

remestemcel-L-rknd (Ryoncil)

HCPCS: J3402 Injection, remestemcel-l-rknd, per therapeutic dose (Ryoncil)

LOB:	MCAL
Duration of Approval:	New: Four weeks (Eight doses) COC: Four weeks (Four doses for partial/mix response; eight doses for recurrence)
Quantity Limit:	Per FDA-Approved/Compendia-Supported Dosing
MCG Available:	No
DHCS Drug Policy:	No

Requires Prior Authorization (PA)

Ryoncil (remestemcel-L-rknd) injection

****All requests must be approved by a Medical Director******PA CRITERIA FOR APPROVAL:**

1. The member has a diagnosis for a Food and Drug Administration (FDA)-approved indication (refer to package insert under References) **OR** a compendia-supported (Drugdex or American Hospital Formulary Service [AHFS]) indication **AND**
2. The medication is prescribed by an oncologist/hematologist or transplant specialist **AND**
3. The member is more than 18 years old **AND**
4. The member has acute graft versus host disease (aGvHD) following allogeneic hematopoietic stem cell transplant (HSCT) with disease severity classified as Grade B, C or D per the international blood and marrow transplantation registry (IBMTR) grading system (excluding Grade B with skin-only involvement) **AND**
5. The member has steroid-refractory acute aGvHD as evidenced by **ONE** of the following (**a, b or c**) (**Note:** To calculate dosing equivalencies, use [steroid conversion calculator](#)):
 - a. Progression within three to five days of treatment with ≥ 2 mg/kg per day of prednisone or equivalent
 - b. No improvement within five to seven days of treatment with ≥ 2 mg/kg per day of prednisone or equivalent
 - c. Partial response after more than 28 days of immunosuppressive treatment including ≥ 2 mg/kg per day of prednisone or equivalent**AND**
6. For members 12 years of age and older: The member has a history of failure, contraindication or reasons for intolerance to ruxolitinib (Jakafi) (**Note:** Jakafi is PA required under Medi-Cal Rx) **AND**
7. The member has no known hypersensitivity to dimethyl sulfoxide (DMSO) or porcine and bovine proteins

Continuation of Therapy

1. The member has a diagnosis for an FDA-approved indication (refer to package insert under References) **OR** a compendia-supported (Drugdex or AHFS) indication **AND**
2. The medication is prescribed by an oncologist/hematologist or transplant specialist **AND**
3. Documentation is provided showing **ONE** of the following responses after completing the initial eight doses (**a, b or c**):
 - a. Partial response (defined as organ improvement of at least one stage without worsening in any other organ)
 - b. Mixed response (defined as improvement of at least one organ with worsening in another organ as per IBMTR grading system)
 - c. Recurrence of aGvHD following a complete response

OTHER INFORMATION:**IBMTR severity index criteria**

* The overall grade is determined by the combination of organ stages

Grade	Skin	Liver	Lower GI	Upper GI
-------	------	-------	----------	----------

remestemcel-L-rknd (Ryoncil)

HCPCS: J3402 Injection, remestemcel-l-rknd, per therapeutic dose (Ryoncil)

A	1	0	0	0
B	2	1-2	1-2	1
C	3	3	3	N/A
D	4	4	4	N/A

Organ Staging

<u>Stage</u>	<u>Skin</u>	<u>Liver</u>	<u>Lower GI</u>	<u>Upper GI</u>
0	No rash	Bilirubin < 2 mg/dL	Diarrhea Adult: < 500 mL/day or < 280 mL/m2 Child: < 10 mL/kg/day	No or intermittent nausea or vomiting
1	Maculopapular rash on < 25% of BSA	Bilirubin 2–3 mg/dL	Diarrhea Adult: 500–1000 mL/day or 280–555 mL/m2 Child: 10–19 mL/kg/day	Persistent nausea, vomiting or anorexia
2	Maculopapular rash on ≥ 25% - 50% of BSA	Bilirubin 3.1–6 mg/dL	Diarrhea Adult: 1001–1500 mL/day or 556–833 mL/m2 Child: 20–30 mL/kg/day	N/A
3	Maculopapular rash on > 50% BSA or generalized erythroderma	Bilirubin 6.1–15 mg/dL	Diarrhea Adult: > 1500 mL/day or >833 mL/m2 Child: > 30 mL/kg/day	N/A
4	Generalized erythroderma with bullous and desquamation	Bilirubin >15 mg/dL	Severe abdominal pain with or without ileus or stool with frank blood or melena (regardless of stool volume)	N/A

HCPCS	Description	Brand name
J3402	Injection, remestemcel-l-rknd, per therapeutic dose	Ryoncil
**Refer to DHCS Physician-Administered Drugs (PADs) Special Billing for Ryoncil for billing information and follow allowable number of units to approve. **		

REFERENCES:

1. Ryoncil Prescribing Information. www.ryoncil.com/pdfs/prescribing-information.pdf?1. 09/2025.
2. Rowlings PA, Przepiorka D, Klein JP, et al. IBMTR Severity Index for grading acute graft-versus-host disease: retrospective comparison with Glucksberg grade. British journal of haematology. 1997;97(4):855-864.
3. Mesoblast, Inc. A Single-arm, Prospective Study of Remestemcel-L, Ex-vivo Cultured Adult Human Mesenchymal Stromal Cells, for the Treatment of Pediatric Participants Who Have Failed to Respond to Steroid Treatment for Acute Graft-Versus-Host Disease (aGVHD). NLM Identifier: NCT02336230. [cdn.clinicaltrials.gov/large-docs/30/NCT02336230/Prot_SAP_000.we can add for members ages >12, T/F JAKafipdf](https://cdn.clinicaltrials.gov/large-docs/30/NCT02336230/Prot_SAP_000.we%20can%20add%20for%20members%20ages%20>12,%20T/F%20JAKafipdf)
4. National Comprehensive Cancer Network (NCCN) Hematopoietic Cell Transplantation www.nccn.org/professionals/physician_gls/pdf/hct.pdf. Version 2.2026. April 2026.
5. Penack O, Marchetti M, Aljurf M, et al. Prophylaxis and management of graft-versus-host disease after stem-cell transplantation for haematological malignancies: updated consensus recommendations of the European Society for Blood and Marrow Transplantation. The Lancet Haematology. 2024; 11(2): e147-e159. www.thelancet.com/action/showPdf?pii=S2352-3026%2823%2900342-3

P&T APPROVAL HISTORY:

May 2025 P&T Drug Review