Medical Policy:

Ryoncil® (remestemcel-L-rknd) intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.437	April 30, 2025	April 30, 2025

Definitions

Ryoncil is an allogeneic bone marrow-derived mesenchymal stromal cell therapy indicated for the treatment of steroid-refractory acute graft-versus-host disease (GVHD) in pediatric patients ≥ 2 months of age

Length of Authorization

Coverage will be provided for 1 month and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time) [HCPCS Unit]:

• 225 million MSC twice a week for 4 weeks (up to 16 total doses)

Guideline

I. INITIAL CRITERIA

Coverage for is provided for treatment of the following conditions:

• Patient is at least 2 months of age; **AND**

1. **Acute Graft-Versus-Host Disease (aGVHD) †**

A. Patient has steroid-refractory disease (defined as disease that shows progression within 3 days, or no improvement within 7 days of consecutive treatment with 2 mg/kg/day methylprednisolone or equivalent); **AND**
B. Patient does not have skin-only involvement or evidence of encephalopathy or diffuse alveolar hemorrhage or other active pulmonary disease; **AND**
C. Patient does not have a known hypersensitivity to dimethyl sulfoxide (DMSO) or porcine and bovine proteins; **AND**
D. Patient is post-allogeneic stem cell transplant (*Note: Symptoms of aGVHD typically appear before day 100)*

II. RENEWAL CRITERIA

1. Patient continues to meet the universal and other indication-specific relevant criteria identified in Initial Criteria; **AND**
2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion related reactions, hypersensitivity reactions, etc.; **AND**
   A. Patient has experienced at minimum a partial response (defined as organ improvement of at least 1 stage without worsening in any other organ) OR a mixed response (defined as improvement in at least 1 evaluable organ with worsening in another); **AND**
      i. Patient will require treatment with four additional (weekly) doses; **OR**
   B. Patient is experiencing an aGVHD flare after achieving a complete response [CR]); **AND**
      i. Patient will require treatment with eight additional (twice weekly) doses

Note: Patients who experience a complete response (defined as resolution of aGVHD in all involved organs) OR no response, may not renew coverage and will be reviewed on a case-by-case basis

Applicable Procedure Codes

Code	Description
C9399	Unclassified drugs or biologicals
J3590	Unclassified biologics

Applicable NDCs

Code	Description
73648-00111-xx	Ryoncil <12.5kg 1 x 3.8 ML
73648-0112-xx	Ryoncil 12.5kg To <25kg 2 x 3.8 ML
73648-0113-xx	Ryoncil 25kg To <37.5kg 3 x 3.8 ML
73648-0114-xx	Ryoncil 37.5kg To <50kg 4 x 3.8 ML
73648-0115-xx	Ryoncil 50kg To <62.5kg 5 x 3.8 ML
73648-0116-xx	Ryoncil 62.5kg To <75kg 6 x 3.8 ML
73648-0118-xx	Ryoncil 75kg To <87.5kg 7 x 3.8 ML
73648-0118-xx	Ryoncil 87.5kg To <100kg 8 x 3.8 ML

ICD-10 Diagnoses

Code	Description
D89.810	Acute Graft-Versus-Host Disease

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	04/30/2025	New Policy

References

1. Ryoncil® intravenous infusion [prescribing information]. New York, NY: Mesoblast; December 2024.