blue california
Promise Health Plan

remestemcel-L-rknd (Ryoncil)

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 x 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.
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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

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

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