REBYOTA® Guide for Leveraging EPIC Electronic Health Record

FUNCTIONALITY TO SUPPORT IMPLEMENTATION

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

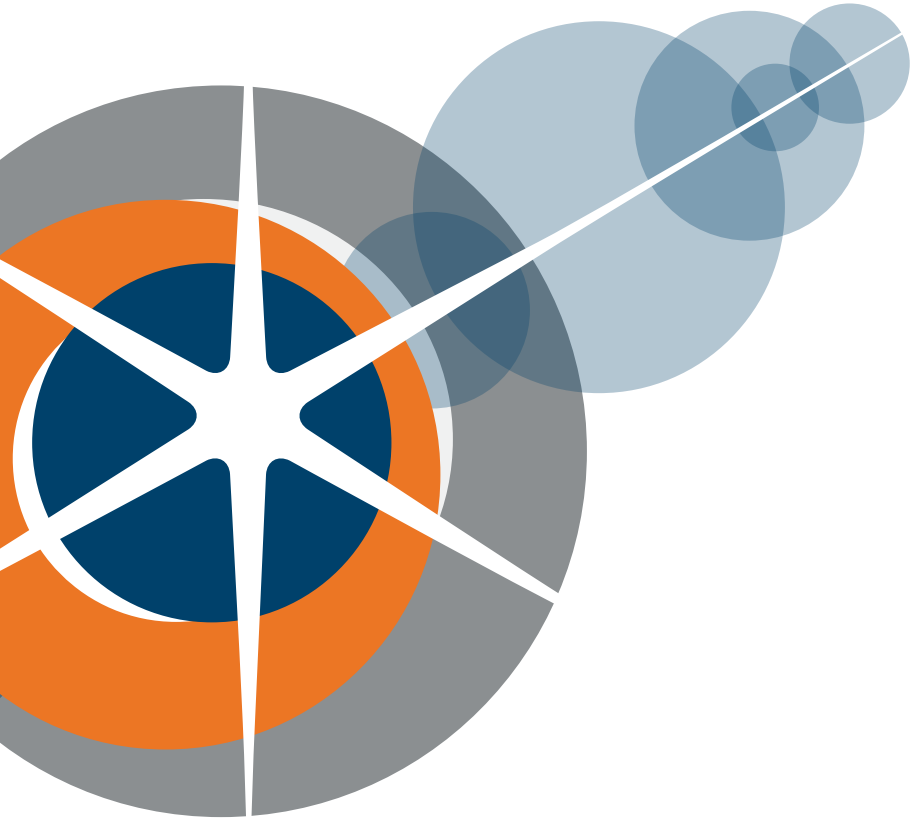
GO BEYOND

Please see Important Safety Information on the last page and full Prescribing Information.

Background

This guide is intended to assist healthcare providers (HCPs) and health systems in configuring their EMR/EHR to facilitate prescribing of REBYOTA® (fecal microbiota, live – jslm) indicated for the prevention of recurrence of Clostridioides difficile infection (CDI). Functions, locations, and terminology used in this guide may differ based on the software version implemented within a facility. This guide should not replace instructions from your internal or external EHR support teams. Ferring does not endorse any specific EHR systems.

This document is for informational purposes only. All clinical decisions are the responsibility of the HCP, and the examples provided in this guide are not meant as guidance for medical treatment. This document is not intended to provide any clinical recommendations, as treatment decision-making is the sole responsibility of an HCP.



Epic Instructions

Considerations

Electronic health record (EHR) systems and hospital and health system processes will vary. Modify procedures within this document as necessary to meet your institutional needs. It is the responsibility of the medical group to implement, test, monitor, and ensure the ongoing operation of any EHR tools. A new order set will be available once the optimization process is complete. If the original order set used to update or create the new order set includes REBYOTA, confirm the original order set is retired.

Instructions

Epic's SmartSets are often utilized to support complex therapies in the outpatient setting for orders, prescriptions, patient information, and follow-up visits, among other things. If your institution has an existing SmartSets for recurrence of Clostridioides difficile infection (CDI), it can be updated to include REBYOTA, or a new SmartSet for REBYOTA can be created. If an existing SmartSet for recurrent CDI does not exist, a request can be initiated to create a new SmartSet to include these orders and any other orders that may be appropriate. Refer to your institution's IT policy for guidance.

SmartSets containing SmartGroups and Therapy Plans containing OrderGroups are created and maintained by the health system EHR IT team.

