Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Fecal Microbiota Transplantation

Policy Number: PG0222
Last Reviewed Date: 04/01/2025
Last Revised: 04/01/2025

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE:

X Professional
X Facility

DESCRIPTION:

Fecal Microbiota Transplantation (FMT), also known as fecal bacteriotherapy, fecal transplant, fecal transfusion, and probiotic infusion) is the transplantation of fecal bacteria from a healthy donor into the gastrointestinal (GI) tract of an individual recipient for the treatment of recurrent Clostridium difficile (C. difficile) infection (CDI). CDI can result in mild diarrhea to life-threatening fulminant pseudomembraneous colitis. It is unclear what causes C difficile overgrowth, but disruption of the normal colonic flora in conjunction with colonization by C difficile are major components. Disruption of the normal colonic flora occurs most commonly following administration of oral, parenteral, or topical antibiotics. It most often affects older adults and may occur as a result of antibiotic therapy, which disrupts the normal bacterial flora in the GI tract. If the cessation of antibiotic therapy does not restore normal colonic flora, the introduction of healthy bacterial flora via FMT is suggested.

The goal of FMT is to replace damaged and/or disordered native microbiota with a stable community of donor microorganisms. The treatment is based on the premise that an imbalance in the community of microorganisms residing in the gastrointestinal tract (i.e., dysbiosis) is associated with specific disease states, including susceptibility to infection.

FMT is generally performed by a gastroenterologist. The procedure involves the instillation of a solution derived from a healthy donor's fecal matter. The stool can be infused as a liquid suspension into a patient's upper gastrointestinal tract via several different methods: colonoscope, endoscope, nasoduodenal/jejunal tube, nasogastric tube, retention enema, sigmoidoscopy, a combination (upper and lower) approach, or orally via capsules (i.e., encapsulated FMT).

Other potential uses of FMT include treatment of conditions in which altered colonic flora may play a role. These include inflammatory bowel disease, irritable bowel syndrome, idiopathic constipation, and non-gastrointestinal disease such as multiple sclerosis, obesity, autism, and chronic fatigue syndrome. However, for these conditions, the contribution of alterations in colonic flora to the disorder is uncertain or controversial.

In 2022 REBYOTA (fecal microbiota, live-jslm) was approved by the FDA for the prevention of recurrence of CDI in individuals aged 18 years of age and older following antibiotic treatment for recurrent CDI. It is a 150 mL suspension that is meant to be administered rectally 24-72 hours after the last dose of antibiotics for CDI.

In 2023, VOWST (fecal microbiota spores, live-brpk) was approved by the FDA for the prevention of recurrence of CDI in individuals aged 18 years of age and older following antibiotic treatment for recurrent CDI. It is a single dose of four capsules taken orally once daily for three consecutive days.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

- **Fecal Microbiota Transplantation (44705, 0780T, G0455) does not require prior authorization when the coverage criteria indicated below is met.**
- **Rebyota does not require a prior authorization when the coverage criteria indicated below is met.**
- **Vowst is a pharmacy drug and does require PA through the pharmacy department**

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

FMT involves the infusion of intestinal microorganisms via transfer of stool from a healthy individual into a diseased patient, with the intent of restoring normal intestinal flora. The stool can be infused as a liquid suspension into a patient's upper gastrointestinal tract through a nasogastric tube or gastroscopy, or the stool can be infused into the colon through a colonoscope or rectal catheter, or administered orally via capsules (i.e., encapsulated FMT).

FMT (via colonoscopy, rectal delivery, nasoduodenal gastric tube, nasojejunal gastric tube, or frozen capsule) (subject to Limitations and Administrative Guidelines) is covered as a treatment for recurrent or relapsing Clostridium difficile infection (CDI) as indicated by a positive C. difficile toxin stool test and defined as one of the following:

- At least 3 episodes of mild to moderate CDI and failure of a 6-8 week taper with vancomycin with or without an alternative antibiotic (e.g., rifaximin, nitazoxanide)
- At least two episodes of severe CDI resulting in hospitalization and associated significant morbidity
- Moderate CDI not responding to standard therapy (vancomycin) for at least a week
- Severe fulminant C. difficile colitis with no response to standard therapy after 48 hours

A repeat FMT is considered established in individuals who experience a recurrence of Clostridioides difficile infection within 8 weeks of an initial FMT.

