

STEP THERAPY POLICY

- POLICY:** Carbinoxamine Step Therapy Policy
- Carbinoxamine maleate 6 mg tablets (generics)
 - RyVent™ (carbinoxamine maleate 6 mg tablets – Carwin Pharmaceuticals)
 - Karbinal™ ER (carbinoxamine maleate 4 mg/5 ml oral suspension, extended-release – Aytu Therapeutics, LLC)

REVIEW DATE: 04/07/2021

OVERVIEW

Carbinoxamine maleate, a histamine H₁ receptor blocker with anticholinergic and sedative properties, is 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 It is 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

Table 1. Comparison of Carbinoxamine Dose¹⁻⁵

Age	Oral dose of tablets containing carbinoxamine 4 mg	Oral dose of tablets containing carbinoxamine 6 mg	Oral dose of solution containing 4 mg/5 mL	Oral dose of extended-release suspension containing carbinoxamine 4 mg/5 mL
Adults	1 to 2 tablets (4 to 8 mg) orally 3 to 4 times daily	1 tablet (6 mg) orally 3 to 4 times daily	5 to 10 mL (4 to 8 mg) orally 3 to 4 times daily	7.5 to 20 mL (6 to 16 mg) orally every 12 hours
Children 12 years of age and older	1 to 2 tablets (4 to 8 mg) orally 3 to 4 times daily	Not recommended	5 to 10 mL (4 to 8 mg) orally 3 to 4 times daily	7.5 to 20 mL (6 to 16 mg) orally every 12 hours
Children 6 to 11 years of age	0.5 to 1 tablet (2 to 4 mg) orally 3 to 4 times daily	Not recommended	2.5 to 5 mL (2 to 4 mg) orally 3 to 4 times daily (approximately 0.2 to 0.4 mg/kg/day)	7.5 to 15 mL (6 to 12 mg) orally every 12 hours (approximately 0.2 to 0.4 mg/kg/day)
Children 2 to 5 years of age	Not recommended	Not recommended	1.25 to 2.5 mL (1 to 2 mg) 3 to 4 times daily (approximately 0.2 to 0.4 mg/kg/day; dose should be based on weight whenever possible)	Children 4 to 5 years of age: 3.75 to 10 mL (3 to 8 mg) every 12 hours Children 2 to 3 years of age: 3.75 to 5 mL (3 to 4 mg) every 12 hours (approximately 0.2 to 0.4 mg/kg/day)

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: carbinoxamine 4 mg tablets, carbinoxamine 4 mg/5 ml liquid

Step 2: carbinoxamine maleate 6 mg tablets, RyVent 6 mg tablets, Karbinal ER 4 mg/5 ml suspension

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. No other exceptions are recommended.

REFERENCES

1. Carbinoxamine maleate tablets and oral solution [prescribing information]. Berlin, CT: Breckenridge Pharmaceutical, Inc.; May 2019.
2. Carbinoxamine maleate 6 mg tablets [prescribing information]. Trussville, AL: Foxland Pharmaceuticals, Inc.; November 2017.
3. RyVent™ tablets [prescribing information]. Hazlet, NJ: Carwin Pharmaceutical Associates, LLC: September 2016.
4. Karbinal™ ER oral suspension [prescribing information]. Englewood, CO: Aytu BioScience, Ind.; August 2018.
5. Clinical Pharmacology [database online]. Gold Standard, Inc.; 2021. Available at: <http://www.clinicalpharmacology-ip.com/Default.aspx>. Accessed on March 30, 2021. Search terms: Carbinoxamine