# carbinoxamine 6 mg tablets (Ryvent™, generics)

**Policy #** 00566
Original Effective Date: 06/21/2017
Current Effective Date: 07/12/2021

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

## When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Ryvent™‡ (carbinoxamine 6 mg tablets) and generic carbinoxamine 6 mg tablets to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Ryvent (carbinoxamine 6 mg tablets) or generic carbinoxamine 6 mg tablets will be considered when BOTH of the following criteria are met:

- Patient has tried and failed generic carbinoxamine 4 mg tablets/liquid unless there is clinical evidence or patient history that suggests the use of generic carbinoxamine 4 mg tablets/liquid will be ineffective or cause an adverse reaction to the patient; AND
- Patient has tried and failed TWO additional generic prescription antihistamine products (e.g. levocetirizine, desloratadine, clemastine, diphenhydramine, etc) unless there is clinical evidence or patient history that suggests the use of TWO additional generic prescription antihistamine products will be ineffective or cause an adverse reaction to the patient

## When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Ryvent (carbinoxamine 6 mg tablets) or generic carbinoxamine 6 mg tablets when BOTH of the patient selection criteria are not met to be **not medically necessary.****

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# Background/Overview

Ryvent is a 6 mg tablet containing carbinoxamine. Recently, a 6 mg generic carbinoxamine tablet has become available at an exorbitant price that is even greater than the brand name product's price. Carbinoxamine is also generically available as 4 mg tablets and as an oral solution, and it should be noted that these formulations were the original strength carbinoxamine products on the market. Ryvent and the 6 mg generic carbinoxamine tablets are ~~is~~ approved for the exact same indications as the generic 4 mg products. Those indications are seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and foods, mild, uncomplicated allergic skin manifestations of urticarial and angioedema, dermatographism, adjunctive anaphylactic reaction therapy, and amelioration of the severity of allergic reactions to blood or plasma.

# FDA or Other Governmental Regulatory Approval

**U.S. Food and Drug Administration (FDA)**

Ryvent and the 6 mg generic carbinoxamine tablets are indicated for seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and foods, mild, uncomplicated allergic skin manifestations of urticarial and angioedema, dermatographism, adjunctive anaphylactic reaction therapy, and amelioration of the severity of allergic reactions to blood or plasma.

# Rationale/Source

Ryvent is simply a 6 mg containing carbinoxamine tablet. There is a newly existing 6 mg generic carbinoxamine tablet available at an exorbitant price that is even greater than the brand name product's price. Ryvent and the 6 mg generic carbinoxamine tablets have the exact same indications as generic carbinoxamine 4 mg tablets and liquid, which were the original strength carbinoxamine products on the market. There are no clinical studies in the package insert to give insight into any advantages of the 6 mg products. There have been no head to head studies of the 6 mg products versus generic carbinoxamine 4 mg products in a clinical setting. Based on a review of the available data, there is no advantage of using Ryvent or the 6 mg generic carbinoxamine tablets over generic carbinoxamine 4 mg products.

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# References


1. Ryvent [package insert]. Carwin Pharmaceutical Associates, LLC. Hazlet, New Jersey. September 2019.
2. Carbinoxamine 6 mg tablets [package insert]. Foxland Pharmaceuticals, Inc. September 2019.


# Policy History

Original Effective Date: 06/21/2017
Current Effective Date: 07/12/2021

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| 06/01/2017 | Medical Policy Committee review |
| 06/21/2017 | Medical Policy Implementation Committee approval. New policy. |
| 06/07/2018 | Medical Policy Committee review |
| 06/20/2018 | Medical Policy Implementation Committee approval. No change to coverage. |
| 06/06/2019 | Medical Policy Committee review |
| 06/19/2019 | Medical Policy Implementation Committee approval. No change to coverage. |
| 06/04/2020 | Medical Policy Committee review |
| 06/10/2020 | Medical Policy Implementation Committee approval. Changed the title of the policy to "carbinoxamine 6 g tablets (Ryvent, generics)". Added the newly available 6 mg carbinoxamine tablets to the policy. Updated the background and rationale sections. |
| 06/03/2021 | Medical Policy Committee review |
| 06/09/2021 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |

Next Scheduled Review Date: 06/2022

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services

at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.