

## Fecal Microbiota Transplantation

<b>Policy ID:</b>	HHO-DE-MP-1146
<b>Approved By:</b>	Highmark Health Options – Market Leadership
<b>Provider Notice Date:</b>	12/15/2021; 03/01/2023
<b>Original Effective Date:</b>	01/15/2022; 04/01/2023
<b>Annual Approval Date:</b>	10/27/2021; 08/24/2022
<b>Last Revision Date:</b>	10/27/2021; 08/24/2022
<b>Products:</b>	Medicaid
<b>Application:</b>	All hospitals and providers
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### Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

### POLICY STATEMENT

Highmark Health Options may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary benefits.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

### DEFINITIONS

**Highmark Health Options (HHO)** – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

**Fecal Microbiota Transplantation (FMT)** – Infusion of intestinal microorganisms via transfer of stool from a healthy person into a diseased individual, with the intent of restoring normal intestinal flora. Fecal transplant is proposed for the treatment of treatment-refractory Clostridium difficile infection (CDI).

### POLICY POSITION

Prior authorization is required.

Fecal microbiota transplantation (FMT) may be considered medically necessary for treatment of individuals with recurrent CDI when BOTH of the following are met:

- There have been at least three (3) episodes of recurrent infection; and
- Episodes are refractory to appropriate antibiotic regimens, including at least one (1) regimen of pulsed vancomycin.

All other uses for FMT are considered experimental/investigational and, therefore, not covered because their safety and/or effectiveness cannot be established by review of the available published peer-reviewed literature.

### ELIGIBLE PROCEDURE CODES

CPT Codes	Description
44705	Preparation of fecal microbiota for instillation including assessment of donor specimen.

### ELIGIBLE DIAGNOSIS CODES FOR PROCEDURE CODE 44705

Codes				
A04.71	A04.72			

### References

Bafeta A, Yavchitz A, Riveros C, Batista R, Ravaud P. Methods, and reporting studies assessing fecal microbiota transplantation: A systematic review. *Ann Intern Med.* 2017;167(1):34-39.

Kao D, Roach B, Silva M, et al. Effect of oral capsule vs colonoscopy-delivered fecal microbiota transplantation on recurrent clostridium difficile infection: A randomized clinical trial. *JAMA.* 2017;318(20):1985-1993.

Panchal P, Budree S, Scheeler A, et al. Scaling safe access to fecal microbiota transplantation: Past, present, and future. *Curr Gastroenterol Rep.* 2018;20(4):14.

Costello SP, Hughes PA, Waters O, et al. Effect of fecal microbiota transplantation on 8-week remission in patients with ulcerative colitis: A randomized clinical trial. *JAMA.* 2019;321(2):156- 164.

FDA. Important Safety Alert Regarding Use of Fecal Microbiota for Transplantation and Risk of Serious Adverse Reactions Due to Transmission of Multi-Drug Resistant Organisms 2019.

McDonald LC, Gerding DN, Johnson S 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). *Clin Infect Dis.* 2018;66(7).

Hayes, Inc. Emerging Technology Report. SER-109 for Fecal Microbiota Transplantation. Lansdale, PA: Hayes, Inc.; 07/10/2020.

Hayes, Inc. Emerging Technology Report. RBX2660 for Fecal Microbiota Transplantation. Lansdale, PA: Hayes, Inc.; 06/22/2021.

Quraishi MN, Widlak M, Bhala NA, et al. Systematic review with meta-analysis: The efficacy of fecal microbiota transplantation for the treatment of recurrent and refractory Clostridium difficile infection. *Aliment Pharmacol Ther.* 2017;46(5):479-93.

Jiang ZD, Jenq RR, Ajami NJ, et al. Safety and preliminary efficacy of orally administered lyophilized fecal microbiota product compared with frozen product given by enema for recurrent *Clostridium difficile* infection: A randomized clinical trial. *PLoS One*. 2018;13(11): e0205064.

Staley C, Hamilton MJ, Vaughn BP, et al. Successful resolution of recurrent *Clostridium difficile* infection using freeze-dried, encapsulated fecal microbiota; pragmatic cohort study. *Am J Gastroenterol*. 2017;112(6):940.

Food and Drug Administration (FDA). Fecal microbiota for transplantation: new safety information – Regarding additional protections for screening donors for COVID-19 and exposure to SARSCoV-2 and testing for SARS-CoV-2. 2020.

Tariq R, Pardi DS, Bartlett MG, Khanna S. Low cure rates in controlled trials of fecal microbiota transplantation for recurrent *Clostridium difficile* infection: A systematic review and meta-analysis. *Clin Infect Dis*. 2019;68(8):1351-1358.

Rokkas T, Gisbert JP, Gasbarrini A, Hold GL, Tilg H, Malfertheiner P, et al. A network metaanalysis of randomized controlled trials exploring the role of fecal microbiota transplantation in recurrent *Clostridium difficile* infection. *United European Gastroenterol J*. 2019;7(8):1051-1063.

Khan MY, Dirweesh A, Khurshid T, Siddiqui WJ. Comparing fecal microbiota transplantation to standard-of-care treatment for recurrent *Clostridium difficile* infection: A systematic review and meta-analysis. *Eur J Gastroenterol Hepatol*. 2018;30(11):1309-1317.

Mamo Y, Woodworth MH, Wang T, Dhere T, Kraft CS. Durability, and long-term clinical outcomes of fecal microbiota transplant treatment in patients with recurrent *Clostridium difficile* Infection. *Clin Infect Dis*. 2018;66(11):1705-1711.

**POLICY UPDATE HISTORY**

10/08/2021	Approved in medical policy committee
08/24/2022	Annual review; approved in medical policy committee
09/13/2022	Approved in QI-UM
10/10/2022	Approved in Governance