October 1, 2025

PRIOR AUTHORIZATION CRITERIA FOR RYONCIL EFFECTIVE OCT. 1, 2025

BACKGROUND

On Oct. 1, 2025, Ryoncil, will become a benefit of Medicaid and CHIP. HHSC requires prior authorization for Ryoncil (procedure code J3402) for Medicaid and CHIP, effective for dates of service on or after Nov. 1, 2025.

KEY DETAILS

Ryoncil (remestemcel-L-rknd) is an allogenic bone marrow-derived mesenchymal stromal cell (MSC) therapy approved to treat steroid-refractory acute graft versus host disease (SR-aGVHD) in pediatric clients 2 months of age and older.

Prior Authorization Requirements

Prior authorization approval for an intravenous infusion of Ryoncil (remestemcel-L-rknd) J3402, will be considered when the following criteria are met:

- Client is at least 2 months or older;
- Client has a confirmed diagnosis of aGVHD (diagnosis code – D89.810) following an allogenic hematopoietic stem cell transplant;
- Client has no known hypersensitivity to dimethyl sulfoxide or porcine and bovine proteins; and
- Client's aGVHD is steroid-refractory, as documented by the following:
  - Progression of acute GVHD within three days of consecutive treatment with 2 mg/kg/day of methylprednisolone or equivalent.
  - No signs of improvement within 7 days of therapy with 2mg/kg/day of methylprednisolone or equivalent treatment.

Continuation Therapy

For continuation of Ryoncil therapy, providers are required to monitor the client for the parameters listed below:

- Client has received Ryoncil for at least 28 days;
- Client has documentation of partial or mixed response to Ryoncil treatment; and
- Client is currently receiving or has received Ryoncil without any serious or life-threatening reactions.

RESOURCES

Policy or Operational Documents:	TMPPM Outpatient Drug Services Handbook