



STEP THERAPY POLICY

- POLICY:** Carbinoxamine Step Therapy Policy
- Carbinoxamine maleate 6 mg tablets (generic)
 - Carbzah (carbinoxamine maleate solution – IPG)
 - RyVent™ (carbinoxamine maleate 6 mg tablets – Carwin)
 - Karbinal™ ER (carbinoxamine maleate 4 mg/5 ml oral suspension, extended-release – Aytu)

REVIEW DATE: 09/24/2025

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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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

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 < 2 years of age.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 years 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)	<u>Children 4 to 5 years of age:</u> 3.75 to 10 mL (3 to 8 mg) every 12 hours <u>Children 2 to 3 years of age:</u> 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.

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

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

Carbinoxamine Step Therapy Policy product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

REFERENCES

1. Carbinoxamine maleate tablets and oral solution [prescribing information]. Allentown, PA: Genus Lifesciences; May 2023.
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; 2025. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed on September 19, 2025. Search terms: Carbinoxamine
6. Carbzah oral solution [prescribing information]. Tempe, AZ: IPG; June 2025

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	04/24/2024
Annual Revision	No criteria changes.	04/23/2025
Early Annual Revision	Carbzah Oral Solution: Added to the policy as a Step 2 product.	09/24/2025

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