

Specialty Guideline 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 Indication

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 are considered experimental/investigational and not medically necessary.

Coverage Criteria

Acute Graft versus Host Disease

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:

- 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 of 2 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when either of the following criteria are met:

- Partial or mixed response - there is an improvement in symptoms and there is no evidence of unacceptable toxicity while on the current regimen. (Maximum of 4 infusions)
- Recurrence after complete response -all members (including new members) requesting authorization for continuation of therapy must meet all the requirements in the coverage criteria section. (Maximum of 8 infusions)

References

1. Ryoncil [package insert]. New York, NY: Mesoblast, Inc.; December 2024.