# SAMPLE HOSPITAL WORKFLOW:
## Patient Set-up and Administration Details for REBYOTA® (fecal microbiota, live-jslm).

**OBJECTIVE:** After surveying protocols and best practices from offices prescribing REBYOTA® (fecal microbiota, live-jslm), this sample protocol represents a consistent and streamlined approach within an **Endoscopy Center**.

**APPLIES TO:** All staff involved in the ordering and administration of REBYOTA.

### PRE-ADMINISTRATION PROCESS:

1. Referring physician identifies potential patient and their office conducts the benefit verification by contacting insurer directly through own process.
2. Referring Physician's office receives benefit summary through own process and notifies patient of status.
3. In the event a prior authorization is required, Referring Physician's office completes and submits the Prior Authorization form to the insurer.
   a. candidate meets criteria and agrees with OOP, continue this process.
4. Referring physician places an order for a procedure in EMR, this will create a referral to be used for scheduling and prior authorization.
   a. Pharmacy is alerted to order REBYOTA in accordance with administration date.
   b. Administration is scheduled for 1-3 days after completion of antibiotic.
5. Upon receipt of REBYOTA, the product can:
   a. Stay frozen in the unopened AEROSAFE box for up to 5 days from the date on box.
   b. Be removed from the orange delivery box and immediately stored in an ultracold freezer.
   c. Or be removed from the orange delivery box and stored in the refrigerator immediately to thaw if administering within 5 days.

   Please note: REBYOTA must be thawed in the refrigerator at least 24 hours prior to administration (can be in the refrigerator up to 5 days). The administration kit (blue box) should not be stored in the refrigerator.
   For full shipper box (AEORSAFE) return instructions and REBYOTA storage and handling see https://www.REBYOTAhcp.com/order-REBYOTA/ and Full Prescribing Information
6. Endo nurse counsels patient on the following:
   a. Stop antibiotics 24-72 hours before REBYOTA administration.
   b. Wear loose fitting clothing day of procedure.
   c. If possible, have a bowel movement at home prior to office visit.
   d. Prepare to lay on the exam table for approximately 20-30 minutes.
   e. Appropriately sanitize personal belongings and home after administration to reduce chance of reinfection.
7. Endo calls pharmacy >24 hours prior to patient appointment to ensure REBYOTA has at least 24 hours to thaw in the refrigerator.

### INDICATION

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 full Prescribing Information at www.REBYOTAHCP.com.**

This sample workflow provides examples of individuals in an Endoscopy Center who might be responsible for the described tasks. Tasks should be delegated on a case-by-case basis according to the clinical judgment and practices of supervising healthcare providers.

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

## DAY OF ADMINISTRATION:

1. Patient is checked in and the Endo nurse enters the REBYOTA® order from the Endoscopy Procedure order set.
2. Pharmacy delivers REBYOTA and administration tubing set to Endo.
3. The patient is asked to use the bathroom.
4. The patient is then placed in a room and their vitals are checked.
5. The patient lays on their left side on the examination table with a disposable pad underneath them.
6. Procedure is explained and REBYOTA is administered.
7. The patient lays on the table for up to 15 minutes.
8. Vitals are re-checked.
9. Discharge instructions are given.
   a. Per package insert, patients should not take any oral antibiotic therapy for up to 8 weeks after administration of REBYOTA unless directed by their physician.
10. Clean the examination room per hospital protocol.
11. Dispose of all components in medical waste.
12. Administration is documented on the MAR.

## POST ADMINISTRATION:

1. Following day of administration, Endo Manager calls patient to follow-up.
2. Patient to follow up with referring HCP 2 weeks post administration.

## IMPORTANT SAFETY INFORMATION (Continued)

**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 REBYOTA administration 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 see full Prescribing Information at www.REBYOTAHCP.com.**

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Microbiome Therapeutics Development