Fecal Microbiota Transplant

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

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, 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 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 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 follows the criteria hierarchy described in the Clinical Criteria Used in UM Decisions policy for coverage of Fecal Microbiota Transplantation and considers services medically necessary when:

- The condition and service(s) pair on a funded line of the HERC Prioritized List of Health Services, and
- Any relevant Guideline criteria is met, and
- Service(s) are medically necessary and appropriate for the specific member.
- None of the limitations or exclusions outlined in OARs 410-141-3825 and 410-120-1200 apply.

Additional coverage options for unfunded conditions and services are provided as described in Covered Services OAR 410-141-3820.

PacificSource Community Solutions (PCS) follows the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) coverage requirements in OAR 410-151-0002 through 410-151-0003 for EPSDT beneficiaries. Relevant coverage guidance, including but not limited to Guideline Note 165, may be used to assist in informing a determination of medical necessity and medical appropriateness during the individual case review. A case-by-case review for EPSDT Medical Necessity and EPSDT Medical Appropriateness as defined in OAR 410-151-0001 is required prior to denying. Refer to the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) policy for details.

PCS follows the “Unlisted, Unspecified, and Not Otherwise Specified Procedure Codes” policy for requests for unlisted codes.

Medicare

PacificSource Medicare follows CMS guidelines and criteria. In the absence of CMS guidelines and criteria, PacificSource Medicare will follow commercial criteria within a specific PacificSource policy, as applicable, or external criteria for determination of coverage and medical necessity coverage.

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)

Note: PacificSource Community Solutions (PCS) and PacificSource Medicare require items listed on this policy's E/I/U list, to be reviewed by medical necessity review guidelines. Please see related policy, "Clinical Criteria Used in UM Decisions" to review criteria hierarchy and "Medical Necessity Reviews" for determination of coverage and medical necessity guidelines.

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-

Related Policies

Clinical Criteria Used in UM Decisions

Clinical Resources Used for Medical Necessity Determinations When No Other UM Clinical Criteria or Guideline Exists

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)

Unlisted, Unspecified, and Not Otherwise Specified Procedure Codes

Medically Necessity Reviews

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), e0210016. 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.2017.1707710016. 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

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

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

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

Appendix

Policy Number:

Effective: 5/1/2020 **Next review:** 1/1/2027

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, 410-151-0003.

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