

NO. 91603-R4

# FECAL MICROBIOTA TRANSPLANTATION / FECAL BACTERIOTHERAPY

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**Instruction for use:** This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

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## I. MEDICAL NECESSITY CRITERIA

A. **Fecal Microbiota Transplantation (FMT)/Fecal Bacteriotherapy** is considered medically necessary for any of the following:

1. Recurrent or relapsing *C. difficile* infection (CDI) defined as one of the following:
  - a. 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) OR
  - b. At least 2 episodes of severe CDI resulting in hospitalization and associated with significant morbidity.
2. Moderate CDI not responding to standard therapy (vancomycin) for at least a week.
3. Severe or fulminant *C. difficile* colitis with no response to standard therapy after 48 hours.

B. Testing for donor selection is a covered benefit if the FMT recipient is a Priority Health member.

C. Exclusions

1. FMT for all indications not defined above are considered experimental and investigational and are not covered by Priority Health (e.g. Crohn's disease, Inflammatory Bowel Disease).
2. Oral administration of FMT/fecal bacteriotherapy is considered experimental and investigational.
3. Use of standardized stool sample preparations from a stool bank<sup>1</sup> or similar (e.g., FMT products from [OpenBiome](#)) is considered experimental and investigational.

<sup>1</sup> A stool bank is defined as an establishment that collects, prepares, and stores FMT product for distribution to other establishments, health care providers, or other entities for use in patient therapy or clinical research.

Note: See the [Priority Health Medical Benefit Drug List \(MBDL\)](#) for coverage details for [Rebyota™](#) (fecal microbiota live-jslm) suspension, for rectal use.

## II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the [CMS Online Manual System \(IOMs\)](#) and Transmittals.

For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to [CMS Medicare Coverage Database](#).

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare [Coverage Database website](#) for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
None identified.	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None identified.
First Coast Service Options, Inc.	None identified.
National Government Services, Inc.	None identified.
Noridian Healthcare Solutions	None identified.
Novitas Solutions, Inc.	None identified.
Palmetto GBA	None identified.
WPS Insurance Corporation	None identified.

## III. BACKGROUND

*Clostridioides difficile* (formerly *Clostridium difficile*; *C. diff.*) is a spore-forming, anaerobic, Gram-positive bacterium that produces toxins harmful to the intestinal lining.

***Clostridioides difficile* infection (CDI)** often occurs after standard treatment with antibiotics, which can alter the normal composition of intestinal microbiota and allow *Clostridioides difficile* to multiply, causing diarrhea and colitis. CDI is a serious public health problem as it is highly contagious and can spread through the fecal-oral route as a result of ineffective infection control procedures in the healthcare setting.

**Recurrent CDI (rCDI)** is usually defined as recurrence of symptoms with a positive stool test that occurs within 8 weeks after successful treatment of the CDI episode. rCDI is difficult to eradicate and can lead to substantial morbidity and death. In particular, the depletion of Firmicutes organisms by antibiotics may lower the body's ability to defend against rCDI.

CDI can cause fever, loss of appetite, nausea, abdominal pain, colitis, and diarrhea that can range from mild to life threatening. Complications associated with rCDI include hypotension, dehydration, severe diarrhea, intestinal paralysis, colonic perforation, toxic megacolon, kidney failure, septicemia, and death.

Multiple medical associations have published guidelines and position statements on the use of **fecal microbiota transplantation (FMT)** for ***C difficile* infection (CDI)**. Recommendations include:

American Gastroenterological Association, 2024:

- In immunocompetent adults with recurrent *C difficile* infection, the AGA suggests the use of fecal microbiota–based therapies upon completion of standard of care antibiotics over no fecal microbiota–based therapies. (Conditional recommendation, low certainty evidence)
- In mildly or moderately immunocompromised adults with recurrent *C difficile* infection, the AGA suggests the use of conventional fecal microbiota transplant upon completion of standard of care antibiotics over no fecal microbiota transplant. (Conditional recommendation, very low certainty of evidence)
- In severely immunocompromised adults with recurrent *C difficile* infection, the AGA suggests against the use of fecal microbiota–based therapies upon completion of standard of care antibiotics over no fecal microbiota–based therapies. (Conditional recommendation, very low certainty of evidence)
- In adults hospitalized with severe or fulminant *C difficile* infection not responding to antimicrobial therapy, the AGA suggests the use of conventional fecal microbiota transplant over no fecal microbiota transplant. (Conditional recommendation, very low certainty of evidence)

