



RX.PA.107.MPC Ryoncil (remestemcel-L-rknd)

The purpose of this policy is to define the prior authorization process for Ryoncil[®] (remestemcel-L-rknd).

Ryoncil[®] (remestemcel-L-rknd) is an allogeneic bone marrow derived mesenchymal stromal cell (MSC) therapy indicated for the treatment of steroid-refractory acute graft vs host disease (SR-aGvHD) in pediatric patients 2 months of age and older.

PROCEDURE

A. Initial Authorization Criteria

I. CLINICAL CRITERIA (Use for ALL Drug Requests)

Must meet all of the criteria listed under the respective product:

1. Acute Graft vs Host Disease (aGvHD)

- Must have documentation of the patient's diagnosis of steroid refractory acute graft versus host disease (SR-aGvHD) following an allogeneic hematopoietic stem cell transplant (HSCT)
 - Must have documentation to support SR-aGvHD Grade B to Grade D
 - Grade B – Stage 2 skin involvement; Stage 1 to 2 gut or liver involvement
 - Grade B excludes skin only involvement
 - Grade C – Stage 3 skin, liver, or gut involvement
 - Grade D – Stage 4 skin, liver, or gut involvement
- Ryoncil (remestemcel-L-rknd) will be initiated only if patients have an inadequate response to a systemic corticosteroid
 - Note: Documentation of an inadequate response must be to methylprednisolone 2mg/kg/day or equivalent with disease progression within 3 days of treatment or no improvement within 7 consecutive days.
- Patient does not have a known hypersensitivity to dimethyl sulfoxide (DMSO), porcine or bovine proteins
- Patient must have an acceptable baseline renal function defined as a creatinine clearance > 30 mL/min per 1.73m² prior to initiating Ryoncil
- Provider attests that the patient has not received second line therapy to treat the patient's aGvHD
- Must be prescribed by or in consultation with an oncologist, hematologist, or transplant specialist
- Provider attestation that the member will be evaluated for infectious diseases and formation of ectopic tissue formation
- Must not be used concurrently with Jakafi (ruxolitinib), Imbruvica (ibrutinib), or Rezurock (belumosudil)

- B. Must be prescribed at a dose within the manufacturer’s dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.**
- C. Treatments will be considered investigational or experimental for any other use and will not be covered.**

D. Reauthorization Criteria:

- All prior authorization renewals are reviewed to determine the Medical Necessity for continuation of therapy. Authorization may be extended based upon:

MPC Renewal:

- Chart documentation from the prescriber that the member’s condition has improved based upon the prescriber’s assessment while on therapy.
 - Documentation must show either partial response, mixed response, or recurrence of aGvHD following complete response
 - Partial response is defined as organ improvement of at least one stage without worsening in any other organ
 - Mixed response is defined as improvement of at least one evaluable organ with worsening in another organ as per International Blood and Marrow Transplantation Registry Severity Index Criteria grading system
- Must be prescribed by or in consultation with an oncologist, hematologist, or transplant specialist
- Member has not received more than 16 doses of Ryoncil (remestemcel-L-rknd)
- Must not be used concurrently with Jakafi (ruxolitinib), Imbruvica (ibrutinib), or Rezurock (belumosudil) OR

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria)
- Provider has a documented clinical response of the member’s condition which has stabilized or improved based upon the prescriber’s assessment

Limitations:

| Length of Authorization (if above criteria met) | |
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| Initial Authorization | 1 month |
| Reauthorization | 1 month |

Applicable Codes:

| CODE | DESCRIPTION |
|-------|------------------------|
| J3590 | Unclassified biologics |



REFERENCES

1. Ryoncil [package insert]. New York, NY: Mesoblast, Inc.; Jan 2025.
2. Chao NJ. Clinical manifestations, diagnosis, and grading of acute graft-versus-host disease. In: UpToDate, Connor RF (ed), Wolters Kluwer. (Accessed on July 24, 2025.)

REVIEW HISTORY

| DESCRIPTION OF REVIEW / REVISION | DATE APPROVED |
|----------------------------------|----------------|
| <i>Annual Review</i> | <i>02/2026</i> |
| <i>New Policy</i> | <i>07/2025</i> |