Cromolyn Nebulized Solution

Policy # 00716
Original Effective Date: 01/01/2021
Current Effective Date: 10/10/2022

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 cromolyn nebulized solution to be **eligible for coverage**** when the patient selection criterion is met.

Patient Selection Criteria

Coverage eligibility for cromolyn nebulized solution will be considered when the following criterion is met:

- Patient has tried and failed (e.g., intolerance or inadequate response) ALL of the following: GENERIC montelukast, GENERIC NEBULIZED albuterol, and GENERIC NEBULIZED levalbuterol unless there is clinical evidence or patient history that suggests the use of these 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 cromolyn nebulized solution when the patient has NOT met the patient selection criterion to be **not medically necessary.****

Background/Overview

Cromolyn nebulized solution is a prophylactic agent indicated in the management of patients with bronchial asthma. According to the Global Initiative for Asthma expert treatment guidelines, cromolyn is not recommended for routine use in asthma due to lower efficacy relative to other therapies. The Global Initiative for Asthma also mentions that cromolyn may be considered for

exercise induced bronchospasm, however other therapies are preferred. A multitude of other asthma products exist, which offer more cost-effective options for treatment.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Cromolyn nebulized solution is a prophylactic agent indicated in the management of patients with bronchial asthma.

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 intent of this medical policy is to ensure that members are using the most cost-effective medications for their condition.

References

1. Cromolyn nebulized solution [package insert]. Allex Pharmaceuticals, LLC. Lenexa, Kansas. Updated June 2016.
2. Global Strategy for Asthma Management and Prevention 2020. Global Institute for Asthma. https://ginasthma.org/reports/.
3. UpToDate. Cromolyn Inhalation. Accessed August 2020.

Policy History

Original Effective Date: 01/01/2021
Current Effective Date: 10/10/2022
09/03/2020 Medical Policy Committee review
09/09/2020 Medical Policy Implementation Committee approval. New policy.
09/02/2021 Medical Policy Committee review

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09/08/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/01/2022 Medical Policy Committee review
09/14/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 09/2023

**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.

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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.