

## Medical Policy:

### Ryoncil® (remestemcel-L-rknd) intravenous infusion

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## 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) [HCP/CS 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.