LOUISIANA BLUE

Formulary Exception Process/Non-Formulary Drug Review Process Standard Criteria (Closed Formulary)

Policy # 00543
Original Effective Date: 01/01/2017
Current Effective Date: 01/13/2025

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 non-formulary drugs that do NOT have a dedicated medical policy AND/OR non-formulary drugs that may be listed in a step therapy medical policy to be **eligible for coverage**** when the below patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for non-formulary drugs that do NOT have a dedicated medical policy AND/OR non-formulary drugs that may be listed in a step therapy medical policy will be considered when the following criteria are met for the requested drug:

- Single source brand drugs (drugs withOUT a generic equivalent) OR generic drugs:
  - Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO formulary alternatives for the condition being treated; OR
  - Patient has tried and failed (e.g., intolerance or inadequate response) one formulary alternative if two alternatives DO NOT exist on formulary.
- Multi source brand drugs (drugs WITH a generic equivalent):
  - Patient has tried and failed (e.g., intolerance or inadequate response) the generic equivalent of the requested non-formulary drug AND patient has tried and failed (e.g. intolerance or inadequate response) one additional formulary alternative for the condition being treated; OR
  - Patient has tried and failed (e.g., intolerance or inadequate response) the generic equivalent of the requested non-formulary drug ONLY if there is one formulary alternative present.

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of non-formulary drugs that do NOT have a dedicated medical policy AND/OR non-formulary drugs that may be listed in a step therapy medical policy when the patient selection criteria for the requested drug are NOT met to be **not medically necessary.****

Background/Overview

This policy supports the formulary exception process and the non-formulary drug review process for the BCBSLA closed formulary and should be utilized for those drugs without a dedicated medical policy AND/OR those non-formulary drugs that may be listed in a step therapy medical policy.

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 the use of formulary alternatives. Based on a review of the available data, there is no advantage of using non-formulary drugs over the available formulary drugs on the closed formulary. The closed formulary is a collection of drugs that are equally as effective, yet offer a more economical option than non-formulary drugs.

Policy History

Original Effective Date: 01/01/2017
Current Effective Date: 01/13/2025

12/01/2016	Medical Policy Committee review
12/21/2016	Medical Policy Implementation Committee approval. New policy.
12/07/2017	Medical Policy Committee review
12/20/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/06/2018	Medical Policy Committee review
12/19/2018	Medical Policy Implementation Committee approval. Clarified that non-formulary drugs mentioned in step therapy medical policies may also be subject to this policy.

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12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/03/2020	Medical Policy Committee review
12/09/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/02/2021	Medical Policy Committee review
12/08/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/01/2022	Medical Policy Committee review
12/14/2022	Medical Policy Implementation Committee approval. No change to coverage.
12/07/2023	Medical Policy Committee review
12/13/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/05/2024	Medical Policy Committee review
12/11/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 12/2025

**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.

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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.

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.