatments should be attempted before referral for FMT, the opinion of the panel is that appropriate antibiotic treatments for at least 2 recurrences (i.e., 3 CDI episodes) should be tried.

Pediatric Population

In 2018, an international multidisciplinary panel of experts in pediatric oncology and infectious diseases performed systematic reviews of RCTs for the prevention or treatment of CDI in any population and considered the directness of the evidence to children with cancer and pediatric hematopoietic stem-cell transplantation (HSCT) patients (Diorio 2018). A strong recommendation to not use FMT was made in this population.

In 2019, a joint position paper on FMT for recurrent CDI (rCDI) and other conditions in children was issued from the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (Davidovics 2019). The group of experts acknowledge that controlled trials with FMT for rCDI have not been performed in children, and numerous clinical and regulatory considerations have to be considered when using this untraditional therapy. In general, the group concurs with current adult guidelines when considering FMT for the treatment of rCDI in children and propose FMT be considered in children with one of the following:

- For rCDI (recurrence of symptoms within 8 weeks of treatment for CDI), either:
    - At least 3 episodes of mild to moderate CDI and failure of a 6- to 8- week taper with vancomycin with or without an alternative antibiotic (eg, rifaximin, nitazoxanide), or
    - At least 2 episodes of severe CDI resulting in hospitalization and associated with significant morbidity.
- For moderate CDI not responding to standard therapy (including vancomycin) for at least 1 week. We recommend caution, however, in such cases, with repeated testing for etiologies other than CDI such as IBD.
- For severe CDI or fulminant C difficile colitis with no response to standard therapy after 48 hours.

American Academy of Pediatrics (AAP)

In 2023, the AAP published a clinical report on FMT to provide the general pediatrician with a broad overview to enable appropriate guidance to families seeking FMT as treatment of a child's condition. (Oliva-Hemker 2023). The AAP's summary states that, to date, controlled trials are not available and there are no prospective pediatric clinical trials using FMT to treat CDI. The long-term effects of FMT are unknown. Cohort studies support the use of FMT in pediatric patients with moderate to severe or recurrent CDI but is not recommended for the clinical treatment of any other medical condition.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) views FMT as both a biologic and as a drug with the applicable regulations in respect to procedures and monitoring. The FDA regulates vaccines, blood and blood products, and biologics via the Center for Biologics Evaluation and Research (CBER) which ensures the safety, efficacy, and quality of these products. Refer to the FDA vaccines/blood/biologics website. Available from: https://www.fda.gov/vaccines-blood-biologics [accessed 2026 Aug 1]

The FDA maintains information for consumers and health professionals on vaccine, blood and biologics warnings and other safety information. Available from: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/recalls-biologics (Biologics) | FDA [accessed 2026 Aug 1]

The FDA issued safety alerts on the potential risk of serious or life-threatening infections with the use of FMT and safety protocols for screening protections of donor stool (e.g., multi drug-resistant organisms [MDROs], Escherichia coli, SARS-Co-V-2, COVID-19, and monkeypox virus (FDA 2023).

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
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

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HCPCS Codes

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

ICD10 Codes

Code	Description
A04.7 - A04.72	Enterocolitis due to Clostridium difficile (code range)

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Fecal microbiota transplant or fecal bacteriotherapy are not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.

- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
08/16/12, 08/15/13, 07/17/14, 07/16/15, 06/16/16, 06/15/17, 09/20/18, 09/19/19, 09/17/20, 09/16/21, 09/15/22, 09/21/23, 09/19/24, 09/18/25, 09/17/26	
Date	**Summary of Changes**
09/17/26	• Annual review, policy intent unchanged.
09/18/25	• Annual review, policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
08/16/12	• Original effective date