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 1.73m^2 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)	
Initial Authorization	1 month
Reauthorization	1 month

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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
New Policy	*07/2025*