SENTARA COMMUNITY PLAN
(MEDICAID)

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-305-2331**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

Drug Requested: Ryoncil® (remestemcel-L-rknd) **J3402 (MEDICAL)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosing Limits:

A. Max Units (per dose and over time) [HCPCS Unit]:

- 225 million MSC twice a week for 4 weeks (up to 16 total doses)

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 30 days (one month)

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- ❑ Member is at least 2 months of age
- ❑ Member has a diagnosis of acute graft-versus-host disease (aGVHD)
- ❑ Member has steroid-refractory disease **(NOTE: defined as disease that shows progression within 3 days, or no improvement within 7 days of consecutive treatment with 2 mg/kg/day methylprednisolone or equivalent)**
- ❑ For member's 12 years of age or older: Member must have had an unsuccessful trial, contraindication or intolerance to Jakafi® (ruxolitinib) **(verified by chart notes and or pharmacy paid claims)**
- ❑ Member does **NOT** have skin-only involvement or evidence of encephalopathy or diffuse alveolar hemorrhage or other active pulmonary disease
- ❑ Member does **NOT** have a known hypersensitivity to dimethyl sulfoxide (DMSO) or porcine and bovine proteins
- ❑ Member is post-allogeneic stem cell transplant **(NOTE: Symptoms of aGVHD typically appear before day 100)**

Reauthorization: 30 days (one month). Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., severe infusion related reactions, hypersensitivity reactions)
- ❑ Member must meet **ONE** of the following **(submit documentation)**:
  - ❑ Member has experienced at minimum a partial response **(defined as organ improvement of at least 1 stage without worsening in any other organ)** and will require treatment with four additional (weekly) doses
  - ❑ Member has experienced a mixed response **(defined as improvement in at least 1 evaluable organ with worsening in another)** and will require treatment with four additional (weekly) doses
  - ❑ Member is experiencing an aGVHD flare after achieving a complete response [CR]) and will require treatment with eight additional (twice weekly) doses

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Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

***Approved by Pharmacy and Therapeutics Committee: 5/22/2025**
REVISED/UPDATED/REFORMATTED: 6/4/2025

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****