

**Policy: MP290**

**Section: Medical Benefit Policy**

**Subject: Fecal Microbiota Transplantation**

### Applicable Lines of Business

<b>Commercial</b>	<b>X</b>	<b>CHIP</b>	<b>X</b>
<b>Medicare</b>	<b>X</b>	<b>ACA</b>	<b>X</b>
<b>Medicaid</b>	<b>X</b>		

### I. Policy: Fecal Microbiota Transplantation

#### II. Purpose/Objective:

To provide a policy of coverage regarding Fecal Microbiota Transplantation

#### III. Responsibility:

- A. Medical Directors
- B. Medical Management

#### IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

#### V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

#### Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

**DESCRIPTION:**

Fecal microbiota transplantation is the transplantation of fecal bacteria from a healthy donor into the gastrointestinal tract of a recipient for the treatment of recurrent Clostridium difficile (C. difficile) infection.

**INDICATIONS:**

Fecal microbiota transplantation is considered medically necessary in members with at least three episodes of Clostridium difficile infection and associated diarrhea that is refractory to antibiotic therapy

**EXCLUSIONS:**

Fecal microbiota transplantation is considered experimental, investigational, or unproven for any of the following indications including, but not limited to:

- Autoimmune disorders (e.g., multiple sclerosis)
- Crohn’s disease
- Irritable bowel syndrome (IBS)
- Metabolic syndrome
- Neurological disorders (e.g., Parkinson’s disease)
- Ulcerative colitis
- Pouchitis

**Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.**

**Medicaid Business Segment:**

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis..

**CODING ASSOCIATED WITH:** Fecal Microbiota Transplantation

*The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at [www.cms.gov](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.*

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

44799 Unlisted procedure, intestine

G0455 preparation with installation of fecal microbiota by any method, including assessment of donor specimen

0708T Instillation of fecal microbiota suspension via rectal enema into lower gastrointestinal tract

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

**LINE OF BUSINESS:**

**Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supercede this policy. For PA Medicaid Business segment, this policy applies as written.**

**REFERENCES:**

American Gastroenterological Association (AGA) Website. Fecal microbiota transplant is a promising treatment. June 13, 2013. <http://www.gastro.org>.

ECRI Institute. Emerging Technology Evidence Report. Fecal microbiota transplantation for treating recurrent Clostridium difficile infection. June 30, 2015.

UpToDate® Website. Fecal microbiota transplantation in the treatment of recurrent Clostridium difficile infection. Jan 22, 2016.

Brandt LJ. Fecal transplantation for the treatment of Clostridium difficile infection. Gastroenterol Hepatol. 2012; 8(3):191-194

van Nood E, Vrieze A, Nieuwdorp M, et al. Duodenal infusion of donor feces for recurrent Clostridium difficile. N Engl J Med. 2013 Jan 16

Kelly CP. Fecal microbiota transplantation - An old therapy comes of age. N Engl J Med. 2013 Jan 16

Drekonja D, Reich J, Gezahegn S, et al. Fecal Microbiota Transplantation for Clostridium difficile Infection: A Systematic Review. Ann Intern Med. 2015;162(9):630-638.

Malani PN, Rao K. Expanded evidence for frozen fecal microbiota transplantation for clostridium difficile infection: A fresh take. JAMA. 2016;315(2):137-138.

Lee CH, Steiner T, Petrof EO, et al. Frozen vs fresh fecal microbiota transplantation and clinical resolution of diarrhea in patients with recurrent clostridium difficile infection: A randomized clinical trial. JAMA. 2016;315(2):142-149.

Almeida R, Gerbaba T, Petrof EO, et al. Recurrent Clostridium difficile infection and the microbiome. J Gastroenterol. 2016;51(1):1-10

Quraishi MN, Widlak M, Bhala N, et al. Systematic review with meta-analysis: The efficacy of faecal microbiota transplantation for the treatment of recurrent and refractory Clostridium difficile infection. Aliment Pharmacol Ther. 2017;46(5):479-493

Malani PN, Rao K. Expanded evidence for frozen fecal microbiota transplantation for clostridium difficile infection: A fresh take. JAMA. 2016;315(2):137-138.

