Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 281.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Rebyota (fecal microbiota, live-jslm)

I. Policy:
Rebyota (fecal microbiota, live-jslm)

II. Purpose/Objective:
To provide a policy of coverage regarding Rebyota (fecal microbiota, live-jslm)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Rebyota (fecal microbiota, live-jslm) is a fecal bicrobiome therapy manufactured from human fecal matter sourced from qualified donors. Rebyota is intended to restore intestinal eubiosis to prevent the recurrence of *clostridium difficile* infections (CDI) in patients following antibiotic treatment for recurrent CDI.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Rebyota (fecal microbiota, live-jslm) will be considered medically necessary for commercial, exchange, CHIP, and Medicaid lines of business when ALL of the following criteria are met:

- Documentation of age greater than or equal to 18 years **AND**
- Prescribed by or in consultation with an infectious disease specialist or gastroenterologist **AND**
- Medical record documentation that Rebyota will be used for the prevention of recurrence of C. difficile infections **AND**
- Medical record documentation of a diagnosis of recurrent C. difficile infection based on the results of an appropriate laboratory stool test within 30 days of prior authorization request **AND**
- Medical record documentation that an appropriate standard-of-care antibacterial regimen was used for the treatment of recurrent C. difficile infection (e.g., oral fidaxomicin, oral vancomycin, oral metronidazole) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Zinplava **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

AUTHORIZATION DURATION: If approved, authorization shall be for the authorization of one (1) Rebyota dose with an authorization duration of 30 days

Note: Rebyota is not indicated for the treatment of C. difficile infection infections. There is no information currently available indicating that an individual is unable to receive more than one dose of Rebyota.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

Rebyota (fecal microbiota, live-jslm) will be considered medically necessary for the Medicare line of business when ALL of the following criteria are met:

- Documentation of age greater than or equal to 18 years **AND**
- Prescribed by or in consultation with an infectious disease specialist or gastroenterologist **AND**
- Medical record documentation that Rebyota will be used for the prevention of recurrence of C. difficile infections **AND**
- Medical record documentation of a diagnosis of recurrent C. difficile infection based on the results of an appropriate laboratory stool test within 30 days of prior authorization request **AND**
- Medical record documentation that an appropriate standard-of-care antibacterial regimen was used for the treatment of recurrent C. difficile infection (e.g., oral fidaxomicin, oral vancomycin, oral metronidazole) **AND**
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LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Rebyota [prescribing information]. Roseville, MN: Rebiotix Inc; December 2022.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 5/16/23

Revised: 12/28/23 (references added)

Reviewed: 5/14/24

MA UM Committee approval: 12/31/23