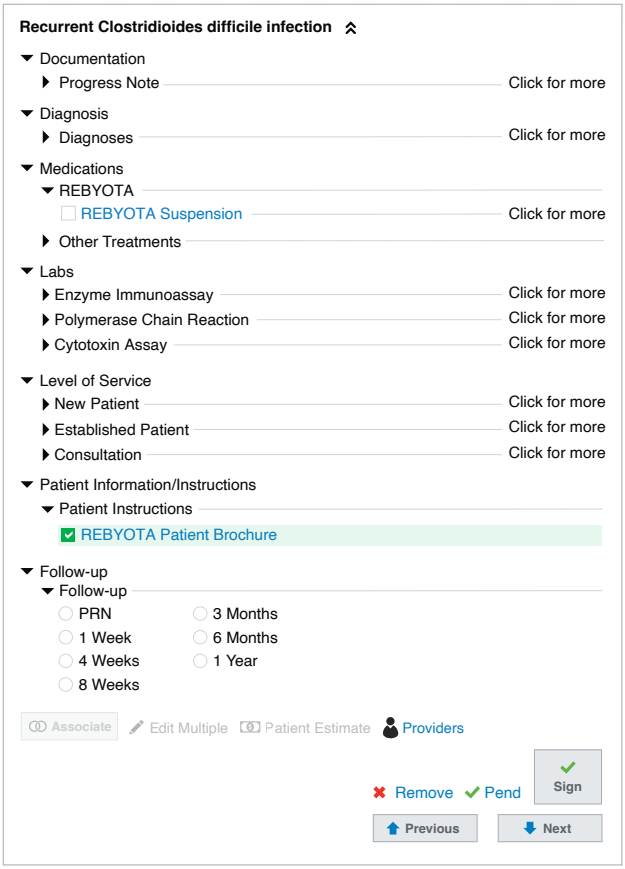
In general, there are 3 primary steps:

1	Identify the SmartSets that need to be updated or identify the update as a new addition to the EMR
2	Provide the appropriate information necessary for the REBYOTA order set
3	Identify the SmartGroup or OrderGroup where the modification will occur

Step 1:
General instructions for creating or updating the Order Groups

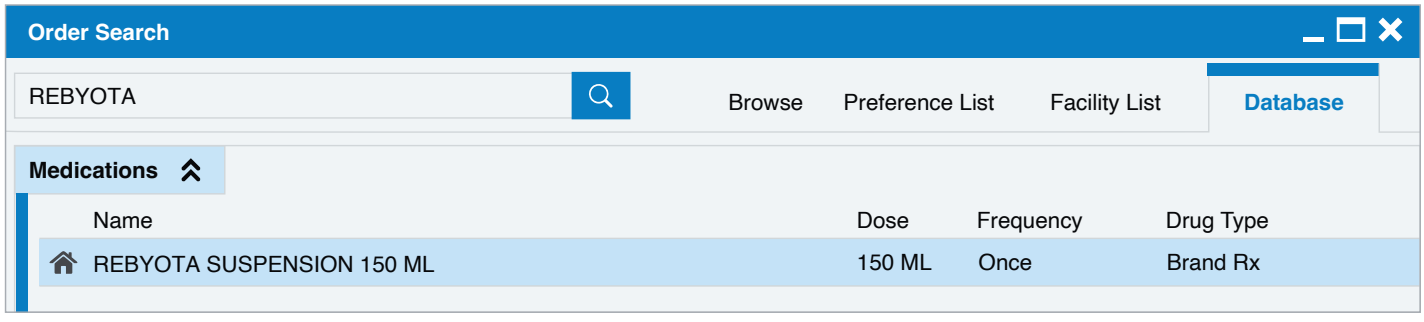
1. Review the Regimen Category Order Group to confirm Medications are values in the category list
2. Select the Order Group Builder
3. Create a new Order Group named “Medications”
4. Set the default category to Medications
5. Create the Order Group REBOYTA

PATIENT INFORMATION: REBYOTA CONNECT



Step 2:
Add the REBYOTA package insert links to the medication record

1. Log in to the Medication Master File (ERX) with authorized user credentials
2. Use the search feature in the Medication Master File to search for and select the desired medication (REBYOTA)
3. Select the Patient Medication References Screen and create a new row.
   a. For Display Name, enter “REBYOTA Package Insert”
   b. In the Text field, enter “See URL for additional REBYOTA dosing and administration information”
   c. In the URL field, enter this hyperlink to access the package insert: **https://www.ferringusa.com/wp-content/uploads/sites/12/2022/12/9009000002_REBYOTA-PI_11-2022.pdf**
4. Save the record
5. Release the record to production after satisfactory testing has been completed

