Cigna National Formulary Coverage Policy

Drug Quantity Management – Per Rx
Potassium Binders – Lokelma® (sodium zirconium cyclosilicate for oral suspension)

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Product Identifer(s)

Effective 1/1/23 to 2/27/23: 109265

Effective 2/28/23: 63480

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. 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.

National Formulary Medical Necessity

This Drug Quantity Management program has been developed to manage dose titration and provide for dose consolidation of Lokelma. 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, unless otherwise noted below.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Lokelma® (sodium zirconium cyclosilicate for oral suspension)	5 gram packets	30 packets	90 packets
	10 gram packets	30 packets	90 packets

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

Lokelma 5 gram packets

1. If the individual requires a maintenance dose of 15 grams daily, approve 90 packets per dispensing at retail and 270 packets per dispensing at home delivery.

Lokelma 10 gram packets

1. If the individual is initiating therapy with Lokelma, approve a one-time override for the requested quantity, not to exceed 34 packets at retail and 94 packets at home delivery.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview
Lokelma, a potassium-binder, is indicated for the treatment of **hyperkalemia** in adults.[1]

Dosing
The recommended starting dose of Lokelma is 10 grams administered orally three times a day for up to 48 hours.[1] For maintenance treatment, the recommended dose is 10 grams once daily. The dose may be titrated up based on the serum potassium level at intervals of 1 week or longer and in increments of 5 grams. Decrease the dose of Lokelma or discontinue if serum potassium is below the target range. The recommended maintenance dose is from 5 grams every other day to 15 grams daily.

In patients receiving chronic hemodialysis, the recommended starting dose is 5 grams once daily administered only on non-dialysis days.[1] A starting dose of 10 grams once daily on non-dialysis days if the patient's serum potassium is > 6.5 mEq/L. Monitor potassium and adjust the Lokelma dose based on pre-dialysis serum potassium value after the long inter-dialytic interval and desired target range. The recommended maintenance dose is from 5 grams to 15 grams once daily, on non-dialysis days.

Availability
Lokelma is available in 5 gram and 10 gram packets.[1]

References

1. Lokelma® powder for oral suspension [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; October 2021.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No criteria changes.	09/20/2022