Fecal Microbiota Transplant

LOB(s):	State(s):
☒ *Commercial* ☒ *Medicare*	☒ *Idaho* ☒ *Montana* ☒ *Oregon* ☒ *Washington* ☐ *Other:*
☒ *Medicaid*	☒ *Oregon* ☐ *Washington*

Enterprise Policy

PacificSource is committed to assessing and applying current regulatory standards, widely-used treatment guidelines, and evidenced-based clinical literature when developing clinical criteria for coverage determination. Each policy contains a list of sources (references) that serves as the summary of evidence used in the development and adoption of the criteria. The evidence was considered to ensure the criteria provide clinical benefits that promote patient safety and/or access to appropriate care. Each clinical policy is reviewed, updated as needed, and readopted, at least annually, to reflect changes in regulation, new evidence, and advancements in healthcare.

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 determinations 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

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 prolonged antibiotic use. Recurrent Clostridium difficile infection can lead to potentially prolonged severe complications, including chronic diarrhea and colitis. Fecal Microbiota Transplantation may be a treatment option for recurrent Clostridium difficile infection that has not responded to antibiotic treatment (oral vancomycin is the usual first line therapy).

Criteria

Commercial

Prior authorization is required

PacificSource considers fecal microbiota transplantation to be medically necessary for treatment of members with recurrent Clostridium Difficile infection when **ALL** of the following is met:

1. Positive Clostridium Difficile diagnostic testing
2. The member is age 18 years or older
3. A history of at least one prior Clostridium Difficile infection

4. Symptoms have persisted despite completion of at least two courses of antibiotics, one of which was vancomycin (unless member is allergic to or has a contraindication to vancomycin)
5. Treatment will be administered by upper or lower gastrointestinal infusion (i.e., colonoscopy, endoscopy, nasogastric tube, retention enema)
6. Fecal microbiota transplantation donor stool testing must include multi drug resistant organisms (MDRO) testing to exclude use of stool that tests positive for MDRO

Medicaid

PacificSource Community Solutions (PCS) follows EPSDT coverage requirements in OAR 410-151-0002 for members under the age of 21. Coverage of Fecal Microbiata Transplant is determined through case-by-case reviews for EPSDT Medical Necessity and EPSDT Medical Appropriateness defined in OAR 410-151-0001. Guideline Note 165 may be used to assist in informing a determination of medical necessity and medical appropriateness during the individual case review.

PacificSource Community Solutions follows Guideline Note 165 of the Health Evidence Review Commission (HERC) Prioritized List of Health Services and the general coverage requirements, limitations, and exclusions outlined in OARs 410-141-3820, 410-141-3825, and 410-120-1200 to determine coverage of Fecal Microbiata Transplant in adult members, 21 years and older.

Medicare

PacificSource Medicare follows CMS guidelines and criteria. In the absence of CMS guidelines and criteria, PacificSource Medicare will follow internal policy for determination of coverage and medical necessity.

Experimental/Investigational/Unproven

PacificSource considers Fecal Microbiota Transplant as experimental, investigational, or unproven for the following:

- Oral administration
- First-line therapy for Clostridium difficile infection
- All indications other than recurrent Clostridium Difficile infection (including, but not limited to Crohn's disease, inflammatory bowel diseases, Ulcerative colitis)

Coding Information

The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

0780T	Instillation of fecal microbiota suspension via rectal enema into lower gastrointestinal tract-
44705	Preparation of fecal microbiota for instillation, including assessment of donor
44799	Unlisted Procedure, small intestine
G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen-

References

Cammarota, G., Ianiro, G., & Gasbarrini, A. (2014). Fecal microbiota transplantation for the treatment of Clostridium difficile infection: a systematic review. Journal of clinical gastroenterology, 48(8), 693–702. https://doi.org/10.1097/MCG.0000000000000046

Gupta, S., Allen-Vercoe, E., & Petrof, E. O. (2016). Fecal microbiota transplantation: in perspective. Therapeutic advances in gastroenterology, 9(2), 229–239. https://doi.org/10.1177/1756283X15607414

Hui, W., Li, T., Liu, W., Zhou, C., & Gao, F. (2019). Fecal microbiota transplantation for treatment of recurrent C. difficile infection: An updated randomized controlled trial meta-analysis. PloS one, 14(1), e02 Kao, D., Roach, B., Silva, M., Beck, P., Rioux, K., Kaplan, G. G., Chang, H. J., Coward, S., Goodman, K. J., Xu, H., Madsen, K., Mason, A., Wong, G. K., Jovel, J., Patterson, J., & Louie, T. (2017). Effect of Oral Capsule- vs Colonoscopy-Delivered Fecal Microbiota Transplantation on Recurrent Clostridium difficile Infection: A Randomized Clinical Trial. JAMA, 318(20), 1985–1993. https://doi.org/10.1001/jama.2017.1707710016. https://doi.org/10.1371/journal.pone.0210016

Kao, D., Roach, B., Silva, M., Beck, P., Rioux, K., Kaplan, G. G., Chang, H. J., Coward, S., Goodman, K. J., Xu, H., Madsen, K., Mason, A., Wong, G. K., Jovel, J., Patterson, J., & Louie, T. (2017). Effect of Oral Capsule- vs Colonoscopy-Delivered Fecal Microbiota Transplantation on Recurrent Clostridium difficile Infection: A Randomized Clinical Trial. JAMA, 318(20), 1985–1993. https://doi.org/10.1001/jama.2017.17077

Rao, K., & Safdar, N. (2016). Fecal microbiota transplantation for the treatment of Clostridium difficile infection. Journal of hospital medicine, 11(1), 56–61. https://doi.org/10.1002/jhm.2449

The Health Evidence Review Commission (HERC) Prioritized List of Health Services https://www.oregon.gov/oha/HSD/OHP/Pages/Prioritized-List.aspx

Oregon Administrative Rules (OARs). Oregon Health Authority. Health Systems: Medical Assistance Programs – Chapter 410 https://secure.sos.state.or.us/oard/displayChapterRules.action?selectedChapter=87

Appendix

Policy Number:

Effective: 5/1/2020 **Next review:** 1/1/2026

Policy type: Enterprise

Author(s):

Depts.: Health Services

Applicable regulation(s): OARs 410-141-3820, 410-141-3825, 410-120-1200, 410-151-0001, 410-151-0002

Commercial OPs: 12/2024

Government OPs: 12/2024