



## Fecal Microbiota Transplant

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<b>State(s):</b> <input checked="" type="checkbox"/> Idaho <input checked="" type="checkbox"/> Montana <input checked="" type="checkbox"/> Oregon <input checked="" type="checkbox"/> Washington <input type="checkbox"/> Other:	<b>LOB(s):</b> <input checked="" type="checkbox"/> Commercial <input checked="" type="checkbox"/> Medicare <input checked="" type="checkbox"/> Medicaid
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### Enterprise Policy

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Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determination are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

### Background

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Fecal microbiota transplantation (FMT) also known as stool transplant or fecal bacteriotherapy, involves the transfer of fecal material from a healthy donor to the intestinal tract of a recipient with the intent of restoring normal intestinal flora and function.

*Clostridium difficile* infection (CDI) is a serious and common bowel condition associated with hospital acquired infections and antibiotic use. Recurrent CDI can lead to potentially prolonged severe complications, including chronic diarrhea and colitis. FMT may be a treatment option for recurrent CDI that has not responded to antibiotic treatment (oral vancomycin is the usual first line therapy).

### Criteria

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#### Commercial

#### **Preauthorization is required.**

Fecal microbiota transplantation may be considered medically necessary for treatment of patients with recurrent *Clostridium difficile* (C. diff) infection when ALL of the following are met:

- Diagnostic testing has confirmed presence of *Clostridium difficile*; and
- The patient is age 18 years or older; and
- There has been at least one previous episode of *Clostridium difficile* infection; and
- Symptoms have persisted despite completion of at least two courses of antibiotics, one of which was vancomycin (unless patient is allergic to or has a contraindication to vancomycin); and

- Treatment will be administered by upper or lower gastrointestinal infusion (i.e. colonoscopy, endoscopy, nasogastric tube, retention enema); and
- The stool donor must be known to either the patient who is to receive the FMT or the treating physician. (use of a stool bank is not covered)
- FMT donor stool testing must include multi drug resistant organisms (MDRO) testing to exclude use of stool that tests positive for MDRO.

PacificSource considers fecal microbiota transplants experimental, investigational or unproven for all other indications not listed above.

### Medicaid

PacificSource Medicaid does not follow this policy but follows Guideline Note 165 of the OHP Prioritized List of Health Services.

### Medicare

Medicare does not require preauthorization for Fecal Microbiota Transplant. PacificSource Medicare follows CMS guidelines and criteria. In the absence of internal policy guidelines, CMS criteria, and evidence-based criteria, requests are reviewed on an individual basis for determination of coverage and medical necessity.

### Coding Information

Codes	Description
44705	Preparation of fecal microbiota for instillation, including assessment of donor
45378	Colonoscopy, flexible, proximal to Splenic flexure; Dx W/Wo specimens/colon Decomp (Sep Proc)
G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen
J3590	Unclassified biologics (when billing represents encapsulated stool for transplant)

### References

Gupta S et al. Fecal Microbiota Transplantation: In Perspective. *Therapeutic Advances in Gastroenterology*. 2016, Vol9(2) 229-239. Accessed 6/20/2018, 5/1/2019, 4/24/2020  
<https://www.ncbi.nlm.nih.gov/pubmed/26929784>

Hayes Health Technology Brief. Fecal Microbiota Transplant for Refractory or Recurrent Clostridium Difficile Infection in Adults. Winifred S. Hayes, Inc., August 11, 2016, annual review October 1, 2018

Krishna R et al. Fecal Microbiota Transplantation for the Treatment of *Clostridium difficile* Infection. *J Hosp Med*. 2016 Jan; 11(1): 56–61. Accessed 6/20/2018, 5/1/2019, 4/24/2020

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4908581/>

U.S. Food and Drug Administration (FDA). Enforcement policy regarding investigational new drug requirements for use of fecal microbiota for transplantation to treat Clostridium difficile infection not responsive to standard therapies. March 1, 2016, April 24, 2020

<https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/vaccines/ucm488223.pdf>

Marion DW. Pacing the diaphragm: Patient selection, evaluation, implantation, and complications. UpToDate, April 2, 2020. Post TW (Ed), UpToDate, Waltham, MA.

## Appendix

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**Policy Number:** [Policy Number]

**Effective:** 5/1/2020

**Next review:** 5/1/2021

**Policy type:** Enterprise

**Author(s):** [Authors]

**Depts:** Health Services

**Applicable regulation(s):** N/A

**External entities affected:** N/A