Rezurock (belumosudil)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Rezurock (belumosudil) drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Rezurock is indicated for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy.

POLICY

Criteria for Initial Approval

Chronic Graft versus Host Disease (cGVHD)

Authorization of 12 months may be granted for treatment of cGVHD when all of the following criteria are met:

1. The member has failed two or more lines of systemic therapy
2. The member is at least 12 years of age

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for treatment of cGVHD when all of the following criteria are met:

1. The member does not have evidence of unacceptable toxicity while on the current regimen

2. The member has not experienced clinically significant progression of cGVHD (i.e., progression that requires new systemic therapy) while on the current regimen

Rezurock is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Medication	Quantity Limit	FDA-recommended dosing
Rezurock (belumosudil) 200 mg tablets	30 per 30 days	Standard dosing: 200 mg orally once daily

CLINICAL RATIONALE

Background

Graft-versus-host disease (GVHD) is a condition that can develop after an allogeneic hematopoietic cell transplant (HCT), in which the donor lymphocytes recognize the recipient's tissues as foreign, resulting in immune-mediated cellular injury of several bodily organs, such as the skin, gastrointestinal (GI) tract, and the liver. GVHD is a major complication of allogeneic HCT and is associated with significant morbidities and mortality. GVHD can be classified as acute or chronic GVHD; Acute GVHD is characterized by maculopapular rash, GI complications including nausea, vomiting, anorexia, and diarrhea, and hyperbilirubinemia and typically occurs in the early posttransplant period while chronic GVHD usually develops within the first year after HCT but can also develop many years later and is associated with features such as fasciitis, lichen sclerosis–like skin changes, and esophageal webbing.

First-line therapy for the treatment of chronic GVHD includes continuation or resumption of original immunosuppressive agent with/or systemic corticosteroids About 50% of patients will not respond and be classified as having steroid-refractory disease, and enrollment in a clinical trial or the addition of a systemic agent to corticosteroids with a steroid taper as clinically feasible is indicated. While many immunosuppressant agents (e.g., calcineurin inhibitors, hydroxychloroquine, methotrexate, mycophenolate mofetil) are used off-label for cGVHG, only Rezurock and Imbruvica (ibrutinib) are FDA-approved for this indication.

Efficacy

The efficacy of Rezurock was evaluated in a phase II, open-label, randomized, multicenter trial (ROCKstar). The trial enrolled 132 patients who had a diagnosis of cGVHD and had failed 2-5 prior lines-of-treatment and were on a stable dose of corticosteroids for two weeks prior to screening. Patients were excluded if they were currently receiving Imbruvica but were allowed if there had been a washout period of at least 28 days. Patients were randomized to receive Rezurock 200 mg daily or Rezurock 200 mg twice daily with a primary endpoint of overall response rate (ORR) and key secondary endpoints of duration of response (DOR), failure-free survival, and reduction in Lee Symptom Scale (LSS) score.

Endpoint	Rezurock 200 mg PO daily (n=66)	Rezurock 200mg PO BID (n=66)
ORR	73%	74%

CR	5%	2%
PR	68%	73%
DOR	Not reached	Not reached
Estimate of failure-free surival at 6 months	74% (95% CI 61 to 83)	81% (95% CI 70 to 89)
≥ 7-point reduction of LSS score	39%	33%
Median follow-up of 8 months; median time to response was 4 weeks		

Safety

In ROCKstar, the incidence of treatment-emergent adverse events was 71% and serious AEs occurred in 9% of patients. The most common reactions were infections, weakness, vomiting, diarrhea, and dyspnea. Infection was the most common grade 3 or 4 adverse event, occurring in 16% of patients and sixteen patients discontinued Rezurock due to TEAEs. Additionally, there were 8 deaths within the study population, 4 of which the FDA reviewer determined were unrelated to Rezurock and 4 of which a relation could not be excluded. This was considered tolerable in this patient population. The manufacture recommends monthly liver function test monitoring.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Not applicable (N/A)

REFERENCES

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- National Comprehensive Cancer Network (NCCN). Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Hematopoietic Cell Transplantation V.3.2021. © National Comprehensive Cancer Network, Inc 2021. All rights reserved. Accessed 2021 August 19. To view the most recent and complete version of the guideline, go online to NCCN.org. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, NCCN GUIDELINES®, and all other NCCN Content are trademarks owned by the National Comprehensive Network, Inc.
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POLICY HISTORY

Policy #: 05.04.45
Original Effective Date: November 12, 2021
Reviewed: February 2022
Revised: October 2021
Current Effective Date: November 12, 2021