American Academy of Pediatrics, 2023:

- Studies support the use of FMT in pediatric patients with moderate to severe or recurrent CDI.
- Do-it-yourself, at-home FMT should not be performed in children for safety reasons.
- It is recommended that FMT be performed in a center with experience in the procedure.

National Care Institute for Health and Care Excellence, 2022:

- Faecal microbiota transplant (FMT) is recommended as an option to treat recurrent *Clostridioides difficile* infection in adults who have had 2 or more previous confirmed episodes.

American College of Gastroenterology, 2021:

- We suggest fecal microbiota transplantation (FMT) be considered for patients with severe and fulminant CDI refractory to antibiotic therapy, particularly, when patients are deemed poor surgical candidates (strong recommendation, low quality of evidence).
- We recommend patients experiencing their second or further recurrence of CDI be treated with FMT to prevent further recurrences (strong recommendation, moderate quality of evidence).
- We recommend FMT be delivered through colonoscopy (strong recommendation, moderate quality of evidence) or capsules (strong recommendation, moderate quality of evidence) for treatment of rCDI; we suggest delivery by enema if other methods are unavailable (conditional recommendation, low quality of evidence).
- We suggest repeat FMT for patients experiencing a recurrence of CDI within 8 wk of an initial FMT (conditional recommendation, very low quality of evidence).

Several published guidelines address the use of fecal microbiota transplantation (FMT) for indications other than *C difficile* infection:

- FMT is not recommended for the clinical treatment of any other medical conditions [other than *C difficile*] at this time. (American Academy of Pediatrics, 2023)
- Do not offer FMT routinely to patients with indications other than CDI. (British Society of Gastroenterology/Healthcare Infection Society, 2024)
- In adults with ulcerative colitis, the AGA suggests against the use of conventional fecal microbiota transplant, except in the context of clinical trials. (Conditional recommendation, very low certainty of evidence) (American Gastroenterological Association, 2024)
- Fecal microbiota transplantation (FMT) requires more study and clarification of treatment before use as a therapy for UC [ulcerative colitis]. (American College of Gastroenterology, 2021)
- In adults with Crohn's disease, the AGA suggests against the use of conventional fecal microbiota transplant, except in the context of a clinical trial. (Conditional recommendation, very low certainty of evidence) (American Gastroenterological Association, 2024)
- In adults with pouchitis, the AGA suggests against the use of conventional fecal microbiota transplant, except in the context of clinical trial. (Conditional recommendation, very low certainty of evidence) (American Gastroenterological Association, 2024)

#### IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
<a href="#">American Academy of Pediatrics (AAP)</a>	<a href="#">Fecal Microbiota Transplantation: Information for the Pediatrician (November 20, 2023)</a>
<a href="#">American College of Gastroenterology (ACG)</a>	<a href="#">ACG Clinical Guidelines: Prevention, Diagnosis, and Treatment of <i>Clostridioides difficile</i> Infections (June 2021)</a>  <a href="#">ACG Clinical Guideline: Ulcerative Colitis in Adults (March 2019)</a>
<a href="#">American Gastroenterological Association (AGA)</a>	<a href="#">Fecal microbiota-based therapies for select gastrointestinal diseases (February 21, 2024)</a>
<a href="#">North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN)</a>  <a href="#">European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN)</a>	<a href="#">Fecal Microbiota Transplantation for Recurrent <i>Clostridium difficile</i> Infection and Other Conditions in Children: A Joint Position Paper From the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (January 2019)</a>
<a href="#">British Society of Gastroenterology (BSG)</a>  <a href="#">Healthcare Infection Society (HIS)</a>	<a href="#">The use of faecal microbiota transplant as treatment for recurrent or refractory <i>Clostridioides difficile</i> infection and other potential indications: second edition of joint British Society of Gastroenterology (BSG) and Healthcare Infection Society (HIS) guidelines (February 2024)</a>
<a href="#">National Institute for Health and Care Excellence (NICE)</a>	<a href="#">Medical technologies guidance MTG71. Faecal microbiota transplant for recurrent <i>Clostridioides difficile</i> infection (August 31, 2022)</a>  <a href="#">Interventional procedures guidance IPG485. Faecal microbiota transplant for recurrent <i>Clostridium difficile</i> infection (March 27, 2014)</a>

