

remestemcel-L-rknd (Ryoncil)

Commercial Medical Benefit Drug Policy

Place of Service

Outpatient Facility Infusion Administration

Hospital administration

Drug Details

USP Category: IMMUNOLOGICAL AGENTS

Mechanism of Action: Allogeneic bone marrow-derived mesenchymal stromal cell (MSC) therapy

HCPCS:

J3402:Injection, remestemcel-L-rknd, per therapeutic dose

How Supplied:

Cell suspension in a target concentration of 6.68×10^6 MSCs per mL in 3.8 mL contained in a 6 mL cryovial

Condition(s) listed in policy (see coverage criteria for details)

- Pediatric Steroid-Refractory Acute Graft Versus Host Disease (SR-aGVHD)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Pediatric Steroid-Refractory Acute Graft Versus Host Disease (SR-aGVHD)

Meets medical necessity if all the following are met:

1. Age is 2 months to 17 years
2. Steroid refractory aGVHD

Covered Doses:

2×10^6 mesenchymal stromal cell (MSC)/kg given intravenously twice per week for 4 consecutive weeks for a total of 8 infusions (doses administered at least 3 days apart). An additional 8 doses may be given depending on the patient's response after 28 days.

Coverage Period:

One treatment course of up to 16 total infusions

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Effective: 10/01/2025

Page 1 of 2

ICD-10:

D89.810, D89.812, T86.09

Additional Information

• RYONCIL Kit Sizes

| Patient weight (kg) | Kit contents (single infusion) | | | | | Number of kits needed for: | | |
|---------------------|--------------------------------|----------------|---------------|--------------------|--------------|----------------------------|------------|------------------|
| | 4-vial cartons | 1-vial cartons | Total cartons | # of alcohol wipes | NDC Number | Initial course | 2nd course | Relapse after CR |
| <12.5 | 0 | 1 | 1 | 1 | 73648-111-01 | 8 | 4 | 8 |
| 12.5-<25 | 0 | 2 | 2 | 2 | 73648-112-02 | | | |
| 25-<37.5 | 0 | 3 | 3 | 3 | 73648-113-03 | | | |
| 37.5-<50 | 1 | 0 | 1 | 4 | 73648-114-01 | | | |
| 50-<62.5 | 1 | 1 | 2 | 5 | 73648-115-02 | | | |
| 62.5-<75 | 1 | 2 | 3 | 6 | 73648-116-03 | | | |
| 75-<87.5 | 1 | 3 | 4 | 7 | 73648-117-04 | | | |
| 87.5-<100 | 2 | 0 | 2 | 8 | 73648-118-02 | | | |

References

1. National Comprehensive Cancer Network. Hematopoietic stem cell transplant (Version 2.2024). Available at: www.nccn.org.
2. Ryoncil (remestemcel-L) Prescribing Information. Mesoblast, Inc, New York, NY: January 2025.

Review History

Date of Last Annual Review: 1Q2025

Changes from previous policy version:

- Added HCPCS J3402, effective 10/1/2025

Blue Shield of California Medication Policy to Determine Medical Necessity
 Reviewed by P&T Committee