

02-40000-24

Original Effective Date: 09/15/14

Reviewed: 12/08/23

Revised: 01/01/24

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.

[Position Statement](#)

[Billing/Coding](#)

[Reimbursement](#)

[Program Exceptions](#)

[Definitions](#)

[Related Guidelines](#)

[Other](#)

[References](#)

[Updates](#)

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.

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.

REFERENCES:

1. American College of Gastroenterology (ACG). Guidelines for diagnosis, treatment, and prevention of *Clostridium difficile* infections. February 2013). Accessed at <http://gi.org> on 07/22/14.
2. Aroniadis OC, Brandt LJ. Intestinal microbiota and the efficacy of fecal microbiota transplantation in gastrointestinal disease. *Gastroenterol Hepatol (N Y)*. 2014 Apr;10(4):230-7.
3. Blue Cross Blue Shield Association Evidence Positioning System®. 2.01.92 - Fecal Microbiota Transplantation, 12/21.
4. Bouri S, Hart A. Fecal microbial transplantation: an update. *Curr Opin Clin Nutr Metab Care*. 2018 Sep;21(5):405-410. doi: 10.1097/MCO.0000000000000488. PMID: 29939968.
5. Cammarota G, et al. European consensus conference on faecal microbiota transplantation in clinical practice. *Gut*. 2017 Apr;66(4):569-580.
6. Choi HH, Cho YS. Fecal Microbiota Transplantation: Current Applications, Effectiveness, and Future Perspectives. *Clin Endosc*. 2016 May;49(3):257-65.
7. ClinicalTrials.gov. NCT01972334, Stool Transplant in Pediatric Patients With Recurring *C Difficile* Infection. Last updated March 2014.
8. ClinicalTrials.gov. NCT01226992, Oral Vancomycin Followed by Fecal Transplant Versus Tapering Oral Vancomycin. Last updated January 2013.

9. ClinicalTrials.gov. NCT01545908, Fecal Biotherapy for the Induction of Remission in Active Ulcerative Colitis. Last updated April 2014.
10. ClinicalTrials.gov. NCT01793831, Standardized Fecal Microbiota Transplantation for Crohn Diseases. Last updated December 2013.
11. ClinicalTrials.gov. NCT01398969, Multi-Centre Trial of Fresh vs. Frozen-and-Thawed HB T(Fecal Transplant)for Recurrent CDI. Last updated February 2014.
12. Cohen NA, Maharshak N. Novel Indications for Fecal Microbial Transplantation: Update and Review of the Literature. *Dig Dis Sci.* 2017 May;62(5):1131-1145. doi: 10.1007/s10620-017-4535-9. Epub 2017 Mar 17. PMID: 28315032.
13. ECRI Institute Emerging Technology Report: Fecal Microbiota Transplantation for Treating Recurrent *Clostridium difficile* Infection (06/20/13).
14. ECRI Institute Health Technology Forecast: Fecal microbiota transplantation concept developed into synthetic stool alternative for *C. difficile* infection (01/18/13).
15. ECRI Institute Health Technology Forecast: Study suggests fecal transplant is more effective than vancomycin for recurrent *Clostridium difficile* infection (01/25/13).
16. Fairhurst NG, Travis SPL. Why is it so difficult to evaluate faecal microbiota transplantation as a treatment for ulcerative colitis? *Intest Res.* 2018 Apr;16(2):209-215.
17. First Coast Service Options, Inc. (FCSO). Florida Medicare Part B Local Coverage Determination L29288, Noncovered Services (02/02/09). Retired 09/30/15.
18. First Coast Service Options, Inc. (FCSO). Florida Medicare Part B Local Coverage Determination L33777, Noncovered Services. (10/01/15) Retired 07/01/20.
19. Florida State Statutes 765.523 – Discrimination in access to anatomical gifts and organ transplants prohibited; Florida Statute 627.64197 – Coverage for organ transplants; 627.65736 – Coverage for organ transplants; and 641.31075 – Coverage for organ transplants. Accessed at <http://www.flsenate.gov/>.
20. Gallo A, Passaro G, Gasbarrini A, Landolfi R, Montalto M. Modulation of microbiota as treatment for intestinal inflammatory disorders: An update. *World J Gastroenterol.* 2016 Aug 28;22(32):7186-202.
21. Gough E, Shaikh H, Manges AR. Systematic review of intestinal microbiota transplantation (fecal bacteriotherapy) for recurrent *Clostridium difficile* infection. *Clin Infect Dis* 2011; 53(10):994-1002.
22. Guo B, Harstall C, Louie T et al. Systematic review: faecal transplantation for the treatment of *Clostridium difficile*-associated disease. *Aliment Pharmacol Ther* 2012; 35(8):865-75.
23. Heath RD, et al. Fecal microbiota transplantation and its potential therapeutic uses in gastrointestinal disorders. *North Clin Istanb.* 2018 Feb 12;5(1):79-88.
24. Kao D, et al. Effect of Oral Capsule- vs Colonoscopy-Delivered Fecal Microbiota Transplantation on Recurrent *Clostridium difficile* Infection: A Randomized Clinical Trial. *JAMA.* 2017 Nov 28;318(20):1985-1993.
25. Kelly CR, Yen EF, Grinspan AM, et al. Fecal Microbiota Transplantation Is Highly Effective in Real-World Practice: Initial Results From the FMT National Registry. *Gastroenterology.* 2021 Jan;160(1):183-192.e3. doi: 10.1053/j.gastro.2020.09.038. Epub 2020 Oct 1.
26. Mattila E, Uusitalo-Seppala R, Wuorela M, et al. Fecal transplantation, through colonoscopy, is effective therapy for recurrent *Clostridium difficile* infection. *Gastroenterology* 2012;142:490-496.
27. McCarville JL, Caminero A, Verdu EF. Novel perspectives on therapeutic modulation of the gut microbiota. *Therap Adv Gastroenterol.* 2016 Jul;9(4):580-93.
28. National Institute for Health and Care Excellence. Interventional Procedure Guidance (IPG) 485: Faecal microbiota transplant for recurrent *Clostridium difficile* infection. March 2014. Accessed at <https://www.nice.org.uk/>.

