BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 5/18/17**
SECTION: DRUGS	**LAST REVIEW DATE: 5/16/19**
	LAST CRITERIA REVISION DATE: 5/16/19
	ARCHIVE DATE:

KARBINAL™ER (carbinoxamine maleate) extended release oral suspension

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

KARBINAL™ER (carbinoxamine maleate) extended release oral suspension (cont.)

Criteria:

- **Criteria for initial therapy:** Karbinal ER (carbinoxamine) is considered ***medically necessary*** when **ALL** of the following criteria are met:

  1. Individual is 2 years of age or older

  2. Medical record documentation of a confirmed diagnosis of **ONE** of the following:
     - Allergic conjunctivitis due to inhalant allergens and foods
     - Amelioration of the severity of allergic reactions to blood or plasma
     - As therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled
     - Dermatographism (also known as dermographism)
     - Mild, uncomplicated allergic skin manifestations of urticaria and angioedema
     - Seasonal and perennial allergic rhinitis
     - Vasomotor rhinitis

  3. Medical record documentation that the individual is unable to use **ALL** of the following due to failure, adverse drug event, or contraindication:
     - Carbinoxamine 4 mg tablets
     - Carbinoxamine 4 mg/5 mL solution

  4. Absence of **ALL** of the following contraindications:
     - Children younger than 2 years of age
     - Woman nursing an infant of child
     - Individual who is hypersensitive to the drug or any of the inactive ingredients
     - Individual using a monoamine oxidase inhibitor

  Initial approval duration: 6 months

- **Continuation of coverage (renewal request):** Karbinal ER (carbinoxamine) is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Individual's condition responded and has not worsened while on therapy
     - Response is defined as:
       - No evidence of disease progression
       - Functionality retained in most activities of daily living
       - Documented evidence of efficacy, disease stability and/or improvement

  2. Individual has been adherent with the medication

  3. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use

  4. There are no significant interacting drugs

  Renewal duration: 12 months

KARBINAL™ER (carbinoxamine maleate) extended release oral suspension (cont.)

- Karbinal ER (carbinoxamine) for all other indications not previously listed is considered ***experimental or investigational*** based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

Description:

Karbinal ER™ contains carbinoxamine maleate, a histamine-1 receptor blocking agent. It is indicated for the symptomatic treatment of: 1) seasonal and perennial allergic rhinitis; 2) vasomotor rhinitis; 3) allergic conjunctivitis due to inhalant allergens and foods; 4) mild, uncomplicated allergic skin manifestations of urticaria and angioedema; 5) dermatographism; 6) as therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled; and 7) amelioration of the severity of allergic reactions to blood or plasma.

Carbinoxamine maleate, an ethanolamine derivative, is an antihistamine with anticholinergic (drying) and sedative properties. Carbinoxamine competes with histamine for receptor sites on effector cells in the gastrointestinal tract, blood vessels and respiratory tract.

Karbinal ER extended-release oral suspension contains carbinoxamine complexed with polistirex equivalent to 4 mg carbinoxamine maleate in 5 mL. Use of Karbinal ER 16 mg every 12 hours is equivalent to use of carbinoxamine immediate release oral solution of 8 mg every 6 hours. Carbinoxamine maleate is also available as a generic 4 mg tablet and a 4 mg/5 mL solution.

Definitions:

Dermatographism (also known as dermagraphism) – "writing on the skin"
A common localized hive reaction, characterized by abrupt onset of welts and hives where the skin is exposed to pressure, scratching, itching or stroking. The lesions are believed to be the result of inappropriate histamine release.

Resources:

Karbinal ER (carbinoxamine) product information accessed 04-29-19 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c40b3f4e-2d71-41a1-a1fc-f64f38724879

Karbinal ER. Package Insert. Revised by manufacturer 09-2013. Accessed 03-24-2017.

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

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Office notes, labs, and medical testing relevant to the request that show medical justification are required.