Clostridium difficile (C-Diff) Step Therapy

Rebyota (fecal microbiota, live-jslm) J1440, Zinplava (bezlotoxumab) J0565 are non-preferred. The preferred products are Medicare Part D Antibiotic Therapies: (See Part D Formulary, no PA required for most preferred Part D alts)

Prior Authorization Step Therapy
Medicare Part B Request Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

☐ **Rebyota**

☐ Had at least 1 recurrence after a primary episode of Clostridioides difficile infection (CDI)

☐ Previously met ONE of the following:

- ☐ Completion of one or more round(s) of standard-of-care antibiotic therapy (ex: metronidazole, vancomycin, fidaxomicin) OR
- ☐ Two or more episodes of severe CDI resulting in hospitalization within the past year

☐ C. difficile stool test with toxin A/B positive results within the previous 30 days

☐ Will not be used in combination with Zinplava

☐ **Zinplava**

☐ Individual has Clostridiodes difficile infection demonstrated by:
- ☐ Passage of three or more loose stools within 24 hours or less; AND
- ☐ Positive stool test for toxigenic Clostridiodes difficile from a stool sample collected no more than 7 days prior to scheduled infusion; AND

☐ Individual is currently receiving antibacterial therapy for Clostridiodes difficile infection (including Dificid, metronidazole, or oral vancomycin); AND

☐ Individual is at high risk of Clostridiodes difficile infection recurrence based on one of the following:
- ☐ 65 years of age or older; OR
- ☐ History of Clostridiodes difficile infection in the past 6 months; OR
- ☐ Immunocompromised state; OR
- ☐ Severe Clostridiodes difficile infection at presentation*; OR
- ☐ Clostridiodes difficile ribotype 027.

Continuation Requests: NONE

Data that supports continued Rebyota treatment does not exist.
Currently, data only supports one repeat course of treatment.

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Bone Resorption Inhibitors PA

Drug Name(s):

REBYOTA	**FECAL MICROBIOTA, LIVE-JSLM**
ZINPLAVA	**BEZLOTOXUMAB**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member has tried and failed at least ONE formulary Part D C-Diff treatment (vancomycin, fidaxomicin, metronidazole) OR
   - There is clinical documentation stating preferred formulary alternatives are contraindicated.
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approval will be for 3 months

FDA Indications:

Rebyota

- Clostridioides difficile infection, Recurrence following antibiotic treatment; Prophylaxis

Zinplava

- Clostridioides difficile infection, Recurrence, in patients currently being treated for Clostridium difficile who are at high risk of recurrence; Prophylaxis

Off-Label Uses:

N/A

Step Therapy Drug(s) and FDA Indications:

Firvanq Kit, Dificid, Flagyl:

- Clostridioides difficile infection, Primary prophylaxis in allogeneic hematopoietic cell transplant recipients
- Clostridioides difficile infection, Primary prophylaxis in patients at high risk for developing healthcare facility-onset C difficile infection

Age Restrictions:

Rebyota: Safety and effectiveness have not been established in pediatric patients

Zinplava: (1 year or older) 10 mg/kg IV over 60 minutes as a single dose; the safety and efficacy of repeat administration has not been studied

Other Clinical Consideration:

N/A

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?navitem=headerLogout#

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