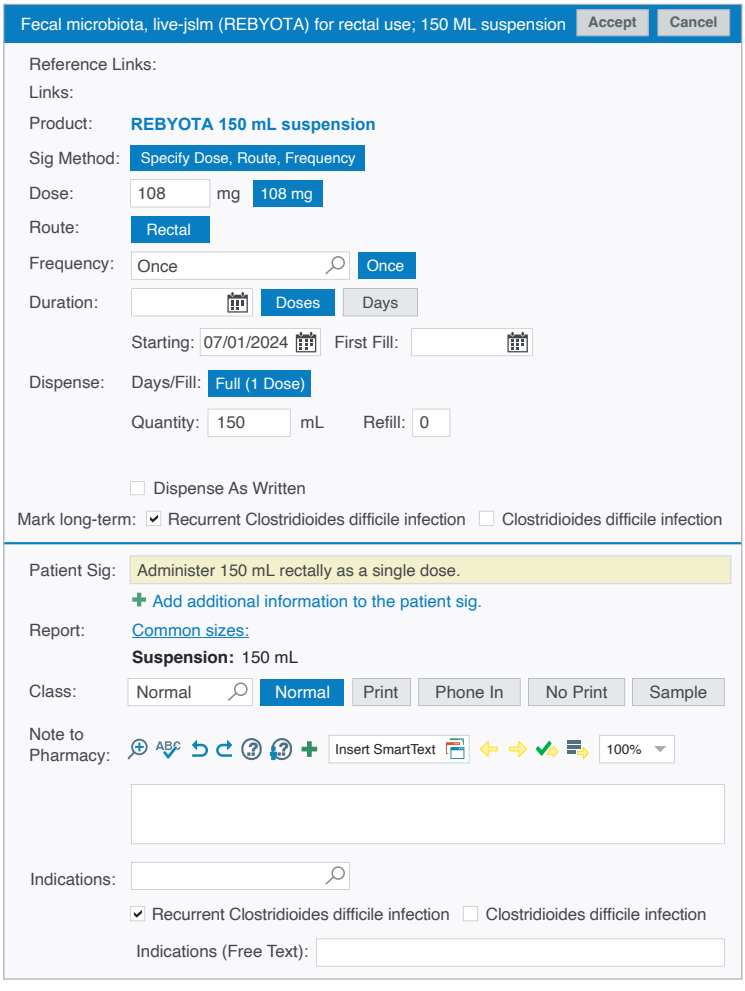


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Step 3:
Add the Order Groups to the REBYOTA order for recurrent CDI

The steps below detail how to add the Order Group created in Step 1 to an existing protocol to create a new REBYOTA order for recurrent CDI order set:

1. Search for order sets using the search query “recurrent CDI (clostridium difficile infection)”; note that an existing REBYOTA order set may be available to update
   a. **Note:** the existing order set will serve as a template for the new REBYOTA order set only; if the original order set used to update or create the new REBYOTA order set includes REBYOTA, confirm the original order set is retired or removed from the EHR production system according to your institution’s EHR governing principles
   b. Select the treatment regimen and add the newly created order group(s) from Step 1 to the treatment regimen: a single dose of 150 mL rectally 24-72 hours after the last dose of antibiotics
2. Update the protocol description to “REBYOTA for recurrent CDI”
3. Click Save
4. Release to production environment after satisfactory testing has been completed



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INDICATION

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

Limitation of Use

REBYOTA is not indicated for the treatment of *C. diff* infection.

IMPORTANT SAFETY INFORMATION

- You should not receive REBYOTA if you have a history of a severe allergic reaction (e.g., anaphylaxis) to REBYOTA or any of its components.
- You should report to your doctor any infection you think you may have acquired after administration.
- REBYOTA may contain food allergens.
- Most common side effects may include stomach pain (8.9%), diarrhea (7.2%), bloating (3.9%), gas (3.3%), and nausea (3.3%).
- REBYOTA has not been studied in patients below 18 years of age.
- Clinical studies did not determine if adults 65 years of age and older responded 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 see full Prescribing Information available at **www.REBYOTAhcp.com**.

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FERRING PHARMACEUTICALS

Microbiome Therapeutics Development