

Reference number(s)
6772-A

# 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.

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# 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.