29. National Institute for Health and Care Excellence. Research Recommendation IPG485/1. June 2015. Accessed at <https://www.nice.org.uk/>.
30. Nicholson MR, Mitchell PD, et al. Efficacy of Fecal Microbiota Transplantation for Clostridium difficile Infection in Children. *Clin Gastroenterol Hepatol*. 2020 Mar;18(3):612-619.e1. doi: 10.1016/j.cgh.2019.04.037. Epub 2019 Apr 19.
31. Petrof EO, Gloor GB, Vanner SJ et al. Stool substitute transplant therapy for the eradication of Clostridium difficile infection: 'RePOOPulating' the gut. *Microbiome* 2013; 1(1):3.
32. Postigo R, Kim JH. Colonoscopic versus nasogastric fecal transplantation for the treatment of Clostridium difficile infection: a review of pooled analysis. *Infection*. 2012;40:643-648.
33. Ray A, Smith R, Breaux J. Fecal Microbiota Transplantation for Clostridium difficile Infection: The Ochsner Experience. *Ochsner J*. 2014 Winter;14(4):538-44.
34. Rossen NG, MacDonald JK, de Vries EM, D'Haens GR, de Vos WM, Zoetendal EG, Ponsioen CY. Fecal microbiota transplantation as novel therapy in gastroenterology: A systematic review. *World J Gastroenterol*. 2015 May 7;21(17):5359-71.
35. Schenck LP, Beck PL, MacDonald JA. Gastrointestinal dysbiosis and the use of fecal microbial transplantation in Clostridium difficile infection. *World J Gastrointest Pathophysiol*. 2015 Nov 15;6(4):169-80.
36. Shen ZH, et al. Relationship between intestinal microbiota and ulcerative colitis: Mechanisms and clinical application of probiotics and fecal microbiota transplantation. *World J Gastroenterol*. 2018 Jan 7;24(1):5-14.
37. Shi Y, Dong Y, Huang W, Zhu D, Mao H, Su P. Fecal Microbiota Transplantation for Ulcerative Colitis: A Systematic Review and Meta-Analysis. *PLoS One*. 2016 Jun 13;11(6):e0157259.
38. Sung H, Kim SW, Hong M, Suk KT. Microbiota-based treatments in alcoholic liver disease. *World J Gastroenterol*. 2016 Aug 7;22(29):6673-82.
39. United States Food and Drug Administration (FDA). Guidance for Industry: Enforcement policy regarding investigational new drug requirements for use of fecal microbiota for transplantation to treat Clostridium difficile infection not responsive to standard therapies. (July 2013). Accessed at <http://www.fda.gov> on 07/22/14.
40. UpToDate. Fecal microbiota transplantation for treatment of Clostridioides difficile infection. 2021. Accessed at uptodate.com.
41. Van Nord E, Vrieze A, Nieuwdorp M, et al. Duodenal infusion of donor feces for recurrent Clostridium difficile. *N Engl J Med* 2013;368:407-415.
42. Verbeke F, et al. Faecal microbiota transplantation: a regulatory hurdle? *BMC Gastroenterol*. 2017 Nov 28;17(1):128.
43. Vindigni SM, Surawicz CM. Fecal Microbiota Transplantation. *Gastroenterol Clin North Am*. 2017 Mar;46(1):171-185. doi: 10.1016/j.gtc.2016.09.012. PMID: 28164849.
44. Wang AY, Popov J, Pai N. Fecal microbial transplant for the treatment of pediatric inflammatory bowel disease. *World J Gastroenterol*. 2016 Dec 21;22(47):10304-10315.
45. Wang Y, Zheng F, Liu S, Luo H. Research Progress in Fecal Microbiota Transplantation as Treatment for Irritable Bowel Syndrome. *Gastroenterol Res Pract*. 2019 Dec 1;2019:9759138. doi: 10.1155/2019/9759138.
46. Wang ZK, Yang YS, Chen Y, Yuan J, Sun G, Peng LH. Intestinal microbiota pathogenesis and fecal microbiota transplantation for inflammatory bowel disease. *World J Gastroenterol*. 2014 Oct 28;20(40):14805-20.

47. Wei Y, Gong J, Zhu W, Guo D, Gu L, Li N, Li J. Fecal microbiota transplantation restores dysbiosis in patients with methicillin resistant Staphylococcus aureus enterocolitis. BMC Infect Dis. 2015 Jul 11;15:265.
48. Wei Y, Zhu W, Gong J, Guo D, Gu L, Li N, Li J. Fecal Microbiota Transplantation Improves the Quality of Life in Patients with Inflammatory Bowel Disease. Gastroenterol Res Pract. 2015;2015:517597.
49. Zanella Terrier MC, Simonet ML, Bichard P, Frossard JL. Recurrent Clostridium difficile infections: The importance of the intestinal microbiota. World J Gastroenterol. 2014 Jun 21;20(23):7416-7423.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 12/08/23.

GUIDELINE UPDATE INFORMATION:

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.