Ryclora™ (dexchlorpheniramine oral solution)

Policy # 00668
Original Effective Date: 04/24/2019
Current Effective Date: 05/10/2021

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 Ryclora™‡ (dexchlorpheniramine oral solution) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Ryclora (dexchlorpheniramine oral solution) will be considered when the following criteria are met:

- Patient has tried and failed (e.g., intolerance or inadequate response) TWO other liquid antihistamine products (over the counter or generic prescription) for the condition (e.g., cetirizine liquid, carbinoxamine liquid) unless there is clinical evidence or patient history that suggests alternative liquid antihistamine products will be ineffective or cause an adverse reaction to the patient; AND
- Patient is NOT able to swallow tablets (e.g. has dysphagia or a gastrostomy tube [G-tube]); AND
- Patient is NOT taking any other medications in tablet and/or capsule form.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Ryclora (dexchlorpheniramine oral solution) when the patient selection criteria are not met to be **not medically necessary.****

Ryclora™ (dexchlorpheniramine oral solution)

Policy # 00668
Original Effective Date: 04/24/2019
Current Effective Date: 05/10/2021

Background/Overview

Ryclora is indicated for seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and foods, mild, uncomplicated allergic skin manifestations of urticaria and angioedema, dermographism, adjunctive anaphylactic reaction therapy, and amelioration of allergic reactions to blood or plasma.

Other antihistamines exist in liquid form, including cetirizine liquid (available over the counter) and generic carbinoxamine liquid. There is no data that suggests dexchlorpheniramine has any advantages over other available generic (carbinoxamine) or over the counter liquid antihistamine products (cetirizine). Other liquid antihistamines provide an equally efficacious and cost effective option to treatment.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Ryclora is indicated for seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and foods, mild, uncomplicated allergic skin manifestations of urticaria and angioedema, dermographism, adjunctive anaphylactic reaction therapy, and amelioration of allergic reactions to blood or plasma.

Rationale/Source

There are no clinical studies in the package insert to give insight into any advantages of this product. Based on a review of the available data, there is no advantage of using Ryvent over generic carbinoxamine or over the counter cetirizine. Other liquid antihistamines provide an equally efficacious and cost effective option to treatment.

References

1. Ryclora [package insert]. Carwin Pharmaceutical Associates. Hazlet, New Jersey. Updated March 2018.

Policy History

Original Effective Date: 04/24/2019

Ryclora™ (dexchlorpheniramine oral solution)

Policy # 00668
Original Effective Date: 04/24/2019
Current Effective Date: 05/10/2021

Current Effective Date: 05/10/2021
04/04/2019 Medical Policy Committee review
04/24/2019 Medical Policy Implementation Committee approval. New policy.
04/02/2020 Medical Policy Committee review
04/08/2020 Medical Policy Implementation Committee approval. No change to coverage.
04/01/2021 Medical Policy Committee review
04/14/2021 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 04/2022

**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

Ryclora™ (dexchlorpheniramine oral solution)

Policy # 00668
Original Effective Date: 04/24/2019
Current Effective Date: 05/10/2021

recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.