Reference number(s)
6773-A

Standard Medicare Part B Management
Ryoncil

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ryoncil	remestemcel-L-rknd

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Acute Graft versus Host Disease

Ryoncil is indicated for the treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months of age and older.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Acute Graft versus Host Disease (aGvHD)[1]

Authorization of 2 months (maximum of 8 infusions) may be granted for treatment of acute graft versus host disease when all of the following criteria are met:

© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

- The member is a pediatric patient
- The disease is steroid-refractory (progressed within 3 days or did not improve within 7 consecutive days of treatment with methylprednisolone 2 mg/kg/day or equivalent)

Continuation of Therapy

Authorization for 2 months may be granted when either of the following criteria are met:

Partial or mixed response (Maximum of 4 infusions)

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication listed in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
    - An improvement in symptoms AND
    - No evidence of unacceptable toxicity while on the current regimen

Recurrence after complete response with the requested medication (Maximum of 8 infusions)

- All members (including new members) requesting authorization for continuation of therapy must meet all the requirements in the coverage criteria section.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Ryoncil.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Ryoncil are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

References

1. Ryoncil [package insert]. New York, NY: Mesoblast, Inc.; September 2025.

© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.