

DRUG POLICY

Ryoncil® (remestemcel-L-rknd)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Ryoncil is indicated for the treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months of age and older.

POLICY

Criteria for Initial Approval

Acute Graft versus Host Disease

1. Authorization of 2 months (maximum 8 infusions) may be granted for the treatment of acute graft versus host disease when ALL of the following criteria are met:
 - A. The member is a pediatric patient
 - B. The disease is steroid-refractory (progressed within 3 days or did not improve within 7 consecutive days of treatment with methylprednisolone 2 mg/kg/day or equivalent)

Continuation of Therapy

Acute Graft versus Host Disease

1. Authorization of 2 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when either of the following criteria are met:
 - A. Partial or mixed response - there is an improvement in symptoms and there is no evidence of unacceptable toxicity while on the current regimen. (Maximum of 4 infusions)

- B. Recurrence after complete response - all members (including new members) requesting authorization for continuation of therapy must meet all the requirements in the coverage criteria section. (Maximum of 8 infusions)

Other

Ryoncil (remestemcel-L-rknd) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J3402 – Injection, remestemcel-l-rknd, per therapeutic dose (effective 10/1/2025)
- C9339 – Unclassified drugs or biologicals
- J3590 – Unclassified biologics

REFERENCES

- Ryoncil [package insert]. New York, NY: Mesoblast, Inc.; December 2024.

POLICY HISTORY

Policy #: 05.05.89

Original Effective Date: July 25, 2025

Reviewed: January 2026

Revised:

Current Effective Date: July 25, 2025