Lee CH, Steiner T, Petrof EO, et al. Frozen vs fresh fecal microbiota transplantation and clinical resolution of diarrhea in patients with recurrent clostridium difficile infection: A randomized clinical trial. JAMA. 2016;315(2):142-149

Cohen NA, Maharshak N. Novel indications for fecal microbial transplantation: Update and review of the literature. Dig Dis Sci. 2017;62(5):1131-1145.

Cohen NA, Livovsky DM, Yaakovovitch S, et al. A retrospective comparison of fecal microbial transplantation methods for recurrent clostridium difficile infection. Isr Med Assoc J. 2016;18(10):594-599.

Tang G, Yin W, Liu W. Is frozen fecal microbiota transplantation as effective as fresh fecal microbiota transplantation in patients with recurrent or refractory Clostridium difficile infection: A meta-analysis? Diagn Microbiol Infect Dis. 2017;88(4):322-329.

McDonald LC, Gerding DN, Johnson J, Bakken JS 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, 2018;66(7):e1-e48.

ECRI Institute, Fecal Microbiota Transplantation for Treating Irritable Bowel Syndrome (Health Technology Assessment Information: Hotline Response) Aug. 2018.

Aldrich AM, Argo T, Koehler TJ, et al. Analysis of treatment outcomes for recurrent Clostridium difficile infections and fecal microbiota transplantation in a pediatric hospital. Pediatr Infect Dis J. 2019;38(1):32-36

Xu D, Chen VL, Steiner CA, et al. Efficacy of fecal microbiota transplantation in irritable bowel syndrome: A systematic review and meta-analysis. Am J Gastroenterol. 2019;114(7):1043-1050.

Ianiro G, Eusebi LH, Black CJ, et al. Systematic review with meta-analysis: efficacy of faecal microbiota transplantation for the treatment of irritable bowel syndrome. Aliment Pharmacol Ther. 2019;50(3):240-248.

Trang-Poisson C, Kerdreux E, Poinas A, et al. Impact of fecal microbiota transplantation on chronic recurrent pouchitis in ulcerative colitis with ileo-anal anastomosis: Study protocol for a prospective, multicenter, double-blind, randomized, controlled trial. Trials. 2020;21(1):4

Selvig D, Piceno Y, Terdiman J, et al. Fecal microbiota transplantation in pouchitis: Clinical, endoscopic, histologic, and microbiota results from a pilot study. Dig Dis Sci. 2020;65(4):1099-1106.

Liu X, Li Y, Wu K, et al. Fecal microbiota transplantation as therapy for treatment of active ulcerative colitis: A systematic review and meta-analysis. *Gastroenterol Res Pract.*;2021:6612970

Pomares Bascunana RA, Veses V, Sheth CC. Effectiveness of fecal microbiota transplant for the treatment of *Clostridioides difficile* diarrhea: A systematic review and meta-analysis. *Lett Appl Microbiol.* 2021;73(2):149-158.

Ramai D, Zakhia K, Fields PJ, et al. Fecal microbiota transplantation (FMT) with colonoscopy is superior to enema and nasogastric tube while comparable to capsule for the treatment of recurrent *clostridioides difficile* infection: A systematic review and meta-analysis. *Dig Dis Sci.* 2021;66(2):369-380

Wu J, Lv L, Wang C. Efficacy of fecal microbiota transplantation in irritable bowel syndrome: A meta-analysis of randomized controlled trials. *Front Cell Infect Microbiol.* 2022;12:827395.

Huang T, Xu J, Wang M, et al. An updated systematic review and meta-analysis of fecal microbiota transplantation for the treatment of ulcerative colitis. *Medicine* 2022;101(30):e29790.

Bilsen MP, Lambregts MMC, van Prehn J, Kuijper EJ. Faecal microbiota replacement to eradicate antimicrobial resistant bacteria in the intestinal tract -- a systematic review. *Curr Opin Gastroenterol.* 2022;38(1):15-25.

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 5/14

**Revised:** 4/21 (add pouchitis exclusion)

**Reviewed:** 5/15, 5/16, 4/17, 4/18, 4/19, 4/20, 4/22, 4/23, 4/24

**CMS UM Oversight Committee Approval:** 12/23, 7/24

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

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