Select Naloxone Injectable Products

Policy # 00533
Original Effective Date: 01/01/2017
Current Effective Date: 05/08/2023

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 select naloxone injectable products including, but not limited to Zimhi™, 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
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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. 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 Narcannasal 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).
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References

Policy History
Original Effective Date: 01/01/2017
Current Effective Date: 05/08/2023
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
10/03/2019 Medical Policy Committee review
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
Select Naloxone Injectable Products

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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.  
Next Scheduled Review Date: 04/2024

**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.