ATRIO HEALTH PLANS

Graft vs Host Disease

Ryoncil (remestemcel-l-rknd/ td) **J3402**

Prior Authorization Request

Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ **Ryoncil**

☐ Patient has confirmed diagnosis of aGVHD following an allogenic hematopoietic stem cell transplant;

☐ Documentation supports SR-aGvHD Grade B to Grade D

- ☐ Grade B – Stage 2 skin involvement; Stage 1 to 2 gut or liver involvement
- ☐ Grade B excludes skin only involvement
- ☐ Grade C – Stage 3 skin, liver, or gut involvement
- ☐ Grade D – Stage 4 skin, liver, or gut involvement

☐ Patient'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 improvement within 7 days of therapy with 2mg/kg/day of methylprednisolone or equivalent treatment.

☐ Patient' baseline renal function defined as a creatinine clearance > 30 mL/min per 1.73m2 prior to initiating Ryoncil

Please provide **clinical rationale** for any formulary exception: _____

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ Patient had an **adequate response** or **significant improvement** while on this medication.

☐ Chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

☐ o Documentation must show either partial response, mixed response, or recurrence of aGvHD following complete response

- Partial response is defined as organ improvement of at least one stage without worsening in any other organ
- Mixed response is defined as improvement of at least one evaluable organ with worsening in another organ as per International Blood and Marrow Transplantation Registry Severity Index Criteria grading system

☐ Must continue to be prescribed by or in consultation with an oncologist, hematologist, or other specialist

☐ **Member has/will not exceed more than 16 doses of Ryoncil (remestemcel-L-rknd) in total and/or 24 total months of therapy.**

If not, please provide clinical rationale for continuing this medication: _____

_____

- ***Must not be used concurrently with Jakafi (ruxolitinib), Imbruvica (ibrutinib), or Rezurock (belumosudil)***

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Graft vs Host Disease Prior Authorization

Drug Name(s):

RYONCIL **REMESTEMCEL-L-RKND**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
3. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan in accordance with the label.

Exclusion Criteria:

N/A

Prescriber Restrictions:

Oncologist, Hematologist or other related specialist

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Ryoncil

- Acute graft-versus-host disease, Steroid refractory

Off-Label Uses:

N/A

Age Restrictions:

N/A

Other Clinical Consideration:

- **Contraindication: Known hypersensitivity to dimethyl sulfoxide (DMSO) or porcine and bovine proteins**

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Ryoncil&UserSearchTerm=Ryoncil&SearchFilter=filterNone&navitem=searchGlobal#