

Medical Policy:

Fecal Microbiota Transplant (FMT) For Recurrent Clostridium Difficile Infection

POLICY NUMBER	LAST REVIEW
MG.MM.ME.49aC	June 10, 2022

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EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

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Definitions

Clostridium difficile infection (CDI) (Aka C. diff)	<p>Common hospital-acquired (nosocomial) infection; a known cause of morbidity and mortality among older adult hospitalized patients.</p> <p>C. difficile colonizes the human intestinal tract after the normal gut flora has been altered by antibiotic therapy and is the causative organism of antibiotic-associated pseudomembranous colitis.</p> <p>Symptoms include:</p> <ul style="list-style-type: none"> • Watery diarrhea (≥ 3 bowel movements/day ≥ 2 days) • Fever • Loss of appetite • Nausea • Abdominal pain/ tenderness
Recurrent CDI (RCDI)	Episode of CDI that occurs 8 weeks after the onset of a previous episode; provided the symptoms from the previous episode resolved. Recurrence can be due to the

	same (or different) strain and may be due to an impaired immune response and/or alteration of the colonic microbiota.
Refractory CDI	CDI that is unresponsive to the antimicrobial treatment, namely persistence of diarrhea with CD toxin positive or persistent diarrhea with toxin negative in the absence of other possible causes of diarrhea (eg, IBS, IBD, non-CDI antibiotic-associated diarrhea)
Fecal microbiota transplantation (FMT) (Aka fecal bacteriotherapy)	Stool infusion therapy puts healthy donor stool into the stomach, small intestine or colon of an infected patient with RCDI. Healthy intestinal microorganisms act to restore intestinal flora to normal.

Guideline

Members with RCDI are eligible for FMT when the following criteria are met:

1. Third CDI recurrence, even if recurrence is mild
2. Pulsed vancomycin treatment failure
3. Member is not immunocompromised

(For step protocol beginning from mild-to-moderate disease, see [Appendix: CDI severity scoring system and summary of recommended treatments](#))

Note: FMT for refractory CDI may be considered in rare circumstances.

Limitations and Exclusions

The following treatments, which are currently being investigated, are not considered medically necessary due to insufficient evidence of therapeutic value:

1. Immunotherapy (intravenous immune globulin [IVIG]) as a sole therapy
2. Probiotics as adjunct to antibiotics

Procedure Codes

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

ICD-10 Diagnoses

A04.71	Enterocolitis due to Clostridium difficile, recurrent
A04.72	Enterocolitis due to Clostridium difficile, not specified as recurrent

References

American College of Gastroenterology. Guidelines for Diagnosis, Treatment, and Prevention of Clostridium difficile Infections. April 2013. <http://gi.org/guideline/diagnosis-and-management-of-c-difficile-associated-diarrhea-and-colitis/>. June 29, 2022.

Centers for Disease Control and Prevention. FAQs about Clostridium Difficile. November 2020. <https://www.cdc.gov/cdiff/>. Accessed June 29, 2022.

Kelly CP, Lamant JP. Clostridium difficile in adults: Treatment. In: UpToDate, Post TW (Ed). UpToDate. Waltham, MA. (Accessed May 20, 2015)

National Center for Complementary and Integrative Health. Probiotics: What You Need To Know. August 2019. <https://nccih.nih.gov/health/probiotics/introduction.htm>. Accessed June 29, 2022.

Specialty matched clinical peer review.

Revision History

Jun. 11, 2021	Added refractory CDI as covered indication ConnectiCare adopts clinical criteria of its parent corporation EmblemHealth
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APPENDIX

CDI severity scoring system and summary of recommended treatments

Severity	Criteria	Treatment	Comment
Mild-to-moderate disease	Diarrhea plus any additional signs or symptoms not meeting severe or complicated criteria	Metronidazole 500mg orally three times a day for 10 days. If unable to take metronidazole, vancomycin 125 mg orally four times a day for 10 days	If no improvement in 5–7 days, consider change to vancomycin at standard dose (vancomycin 125mg four times a day for 10 days)
Severe disease	Serum albumin <3g/dl plus ONE of the following: WBC ≥15,000 cells/mm ³ , Abdominal tenderness	Vancomycin 125 mg orally four times a day for 10 days	
Severe and complicated disease	Any of the following attributable to CDI: Admission to intensive care unit for CDI Hypotension with or without required use of vasopressors Fever ≥38.5 °C Ileus or significant abdominal distention Mental status changes WBC ≥35,000 cells/mm ³ or <2,000 cells/mm ³ Serum lactate levels >2.2 mmol/l End organ failure (mechanical ventilation, renal failure, etc.)	Vancomycin 500 mg orally four times a day and metronidazole 500 mg IV every 8 h, and vancomycin per rectum (vancomycin 500 mg in 500 ml saline as enema) four times a day	Surgical consultation suggested
Recurrent CDI	Recurrent CDI within 8 weeks of completion of therapy	Repeat metronidazole or vancomycin pulse regimen	Consider FMT after 3 recurrences