Effective Date **9/1/2023**
Next Review Date **9/1/2024**
Coverage Policy Number **IP0190**

Oral Antihistamines

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Related Coverage Resources

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.

Overview

This policy supports medical necessity review for the following oral antihistamines:

- **carbinoxamine maleate**
- **clemastine fumarate**
- **dexchlorpheniramine maleate**
- **RyClora™** (dexchlorpheniramine maleate)

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

The product(s) in the table below are considered medically necessary when the following are met:

Employer Group Non-Covered Products and Preferred Covered Alternatives by Drug List:

Non-Covered Product	Criteria
carbinoxamine maleate 6 mg tablet **clemastine fumarate** 0.5 mg/mL syrup **dexchlorpheniramine maleate** 2 mg/5mL solution **Ryclora** (dexchlorpheniramine) 2 mg/5mL solution	There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **THREE** of the following: • carbinoxamine maleate oral solution • cetirizine oral solution • cyproheptadine hydrochloride oral syrup • fexofenadine oral suspension • hydroxyzine oral syrup • loratadine oral solution *Prescription or OTC products count toward meeting the requirement.*

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Oral antihistamines are considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration is up to 12 months.

Reauthorization approval duration is up to 12 months.

Background

OVERVIEW

Histamine H_1 receptor blocker with anticholinergic and sedative properties, are effective (indicated) for the symptomatic treatment of seasonal and perennial **allergic rhinitis**, **vasomotor rhinitis**, **allergic conjunctivitis**, mild and uncomplicated allergic manifestations of urticarial and angioedema, and **dermatographism**.[1-4] They are also effective (indicated) as a therapy for anaphylactic reactions as an adjunct to epinephrine and other standard measures after acute manifestations are controlled and amelioration of the severity of allergic reactions to blood or plasma. All carbinoxamine maleate products are contraindicated in children younger than 2 years old.[1-4]

References

1. Carbinoxamine maleate tablets and oral solution [prescribing information]. Berlin, CT: Breckenridge; May 2019.
2. Carbinoxamine maleate 6 mg tablets [prescribing information]. Trussville, AL: Foxland; November 2017.
3. RyVent™ tablets [prescribing information]. Hazlet, NJ: Carwin; September 2016.
4. Karbinal™ ER oral suspension [prescribing information]. Englewood, CO: Aytu; August 2021.
5. Clinical Pharmacology [database online]. Elsevier; 2023. Available at: Clinical Pharmacology Home (clinicalkey.com). Accessed on April 12, 2023. Search terms: Carbinoxamine