Fecal Microbiota Transplantation
Clinical Coverage Criteria

Overview

Clostridium difficile infection (CDI) causes intestinal inflammation, diarrhea, and cell death. These infections range in severity from mild symptoms to life threating colitis. Recurrent CDI is defined as an episode of CDI that occurs eight weeks or less after the initial episode that resolved with or without therapy. Initial treatment for CDI is oral antibiotics inclusive of metronidazole and vancomycin.

Fecal Microbiota Transplantation (FMT) is a non-pharmalogical approach for those who failed to respond to oral antibiotic therapies after multiple recurrent infections. FMT refers to the transfer of stool from a healthy donor into the patient's gastrointestinal tract. This is done in order to replace damaged microbiota thus recreating normal and functional microbiota which establishes resistance to further infections. Patient selection, proximity to recurrent CDI episode, and antibiotic treatment prior to FMT all likely influence response to FMT.

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial
☒ Medicare Advantage
☒ MassHealth ACO
☒ NaviCare
☒ PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare does not have an NCD for fecal microbiota transplantation. National Government Services, Inc. does not have an LCD or LCA for fecal microbiota transplantation (MCD search 06-23-2021).

For plan members enrolled in NaviCare and PACE plans, Fallon Health follows guidance from CMS for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health will follow guidance published by MassHealth. When there is no Medicare or MassHealth guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Each PACE plan member is assigned to an Interdisciplinary Team. When there is no Medicare or MassHealth guidance, the member's Interdisciplinary Team is responsible for coverage determinations.

Fecal Microbiota Transplantation requires prior authorization. Requests must be accompanied by supporting documentation. All of the following criteria must be met:

1. The member has had 3 or more recurrent episodes of Clostridium difficile infection as confirmed by positive stool tests, AND
2. The episodes are refractory to appropriate antibiotic therapy regimens, including at least one regimen of tapered and pulsed vancomycin.

Exclusions

- Fecal Microbiota Transplantation is considered investigational for all other indications, including but not limited to Crohn's disease and Inflammatory Bowel Disease.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

For commercial and MassHealth ACO plan members, use CPT code 44705 for specimen preparation. Instillation of microbiota is separately reported.

Code 44705 is not valid for Medicare purposes and should not be used to report fecal microbiota transplantation for Medicare, NaviCare and PACE plan members. HCPCS code G0455 includes the work of preparation AND instillation of the microbiota. Medicare does not pay separately for the instillation of the microbiota.

ICD10 A04.71 (Enterocolitis due to Clostridium difficile, recurrent) or A04.72 (Enterocolitis due to Clostridium difficile, not specified as recurrent) are the only diagnosis codes that will be considered for coverage; all other indications for these procedures will be denied as investigational.

Code	Description
44705	Preparation of fecal microbiota for instillation, including assessment of donor specimen
G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen

References

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Policy history

Origination date:	09/01/2017
Approval(s):	Technology Assessment Committee: 05/24/2017 (approved new policy), 05/15/2018 (updated references), 05/22/2019 (updated references); 07/22/2020 (updated coverage criteria to require at least one regimen of tapered and pulsed vancomycin; updated coding and references). *06/25/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section.*

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.