Fecal microbiota, live-jslm (e.g., Rebyota) is covered (subject to FDA Limitations and Administrative Guidelines) for the prevention of CDI recurrence for patients who meet the following criteria:

- At least 18 years of age or older
- Diagnosis of previous CDI was confirmed by a positive stool test
- There have been at least 3 recurrences that are refractory to standard antibiotic treatment. (A recurrence is defined as an episode of symptom onset and positive assay result following an episode with positive assay result in the previous 2-8 weeks of successful antibiotic treatment
- Other forms of fecal microbiota transplant were not effective or could not be performed
- Therapy is directed at preventing future recurrences and not for treating active CDI
- It has been >24 months since last Rebyota dose and has had another 3 CDI recurrences that are refractory to standard antibiotic treatment
- Administration occurs 24-72 hours after the last dose of antibiotics for CDI
- Patient meets all other FDA criteria for Rebyota use

Fecal microbiota spores, live-brpk (Vowst) is covered (subject to FDA Limitations and Administrative Guidelines) as a one-time use for the prevention of CDI for patients who have a CDI recurrence within 24 months of receiving Rebyota

FMT is experimental/investigational and therefore non-covered for all other indications including the following (not an all-inclusive list):

- Autoimmune disease
- Colon cancer
- Constipation
- Crohn's disease
- Diabetes mellitus
- Fatty liver disease
- Functional gastro-intestinal disorders (e.g., irritable bowel syndrome, functional constipation, functional diarrhea, and functional dyspepsia)
- Graft-versus-host disease of the gut
- Hepatic steatosis
- Idiopathic thrombocytopenic purpura
- Inflammatory bowel diseases
- Insulin resistance
- Metabolic syndrome
- Multiple sclerosis
- Obesity
- Parkinson's disease
- Pouchitis
- Ulcerative colitis

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODE	
44705	Preparation of fecal microbiota for instillation, including assessment of donor specimen
44799	Unlisted procedure, small intestine [Not Covered if used to report any Fecal Microbiota Transplantation noncovered experimental/investigational indications/exclusions.]
45999	Unlisted procedure, rectum [Not Covered if used to report any Fecal Microbiota Transplantation noncovered experimental/investigational indications/exclusions.]
0780T	Instillation of fecal microbiota suspension via rectal enema into lower gastrointestinal tract
HCPCS CODE	
G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen
J1440	Fecal microbiota, live - jslm, 1 ml
ICD-10-CM CODE	
A04.71	Enterocolitis due to Clostridium difficile, recurrent
A04.72	Enterocolitis due to Clostridium difficile, not specified as recurrent

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 09/10/2013

Date	Explanation & Changes
03/13/13	• TAWG determined FMT is an accepted way of treatment
09/10/13	• Policy created and approved by Medical Policy Steering Committee
08/08/17	• Removed ICD-9 codes • Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee as revised
12/16/2020	• Medical policy placed on the new Paramount Medical Policy Format
10/01/2022	• Policy reviewed and updated to reflect most current clinical evidence • Removed diagnosis A04.7 • Added diagnosis A04.71 and A04.72

01/01/2023	• Paramount added covered procedure code 0780T, effective 01/01/2023, for all product lines
04/01/2024	• Medical policy reviewed and updated to reflect the most current clinical evidence • Added coverage criteria for Rebyota and Vowst
04/01/2025	• Medical Policy reviewed and updated to reflect the most current clinical evidence • No changes to policy statement

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

NCDs https://www.cms.gov/medicare-coverage-database/searchresults.aspx?keyword=&keywordType=starts&areaId=s29&docType=NCD&contractOption=all

LCDs https://www.cms.gov/medicare-coverage-database/searchresults.aspx?keyword=&keywordType=starts&areaId=s29&docType=F,P&contractOption=all

National Physician Fee Schedule Relative Value File Calendar Year XXXX, Centers for Medicare & Medicaid Services (CMS) https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files

NCCI Policy Manual for Medicare Services, current version, Chapter 1, General Correct Coding Policies https://www.cms.gov/files/document/medicare-ncci-policy-manual-2023-chapter-1.pdf

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

Centers for Medicare & Medicaid Services (CMS), ICD-10-CM Official Guidelines for Coding and Reporting https://www.cms.gov/medicare/coding/icd10

Centers of Medicare & Medicaid Services (CMS), Medicare Claims Processing Manual, Chapter 23-Fee Schedule administration and coding Requirements https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf

Centers for Medicare & Medicaid Services (CMS), National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services https://www.cms.gov/medicare-medicaid-coordination/national-correct-coding-initiative-ncci/ncci-medicare

Center for Medicare and Medicaid Services, Medicare NCCI Medically Unlikely Edits (MUEs) https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medically-unlikely-edits
U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/

Hayes, Inc., Lansdale, PA: Author. Health Technology Assessments. https://www.hayesinc.com/

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcementpolicy-regarding-investigational-new-drug-requirements-use-fecal-microbiota-0

Food and Drug Administration (FDA)

Industry Standard Review