Clinical Policy: Fecal Microbiota Transplant

Reference Number: IL.CP.MP.517
Last Review Date: 12/20

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

C. Difficile infection	Diarrhea (≥ 3 loose or watery stools per day for at least 2 consecutive days or ≥ 8 loose stools in 48 hours) and a positive stool test for *C. difficile* toxin.
Standard Therapy	≥ 10 days of Vancomycin at a dose of ≥ 125 mg four times per day or ≥ 10 days of metronidazole at a dose of 500 mg three times per day
Severe CDI	Defined by the Infectious Diseases Society of America/Society for Healthcare Epidemiology of America (IDSA/SHEA) as peripheral leukocytosis of 15,000 cells/μL or more or an increase in serum creatinine concentration of 1.5-fold or more above baseline. Severe-complicated infection is defined by hypotension, shock, sepsis, ileus, megacolon, or perforation.
Stool Bank	An establishment that collects, prepares, and stores FMT product for distribution to other establishments, health care providers, or other entities for use in patient therapy or clinical research. An establishment that collects or prepares FMT products solely under the direction of licensed health care providers for the purpose of treating their patients (e.g., a hospital laboratory) is not considered to be a stool bank

Currently, as the standard of care, the FMT preparation must be obtained from a donor known to either the patient or the licensed healthcare provider treating the patient and that the stool donor and stool are qualified by screening and testing performed under the direction of the licensed healthcare provider for the purpose of providing the FMT product to treat his or her patient.

Fecal microbiota transplantation fecal transplant, (fecal transfusion, and probiotic infusion) is the transfer of a liquid suspension of stool from a healthy donor to the patient. The transplant is proposed for the treatment of *Clostridioides* (formerly *Clostridium*) difficile infection (CDI), which can result in mild diarrhea to life-threatening fulminant pseudomembranous colitis. Treatment involves discontinuation of the offending antibiotic and oral administration of metronidazole or Vancomycin. If there is failure of traditional antibiotic therapy, additional treatment with Dificid (fidaxomicin), or addition of cholestyramine to bind clostridial toxins has been shown to result in resolution of the infection. In some cases, patients non-responsive to medical management are treated by surgical colectomy which has a mortality rate of 35 % to 57 %. One of the risks with Fecal Microbiota Transplantation is the transfer of contagious agents (e.g., fungi, parasites, and viruses) from the donor (You et al, 2008; Bakken et al, 2009).

Clostridioides (formerly *Clostridium*) difficile is colonized in the gut of about 3% of normal adults, 40% of hospitalized patients, which in healthy persons is metabolically inactive in the spore form. One third of these will develop C. difficile colitis when exposed to antibiotics. Immunosuppressed patients are at greatest risk of developing CDI.
Brandt and Reddy (2011) stated that with the increasing prevalence of recurrent/refractory CDI and emergence of highly virulent strains of C. difficile alternative treatments to the standard

antibiotic therapies are being sought. One of the more controversial of such alternative treatments is fecal microbiota transplantation (FMT). Although the notion of FMT is foreign -- even startling -- and not esthetic to most people, the concept has been around for many decades. Its benefit and effectiveness dated back more than 50 years to its use for staphylococcal pseudomembranous colitis, and now FMT is showing a great promise as an inexpensive, safe, and highly efficient treatment for recurrent and refractory CDI. Moreover, with a better understanding of the intricacies of the colonic microbiome and its role in colonic pathophysiology, FMT has the potential to become the standard of care for CDI treatment, and a potential answer to other intestinal disorders in years to come.

Resolution of CDI with FMT occurs in over 90% of patients. The donor should be screened for Hepatitis A, B, C, HIV 1 and HIV 2, Syphilis, *Clostridioides* difficile toxin, Ova and Parasites, Enteric pathogens, Salmonella, Shigella, E. coli H0157, Yersinia enterocolitica, and Campylobacter, *Clostridioides* difficile toxins A and B, Some practitioners additionally screen for Cryptosporidium antigen and Giardia antigen Donor serum screening. The FDA issued a recommendation that for stool donated after December 1, 2019, stool may be tested for SARS-CoV-2. The donor should be free of tattoos or body piercings done in the last 6 months, current communicable disease or recent exposure to communicable disease, HIV-1 and HIV-2, and Hepatitis A, B, and C Some practitioners additionally screen for: rapid plasma reagin and fluorescent treponemal antibodyabsorbed Treponema pallidum, immunosuppressive drugs or antibiotics in the last 6 months travel to an area with known infection risk factors in the last 6 months. Analysis beyond this baseline should be determined by the physician's interview and risk assessment, in parallel with an evaluation of the donor/recipient relationship, and any clinical factors supporting/opposing an abbreviated screening. The transplant may be delivered by NG, Nasogastric, Nasojejunal tube, oral capsule, serial retention enemas, flexible sigmoidoscopy or colonoscopy. The provider must obtain informed consent from the member as required by the U.S. Food and Drug Administration's division of Vaccines, Blood and Biologics bulletin 07/18/2013.

Policy/Criteria

I. It is the policy of MeridianHealth affiliated with Centene Corporation® that fecal microbiota transplant is **medically necessary** for the following indications:
   A. Meridian considers Fecal Microbiota Transplantation (FMT)/Fecal Bacteriotherapy medically necessary for persons with *Clostridioides* (formerly *Clostridium*) *Difficile* infection (CDI), with infection confirmed by a positive stool test for *C. Difficile* toxin for any of the following:
      i. Recurrent or relapsing C. difficile infection (CDI) defined as one of the following:
      ii. At least 3 episodes of mild to moderate CDI and failure of standard 10 day course of antibiotic therapy (i.e. metronidazole or vancomycin)
      iii. Severe or fulminant C difficile colitis with no response to standard therapy after 48 hours.

   Testing for donor selection is a covered benefit if the FMT recipient is a Meridian Health member

II. **Absolute Contraindications -** FMT for all indications not defined above are considered experimental and investigational and are not covered such as (not an all-inclusive list):
   A. Previous hemicolectomy
   B. Idiopathic thrombocytopenic purpura
   C. Insulin resistance

D. Metabolic syndrome
E. Multiple sclerosis
F. Inflammatory bowel disease-Crohn's Disease, Ulcerative Colitis
G. Diarrhea with etiology other than *Clostridioides* difficile
H. Irritable Bowel Disease
I. No documentation of failure of multiple trials of standard therapies

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT®* Codes	Description

HCPCS ®* Codes	Description

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

+ Indicates a code(s) requiring an additional character

ICD-10-CM Code	Description

Reviews, Revisions, and Approvals	Date	Approval Date
Original approval date		12/16/11

References

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Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clin Infect Dis 2018; 66:e1.
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17. Fecal Microbiota for Transplantation: Safety Alert-Regarding Additional Safety Protections Pertaining to SARS-CoV-2 and COVID-19. FDA.gov. 03/23/2020
18. State of Illinois Contract between the Department of Healthcare and Family Services and Meridian Health Plan of Illinois, 2018-24-601, Preauthorization and Concurrent Review Requirements, 1.1.2.3.3

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended

to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.