TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Remestemcel-L-rknd (Ryoncil)	**CRITERIA ID:** TX.CC.PHAR.54
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 10/1/2025	**PRODUCT(S):** STAR, STAR Kids, STAR Health, STAR Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: N/A	**REGULATOR MOST RECENT APPROVAL DATE(S):**

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for Remestemcel-L-rknd (Ryoncil)

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a Precision Drug. Centene's Precision Drug Action Committee (PDAC) creates a standardized approach for Centene to manage Precision Drugs and the associated costs for their administration, prior to members presenting with a request for one of these agents. All Precision Drug requests or potential requests must be reported to the PDAC for tracking, regardless of whether agents are carved out, passed through, etc. All Precision Drug medical necessity determinations will be supported by PDAC UM recommendation, utilizing specialist input as directed and allowed by turnaround times.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
PDAC = Precision Drug Action Committee
UM = Utilization Management
CPS = Centene Pharmacy Service
SHP = Superior HealthPlan
SR-aGvHD = steroid-refractory acute graft versus host disease

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of Remestemcel-L-rknd (Ryoncil); procedure code: J3402.

Description/Mechanism of Action:
The mechanism of action of remestemcel-L is unknown. It is thought to be related to immunomodulatory effects. In vitro studies show that mesenchymal stromal cells inhibit T cell activation as measured by proliferation and secretion of pro-inflammatory cytokines.

FDA Approved Indications:
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

Formulations:
RYONCIL is available as a cell suspension for intravenous infusion in a target concentration of 6.68 X 106 MSCs per mL in 3.8 mL contained in a 6 mL cryovial

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Steroid-refractory acute graft versus host disease

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization but ultimate determination will be made by the Medical Director only.
2. Medical necessity determinations will be supported by PDAC UM recommendation. The CPS or SHP pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the medical director but will not make the ultimate determination on any case.
3. Client is at least 2 months or older;
4. Client has a confirmed diagnosis of aGVHD (diagnosis code – D89.810) following an allogenic hematopoietic stem cell transplant;
5. Client has no known hypersensitivity to dimethyl sulfoxide or porcine and bovine proteins; and
6. Client's aGVHD is steroid-refractory, as documented by the following:
    a. Progression of acute GVHD within three days of consecutive treatment with 2 mg/kg/day of methylprednisolone or equivalent.
    b. No signs of improvement within 7 days of therapy with 2mg/kg/day of methylprednisolone or equivalent treatment.

Approval duration: 6 months

II. Continuation Criteria

A. Steroid-refractory acute graft versus host disease

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization but ultimate determination will be made by the Medical Director only.
2. Medical necessity determinations will be supported by PDAC UM recommendation. The CPS or SHP pharmacy clinician will review the UM recommendation with the prior

authorization request for clinical appropriateness and make a recommendation to the medical director but will not make the ultimate determination on any case.

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

Approval duration: 6 months

REFERENCES:
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS:

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document	N/A	9/26/2025