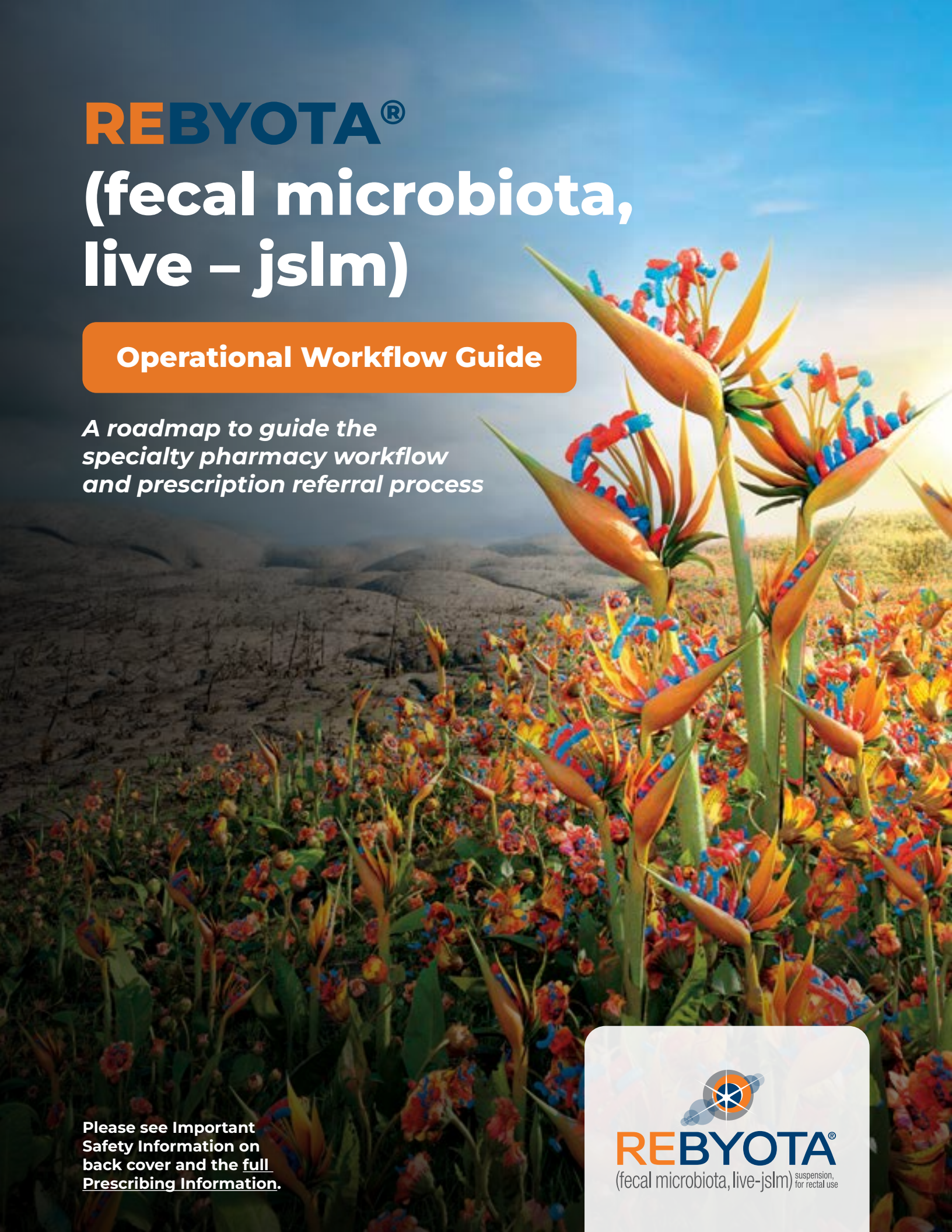
REBYOTA®
(fecal microbiota, live – jslm)

Operational Workflow Guide

A roadmap to guide the specialty pharmacy workflow and prescription referral process



