



DRUG QUANTITY MANAGEMENT POLICY – PER RX

- POLICY:** Immunosuppressive Agents – Rezurock Drug Quantity Management Policy – Per Rx
- Rezurock® (belumosudil tablets – Kadmon)

REVIEW DATE: 09/24/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Rezurock, a kinase inhibitor, is indicated for the treatment of **chronic graft-versus-host disease (GVHD)** in patients ≥ 12 years of age after failure of at least two prior lines of systemic therapy.¹

Dosing

The recommended dose of Rezurock is 200 mg given orally once daily until progression of chronic GVHD that requires new systemic therapy.¹ Rezurock tablets should be swallowed whole; do not cut, crush, or chew. The dose of Rezurock should be increased to 200 mg twice daily when it is co-administered with strong cytochrome P450(CYP)3A inducers or proton pump inhibitors.

Availability

Rezurock is available as 200 mg tablets in bottles of 30.¹

POLICY STATEMENT

This Drug Quantity Management program has been developed to prevent stockpiling and waste, and address potential order entry error of Rezerox. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Rezerox® (belumosudil tablets)	200 mg tablets	30 tablets	90 tablets

Immunosuppressive Agents – Rezerox Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

1. If the patient is taking Rezerox with a strong cytochrome P450(CYP)3A inducer OR with a proton pump inhibitor, approve 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery.
Note: CYP3A4 inducers include, but are not limited to, rifampin, carbamazepine, phenobarbital, phenytoin, rifabutin, rifapentine, and St. John's Wort. Examples of proton pump inhibitors include, but are not limited to, lansoprazole, omeprazole, rabeprazole, esomeprazole, pantoprazole, and dexlansoprazole.

REFERENCES

1. Rezerox® tablets [prescribing information]. Warrendale, PA: Kadmon; April 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/20/2023
Annual Revision	No criteria changes.	09/24/2024

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