REBYOTA® (fecal microbiota, live-jslm) MEDICAL BENEFIT CLAIMS SUBMISSION CHECKLIST

The following information may be needed to support the claim submission.

- ☐ Chart notes of the administration
- ☐ If a prior authorization or pre-determination was required prior to treatment, include the approval number on the billing form (field 23 on CMS 1500 or field 63 on CMS 1450 form
- ☐ If a prior authorization or pre-determination was not required prior to treatment, you may need to demonstrate Medical Necessity when submitting the claim. Please be sure to include chart notes with the following information:

  Clinical documentation for REBYOTA (J1440)

  - ☐ Diagnosis code (ICD-10 code)
    - A04.71 (Enterocolitis due to *Clostridium difficile,* recurrent)
    - A04.72 (Enterocolitis due to *Clostridium difficile*, not specified as recurrent) (accepted by most payers)
  - ☐ Date patient was diagnosed with recurrent CDI
  - ☐ Labs/positive stool test
  - ☐ Antibiotic name and length of therapy to treat CDI
  - ☐ Number of times the patient had documented CDI (submit chart notes if available)
    - Name of drug(s) and days of therapy for previous CDI episodes

INDICATION AND IMPORTANT SAFETY INFORMATION

REBYOTA (fecal microbiota, live – jslm) is indicated for the prevention of recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI.

Limitation of Use

REBYOTA is not indicated for treatment of CDI.

IMPORTANT SAFETY INFORMATION

Contraindications

Do not administer REBYOTA to individuals with a history of a severe allergic reaction (eg, anaphylaxis) to any of the known product components.

Please see Important Safety Information on next page.

REBYOTA®
(fecal microbiota, live-jslm) suspension, for rectal use

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Transmissible infectious agents

Because REBYOTA is manufactured from human fecal matter, it may carry a risk of transmitting infectious agents. Any infection suspected by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Ferring Pharmaceuticals Inc.

Management of acute allergic reactions

Appropriate medical treatment must be immediately available in the event an acute anaphylactic reaction occurs following administration of REBYOTA.

Potential presence of food allergens

REBYOTA is manufactured from human fecal material and may contain food allergens. The potential for REBYOTA to cause adverse reactions due to food allergens is unknown.

Adverse Reactions

The most commonly reported (≥3%) adverse reactions occurring in adults following a single dose of REBYOTA were abdominal pain (8.9%), diarrhea (7.2%), abdominal distention (3.9%), flatulence (3.3%), and nausea (3.3%).

Use in Specific Populations

Pediatric Use

Safety and efficacy of REBYOTA in patients below 18 years of age have not been established.

Geriatric Use

Of the 978 adults who received REBYOTA, 48.8% were 65 years of age and over (n=477), and 25.7% were 75 years of age and over (n=251). Data from clinical studies of REBYOTA are not sufficient to determine if adults 65 years of age and older respond differently than younger adults.

You are encouraged to report negative side effects of prescription drugs to FDA.
Visit www.FDA.gov/medwatch, or call 1-800-332-1088.

Please visit www.REBYOTAHCP.com for full Prescribing Information.

Please click to see the full Prescribing Information.

Disclaimer
The information provided by Ferring is intended to provide general information and is subject to change based on the individual plan coverage. Check the member's benefits for more details. The potential codes are provided for informational purposes only. Ferring does not guarantee coverage or payment of its products.

FERRING PHARMACEUTICALS
Microbiome Therapeutics Development

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