

Select Naloxone Injectable Products

Policy # 00533

Original Effective Date: 01/01/2017

Current Effective Date: 05/01/2026

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.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

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 select naloxone injectable products including, but not limited to Zimhi^{TM†}, to be **eligible for coverage**** when the below patient selection criterion is met:

Patient Selection Criteria

Coverage eligibility will be considered for select naloxone injectable products including, but not limited to Zimhi, when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of other available naloxone products (e.g., generic injection, nasal spray) will be/was ineffective or will/did 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 select naloxone injectable products including, but not limited to Zimhi, WITHOUT clinical evidence or patient history that suggests the use of other available naloxone products (e.g., generic injection, nasal spray) will be/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary.****

Background/Overview

Evzio^{®†}, branded Naloxone auto-injector, and Zimhi are opioid antagonists indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. These products are intended for immediate administration as emergency therapy in settings where opioids may be present. Evzio and branded Naloxone auto-injectors have been discontinued and are no longer targeted by this policy. Zimhi is an injectable product that provides a higher dose of naloxone than standard naloxone therapies on the market.

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There are generic injectable forms of naloxone available (including both syringes and vials) that have been around for quite some time. There is also a Narcan[®] nasal spray available, which is now available as a generic. Another nasal spray, Kloxxado[™], is available in a strength twice that of Narcan nasal spray (and its generic). Generic naloxone injections, Narcan nasal spray (and its generic), and Kloxxado nasal spray are equally efficacious as compared to the injectable products targeted by this policy. Given the clinical information regarding these naloxone injectable products and the availability of alternative products, the use of the alternative products (generic naloxone injection, Narcan nasal spray, generic naloxone nasal spray, Kloxxado nasal spray) is a clinically and economically sensible option.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Zimhi was approved in 2021 for the emergency treatment of known or suspected opioid overdose.

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 use of other available naloxone products (e.g., generic injection, nasal spray) will be ineffective or cause an adverse reaction to the patient. Based on a review of the available data and in the absence of any caveat mentioned, there is no advantage of using these select naloxone injectable products over the other available naloxone products (e.g., generic injection, nasal spray).

References

1. Evzio [package insert]. Kaleo, Inc. Richmond, Virginia. Updated April 2014.
2. Naloxone auto injector [package insert]. IJ Therapeutics. Richmond, Virginia. December 2019.
3. Zimhi [package insert]. Adamis Pharmaceuticals. San Diego, California. Updated October 2021.
4. Kloxxado [package insert]. Hikma Pharmaceuticals. Columbus, Ohio. Updated April 2021.

Policy History

Original Effective Date: 01/01/2017

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10/06/2016 Medical Policy Committee review

10/19/2016 Medical Policy Implementation Committee approval. New Policy.

10/05/2017 Medical Policy Committee review

10/18/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

10/04/2018 Medical Policy Committee review

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10/17/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/03/2019	Medical Policy Committee review
10/09/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/04/2020	Medical Policy Committee review
06/10/2020	Medical Policy Implementation Committee approval. Changed the title of the policy to "Select Naloxone Auto-Injectors". Added the branded Naloxone auto-injector to the policy.
06/03/2021	Medical Policy Committee review
06/09/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/07/2022	Medical Policy Committee review
04/13/2022	Medical Policy Implementation Committee approval. Changed the title of the policy from "Select Naloxone Auto-Injectors" to "Select Naloxone Injectable Products". Added a new product, Zimhi, to the policy.
04/06/2023	Medical Policy Committee review
04/12/2023	Medical Policy Implementation Committee approval. Removed Evzio and branded Naloxone auto-injector from policy since these products have been discontinued and are no longer available.
04/04/2024	Medical Policy Committee review
04/10/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/03/2025	Medical Policy Committee review
04/09/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/02/2026	Medical Policy Committee review
04/10/2026	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2027

****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.

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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.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan’s pharmacy benefit.