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of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 02/12/2026

Ryoncil® (remestemcel-L)

HCPCS: J3402

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved indication
 - b. FDA approved age
 - c. Member has demonstrated progression of disease by day 5 or nonresponse by day 7 while on corticosteroids.
 - d. Trial and failure, contraindication, or intolerance to Jakafi® (ruxolitinib) when age appropriate per FDA labeling.
 - e. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by BCBSM.
 - f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list.
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing
 - b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
 - c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Ryoncil is an allogeneic bone marrow-derived mesenchymal stromal cell (MSC) therapy indicated for the treatment of steroid-refractory acute graft versus host disease (SR-aGVHD) in pediatric patients 2 months of age and older.
- Acute GVHD occurs in approximately 50% of patients who receive an allogeneic bone marrow transplant (BMT). Over 30,000 patients worldwide undergo an allogeneic BMT annually, primarily during treatment for blood cancers, including about 20% in pediatric patients. SR-aGVHD is associated with mortality as high as 90% and significant extended hospital stay costs. Prior to the approval of Ryoncil, there were no FDA-approved treatments in the US for children under 12 with SR-aGVHD. GVHD has been classically divided into acute and chronic variants based on the time of onset using a cutoff of 100 days. However, this conventional division has been challenged by the recognition that signs of acute and chronic GVHD may occur outside of these designated periods. Acute GVHD manifestations include: classic maculopapular rash, abdominal cramps with diarrhea, and rising serum bilirubin concentration. Patients who demonstrate progression of disease by day 5 or nonresponse by day 7 are considered to have corticosteroid resistance.
- The National Comprehensive Cancer Network (NCCN) Hematopoietic Cell Transplantation (HCT) guidelines Version 3.2025 recommend Jakafi as a category 1 option for patients with SR-aGVHD. At this time, Jakafi is only indicated for patients 12 years and older with SR-aGVHD. Per UpToDate for patients with aGVHD grade 2 or higher, systemic glucocorticoids are recommended.
- The safety and effectiveness of Ryoncil were evaluated in a multicenter, single-arm study in 54 pediatric study participants with SR-aGVHD after undergoing allogeneic hematopoietic stem cell transplantation (allo-HSCT). The study enrolled pediatric patients with SR-aGVHD Grade B to D (excluding Grade B skin alone) as per International Blood and Marrow Transplantation Registry Severity Index Criteria (IBMTR) after receiving allo-HSCT. SR-aGVHD was defined as aGVHD that progressed within 3 days or did not improve within 7 consecutive days of treatment with methylprednisolone 2 mg/kg/day or equivalent.
 - The main efficacy outcome measures were Day-28 overall response rate (complete response rate and partial response rate) and the duration of response.
 - The overall response rate was 70% with sixteen study participants (30%) having had a complete response to treatment 28 days after receiving Ryoncil, and 22 study participants (41%) having had a partial response.
 - Overall response rate at Day-28 by baseline disease severity is as follows: Grade B (3/6; 50%), Grade C (16/23; 70%), and Grade D (19/25; 76%).
 - The median duration of response, as calculated from Day-28 response to either progression (worsening by one stage in any organ without improvement in other organs in comparison to prior response assessment), new systemic therapy for aGVHD, or death from any cause, was 54 days

References:

1. Ryoncil [prescribing information]. New York, NY. Mesoblast, Inc. December 2024
2. BioSpace. Press Release. Mesoblast's RYONCIL® is the First U.S. FDA-Approved Mesenchymal Stromal Cell (MSC) Therapy - BioSpace December 18, 2024
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Hematopoietic Cell Transplantation (HCT) (Version 3.2025)– September 24, 2025. NCCN.org
4. Chao NJ. Clinical manifestations, diagnosis, and grading of chronic graft-versus-host-disease. UpToDate. <https://www.uptodate.com/contents/clinical-manifestations-diagnosis-and-grading-of-chronic-graft-versus-host-disease> accessed August 2021

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

Policy History												
#	Date	Change Description										
1.6	Effective Date: 02/12/2026	Annual review – No changes to the criteria were made at this time.										
1.5	Effective Date: 03/03/2025	UM medical management system update for MAPPO and BCNA <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	Yes											
BCNA	Yes											
1.4	Effective Date: 03/31/2025 P&T Date: 02/13/2025	New policy. This criteria replaces previously approved preliminary criteria.										
1.3	Effective Date: 01/09/2025	UM medical management system update for BCBS and BCN <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
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BCBS	Yes											
BCN	Yes											
MAPPO	No											
BCNA	No											
1.2	Effective Date: 12/12/2024	Updated authorization period to align with OncoHealth preferred verbiage.										
1.1	Effective Date: 06/06/2024	Annual review of criteria was performed, no changes were made.										
1.0	Effective Date: 06/08/2023	Preliminary drug review <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
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MAPPO	No											
BCNA	No											

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.

Blue Cross Blue Shield/Blue Care Network of Michigan

Medication Authorization Request Form



This form is to be used by participating physicians to obtain coverage for **drugs covered under the medical benefit**. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

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PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	Name
ID Number	Specialty
D.O.B. ☐ Male ☐ Female	Address
Diagnosis	City /State/Zip
Drug Name	Phone/Fax: P: () - F: () -
Dose and Quantity	NPI
Directions	Contact Person
Date of Service(s)	Contact Person Phone / Ext.

STEP 1: DISEASE STATE INFORMATION

- Is this request for: ☐ Initiation ☐ Continuation *Date patient started therapy:* _____
- Administered by patient or a medical professional? ☐ patient (self) ☐ health care professional (physician, nurse, etc.)
- Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
☐ Hospital outpatient facility (go to #4) *Reason for Hospital Outpatient administration:* _____
☐ Hospital inpatient facility for Car-T therapy only (for example: Kymriah, Yescarta, or Tecartus) (go to #5)
- Please specify location of administration if hospital outpatient infusion: _____
- Please specify location of administration if hospital inpatient infusion: _____
- Please provide the NPI number for the place of administration: _____
- Initiation AND Continuation of therapy:**
 - What is the patient's diagnosis? _____
 - What other medication has the patient received for their condition? Please list _____
 - Please describe the response to previous therapies: _____
 - Will the patient be receiving any other treatment for the listed condition while on this medication? Please list: _____
 - Please list any labs values important for diagnosing or monitoring this patient's condition: _____
- Continuation of therapy:**
 - Has the patient progressed while on this medication? ☐ yes ☐ no
 - How has the patient's condition changed while on this medication?

☐ Improved: Please describe: _____
 ☐ Stable: please describe: _____
 ☐ Worsened; Please describe: _____
 ☐ Other; Please describe: _____

Chart notes are required for the processing of all requests. Please add any other supporting medical information necessary for our review (required)

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name	Physician Signature	Date
Step 2: Checklist	☐ Form Completely Filled Out ☐ Provide chart notes	☐ Attach test results
Step 3: Submit	By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979	By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320

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7/26/2018, 9/18/2018; 1/31/2020; 3/17/2020; 8/9/2021