



## Clinical Policy: Fecal Bacteriotherapy

Reference Number: HNCA.CP.MP.519

Effective Date: 11/16

Last Review Date: 11/19

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Fecal bacteriotherapy is also known as fecal biotherapy, fecal microbiota transplantation (FMT), stool or fecal transplant, fecal transfusion, fecal enema or human probiotic infusion. This procedure refers to the process of transplantation of fecal bacteria from a healthy individual into a recipient as a treatment for those suffering from clostridium difficile infection (CDI), which produces effects ranging from diarrhea to pseudomembranous colitis.

### Policy/Criteria

- I. It is the policy of Health Net of California that fecal bacteriotherapy may be considered medically necessary as a treatment for recurrent or relapsing CDI when the following criteria are met:
  - a. Infection confirmed by a positive stool test for Clostridium difficile toxin,
  - b. There have been at least 3 episodes of recurrent Clostridium difficile infection and associated diarrhea refractory to appropriate antibiotic therapy,
  - c. Patient is not immunocompromised.
  
- II. It is the policy of Health Net of California that fecal bacteriotherapy is investigational for any other indication as there is a paucity of peer-reviewed literature and lack of long-term outcomes regarding safety and efficacy.

### Background

CDI is one of the leading causes of nosocomial gastroenteritis in the United States, particularly among hospitalized patients  $\geq 65$  years of age. Given the challenges in managing recurrent CDI, including increased risk of severe complications, nonpharmacological approaches, including FMT, have been used.

FMT involves infusions of instillation of saline-diluted fecal matter from the specified donor, via a nasoduodenal tube, retention enema, or colonoscope, into the colon of a patient with recurrent CDI and associated diarrhea. Donors must be tested for a wide array of bacterial and parasitic infections. The fecal transplant material is then prepared and administered in a clinical environment to ensure that precautions are taken. Transplantation of fresh donated feces is recommended to take place within 24 hours.

Various moderate quality studies were done, including randomized controlled trials, systematic reviews, case studies and retrospective observational studies. They noted that FMT cures a large proportion of patients with refractory or recurrent CDI who had failed  $\geq 1$  course of standard antibiotic treatment. Adverse reactions were generally rare.



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#### *National Institute for Health and Care Excellence*

Current evidence on FMT for recurrent CDI that has failed to respond to antibiotics and other treatments shows that it is efficacious in reducing symptoms. Therefore the procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.

#### *American College of Gastroenterology*

If there is a third recurrence after a pulsed vancomycin regimen, FMT should be considered. (Conditional recommendation, moderate-quality evidence)

#### *European Society of Clinical Microbiology and Infectious Diseases*

For multiple recurrent CDI unresponsive to repeated antibiotic treatment, FMT is strongly recommended in combination with oral antibiotic treatment.

#### *UpToDate*

Recurrent and severe CDI despite antibiotic therapy is increasingly common. Restoration of the normal fecal microbiota may be important for resolving infection refractory to oral metronidazole or vancomycin. FMT offers a means to durably restore the normal microbiota. It is recommended that FMT be done at a center of expertise in patients with recurrent CDI who have failed multiple courses of antibiotic therapy (Grade 1B).

#### *Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) (2018)*

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

In a June 2019 Safety Communication, the Food and Drug Administration (FDA) informed health care providers and patients of the potential risk of serious or life-threatening infections with the use of fecal microbiota for transplantation (FMT). The agency was made aware of bacterial infections caused by multi-drug resistant organisms (MDROs) that have occurred due to transmission of a MDRO from use of investigational FMT. Two immunocompromised adults who received investigational FMT developed invasive infections caused by extended-spectrum beta-lactamase (ESBL)-producing *Escherichia coli* (*E.coli*). One of the individuals died. The FDA recommends donor screening, testing of donor stool and exclusion for stool that test positive for MDRO.

### Coding Implications

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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
44705	Preparation of fecal microbiota for instillation, including assessment of donor specimen

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

ICD-10-CM Code	Description
A04.7	Enterocolitis due to Clostridium difficile

Reviews, Revisions, and Approvals	Date	Approval Date
Policy Adopted from Health Net NMP#519, Fecal Bacteriotherapy	11/16	
Policy update – no changes	11/17	11/17
Criteria revised based on 2017 guidelines from the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America	11/18	11/18
Added FDA safety recommendations to background section	11/19	11/19

### References

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2. American College of Gastroenterology Guidelines for Diagnosis, Treatment, and Prevention of Clostridium difficile Infections. (2013) Available at: <http://gi.org/guideline/diagnosis-and-management-of-c-difficile-associated-diarrhea-and-colitis/>
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4. Borody TJ, Leis S, Pang G, et al. Fecal microbiota transplantation in the treatment of recurrent Clostridium difficile infection. UpToDate. January 31, 2013.
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11. McDonald, LC, Gerding DN et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) Clinical Infectious Diseases, Volume 66, Issue 7, 19 March 2018, Pages e1–e48, <https://doi.org/10.1093/cid/cix1085>
12. Fecal Microbiota for Transplantation: Safety Communication- Risk of Serious Adverse Reactions Due to Transmission of Multi-Drug Resistant Organisms. Available at: <https://www.fda.gov/safety/medical-product-safety-information/fecal-microbiota-transplantation-safety-communication-risk-serious-adverse-reactions-due>

### **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.

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**Note: For Medicare members,** 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.

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