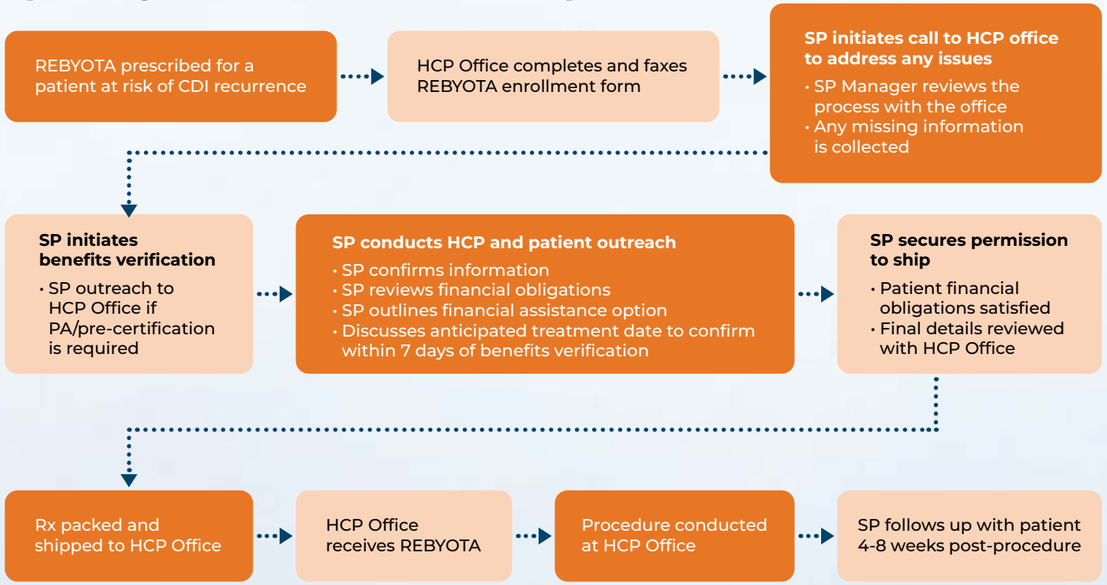
Please see Important Safety Information on back cover and the full Prescribing Information.

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

An Overview of the Process

Successfully navigating the various healthcare system channels requires a collaborative effort by manufacturers, providers, payers, and patients. This partnership can help to better meet patient needs and improve their overall treatment experience. This informational guide is designed to provide some background information that may help minimize any issues when a patient has been prescribed REBYOTA.

REBYOTA Operational Workflow — Specialty Pharmacies & HCP Perspectives



Documentation Checklist

As you know, treatment is time sensitive and many patients require urgent care; as such, when working with your specialty pharmacy provider, it is helpful to provide any relevant information that will expedite your request. The checklist below is a resource you can use to guide you through what information may be potentially required beyond the traditional provider and patient information you usually give.[a]

Clinical documentation

- ☐ Date patient was initially diagnosed with CDI
- ☐ Diagnosis (prevention of rCDI)
- ☐ Diagnosis code (ICD-10 code AØ4.71 or AØ4.72)
- ☐ Chart of progress notes (e.g., history and physical, last visit notes, any previous hospitalizations, etc)
- ☐ Patient weight
- ☐ Number of recurrences after primary episode of CDI treated with antibiotic course and/or documented *Clostridioides difficile*-associated diarrhea
- ☐ Associated medication history including drug name (e.g., fidaxomicin [Dificid®], vancomycin [Vancocin®, Firvanq®], Zinplava™ [bezlotoxumab], or Vowst™ [fecal microbiota spores, lives-brpk]), dates taken, and outcomes of treatment
- ☐ Patient antibiotic clearance date
- ☐ All labs with any results for CDI

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If prescribing REBYOTA electronically (e-prescribing), in addition to those above, include an NPI number, an electronic signature, and whether the prescription must be dispensed as written (if a brand name product is therapeutically required).

[a]Please note that the benefits and services offered through various payers and SPs can vary and, therefore, not everything listed may apply in every case.

Learn More About REBYOTA

Scan here to log onto the REBYOTA Healthcare Professional Website

SPECIALTY PHARMACY ORDERING INFORMATION

Accredo
Prescriptions Tel: 1-866-759-1557
Customer Service Tel: 1-800-411-9943
Hours: Monday-Friday, 9:00 am-11:00 pm ET

Optum Frontier Therapies
Tel: 1-855-768-9727
Hours: Monday-Friday, 8:00 am-9:00 pm ET

Please work with your specialty pharmacy on logistics, handling, and their specific returns and replacement policies.

For more information about ordering REBYOTA, please visit: https://www.rebyotahcp.com/order-rebyota/.

For more information regarding the storage, administration, and handling of REBYOTA, please see the full Prescribing Information.

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

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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.

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 see the full Prescribing Information available at www.REBYOTAhcp.com.

FERRING PHARMACEUTICALS

Microbiome Therapeutics Development

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US-REB-2600012 v2 8/26

