Oral Non-Sedating Antihistamines and Singulair® Products (Branded)

Policy # 00354
Original Effective Date: 06/25/2013
Current Effective Date: 07/08/2024

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 Are 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 brand name oral non-sedating antihistamines (NSAs), including, but not limited to Xyzal®‡ (levocetirizine) and Clarinex®‡ (desloratadine) products OR brand name Singulair®‡ (montelukast) products to be **eligible for coverage**** when one of the below patient selection criteria is met:

Patient Selection Criteria

Coverage eligibility will be considered for brand name oral non-sedating antihistamines (NSAs) OR brand name Singulair (montelukast) products when ONE of the following criteria is met:

- Requested drug is a brand name oral non-sedating anthistamine (NSA): patient has tried and failed a generic prescription oral non-sedating anthistamine ([NSA] e.g. fexofenadine, levocetirizine, desloratadine) OR generic montelukast; OR
- Requested drug is a brand name Singulair product: patient has tried and failed generic montelukast; OR
- There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient.

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand name oral non-sedating antihistamines (NSAs) OR brand name Singulair (montelukast) products when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary**.**

Background/Overview

Singulair (montelukast) is indicated for prophylaxis and chronic treatment of asthma, acute prevention of exercise-induced bronchoconstriction, and the relief of symptoms of allergic rhinitis, seasonal allergic rhinitis, and perennial allergic rhinitis. Oral NSAs such as Clarinex (desloratadine) and Xyzal (levocetirizine) are approved for indications such as chronic idiopathic urticaria, and seasonal and perennial allergic rhinitis.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the generically available drugs will be ineffective or cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveat, there is no advantage of using a brand name oral NSA OR brand name Singulair (montelukast) products over the available generic oral NSAs or montelukast. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

References

1. Singulair [package insert]. Whitehouse Station, NJ: Merck and Co, Inc.; March 2013.
2. Clarinex [package insert]. Whitehouse Station, NJ: Merck and Co, Inc.; September 2012.
3. Xyzal [package insert]. Smyma, GA: UCB, Inc.; 2012.

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Policy History

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06/06/2013 Medical Policy Committee review
06/25/2013 Medical Policy Implementation Committee approval. New policy.
06/05/2014 Medical Policy Committee review
06/18/2014 Medical Policy Implementation Committee approval. No change to coverage.
06/04/2015 Medical Policy Committee review
06/17/2015 Medical Policy Implementation Committee approval. No change to coverage.
06/02/2016 Medical Policy Committee review
06/20/2016 Medical Policy Implementation Committee approval. No change to coverage.
06/01/2017 Medical Policy Committee review
06/21/2017 Medical Policy Implementation Committee approval. No change to coverage.
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. No change to coverage.
06/03/2021 Medical Policy Committee review
06/09/2021 Medical Policy Implementation Committee approval. No change to coverage.
06/02/2022 Medical Policy Committee review
06/08/2022 Medical Policy Implementation Committee approval. No change to coverage.
06/01/2023 Medical Policy Committee review
06/14/2023 Medical Policy Implementation Committee approval. No change to coverage.
06/06/2024 Medical Policy Committee review
06/12/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2025

**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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.