Medical Policy:

Rebyota (fecal microbiota, live-jslm), rectal suspension

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.377	February 21, 2025	February 9, 2023

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

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.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Rebyota is the first microbiome therapy to be approved by the FDA and is manufactured from human fecal matter, which is sourced from qualified donors and has been screened for a panel of transmissible pathogens. It is approved for the prevention of recurrence of C. difficile infection (CDI) in patients ≥18 years of age following antibiotic treatment of recurrent CDI.

Length of Authorization

1 treatment course

Dosing Limits [Medical Benefit]

1 dose (150 mL) rectally, administered 24 to 72 hours after the last dose of antibiotics for Clostridioides difficile infection.

Guideline

1. **Prevention of recurrence of C. difficile infection (CDI)**

A. Age ≥18 years; **AND**
B. Diagnosis of at least 1 recurrent episode of CDI (≥2 total CDI episodes); **AND**
C. Current episode of CDI must be controlled (<3 unformed/loose stools/day for 2 consecutive days); **AND**
D. Positive stool test for C. difficile within 30 days before prior authorization request

Applicable Procedure Codes

Code	Description
J1440	Fecal microbiota, live - jslm, 1 ml

Applicable NDCs

Code	Description
55566-9800-xx	Rebyota, fecal microbiota, live-jslm, 150mL

ICD-10 Diagnoses

Code	Description
A04.71	Entercolitis due to clostridium difficile, recurrent

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/21/2025	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	1/11/2024	Annual Review: No Criteria Changes
EmblemHealth & ConnectiCare	12/6/2023	Added Jcode J1440, removed unclassified codes
EmblemHealth & ConnectiCare	02/09/2023	New Policy

References

1. Product Information: REBYOTA™ rectal suspension, fecal microbiota, live-jslm rectal suspension. Ferring Pharmaceuticals Inc (per manufacturer), Parsippany, NJ, 2022.