## V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration [Fecal Microbiota Products](#) for the most current information.

Product	BL Submission Tracking Number (STN)	Notice date
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	DHHS License No.	
<a href="#">VOWST™</a> (fecal microbiota spores, live-brpk) capsules, for oral administration	<a href="#">BL 125757/0</a> DHHS U.S. License No. 2262	April 26, 2023
<a href="#">REBYOTA™</a> (fecal microbiota, live-jslm) suspension, for rectal use	<a href="#">BL 125739</a> DHHS U.S. License No. 2112	November 30, 2022

## VI. CODING

### ICD-10 Codes that may support medical necessity:

A04.71 Enterocolitis due to *Clostridium difficile*, recurrent

A04.72 Enterocolitis due to *Clostridium difficile*, not specified as recurrent

### CPT/HCPCS Codes:

J1440 Fecal microbiota, live - jslm, 1 ml – See [Priority Health Medical Benefit Drug List](#) for current coverage

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

0780T Instillation of fecal microbiota suspension via rectal enema into lower gastrointestinal tract (*Not Covered for Medicaid*)

44799 Unlisted procedure, small intestine (*submit with explanatory notes if administration is via NG tube or enema*)

*Use appropriate EGD or colonoscopy codes for administration if applicable.*

## VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the [Priority Health Provider Manual](#).

## VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO:** This policy applies to insured HMO/EPO plans.
- **POS:** This policy applies to insured POS plans.
- **PPO:** This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO:** For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL:** For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.

- **MEDICARE:** Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN:** For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the [Michigan Medicaid Fee Schedule](#). If there is a discrepancy between this policy and the [Michigan Medicaid Provider Manual](#), the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

## IX. REFERENCES

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2. Barody TJ, Ramrakha S. Fecal microbiota transplantation in the treatment of *Clostridioides difficile* infection. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on September 19, 2025.)
3. Hayes, Inc. Emerging Technology Report. VE303 (Vedanta Biosciences Inc.) for Prevention of Recurrent *Clostridioides Difficile* Infection. Hayes, Inc. May 18, 2023.
4. Hayes, Inc. Evidence Analysis Research Brief. Repeat Fecal Microbiota Transplantation for Prevention of Recurrent *Clostridioides Difficile* Infection. Hayes, Inc. January 23, 2024.
5. Hayes, Inc. Evolving Evidence Review. Rebyota (Fecal Microbiota, Live-jslm) for Prevention of Recurrent *Clostridioides Difficile* Infection. Hayes, Inc. March 5, 2024. Annual Review April 11, 2025.
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7. Hayes Inc. Health Technology Assessment. Fecal Microbiota Transplant for Refractory or Recurrent *Clostridium Difficile* Infection in Adults. Hayes, Inc. August 11, 2016. Annual Review October 1, 2018.
8. Hayes, Inc. Health Technology Assessment. Fecal Microbiota Transplantation for the Treatment of Crohn Disease. Hayes, Inc. May 5, 2022. Annual Review June 27, 2025.
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11. Hayes, Inc. Medical Code Brief. J1440 – HCPCS codes. Hayes, Inc. May 4, 2023.

12. Kelly CP, Lamont JT, Bakken JS. *Clostridioides difficile* infection in adults: Treatment and prevention. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on September 19, 2025.)

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**Past review dates:** 12/12, 12/13, 11/14, 11/15, 11/16, 11/17, 11/18, 11/19, 11/20, 11/21, 11/22, 11/23, 11/24

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