Select Naloxone Auto-Injectors

Policy # 00533
Original Effective Date: 01/01/2017
Current Effective Date: 07/12/2021

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 provide
d 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 auto-injectors, including, but not limited to Evzio®‡ and the branded Naloxone auto-injector, to be **eligible for coverage**** when the below patient selection criterion is met:

Patient Selection Criteria
Coverage eligibility will be considered for select naloxone auto-injectors, including, but not limited to Evzio®‡ and the branded Naloxone auto-injector, 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 auto-injectors, including, but not limited to Evzio®‡ and the branded Naloxone auto-injector, 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.****

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Background/Overview

Evzio and the branded Naloxone auto-injector are both opioid antagonists indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. These auto-injectors are intended for immediate administration as emergency therapy in settings where opioids may be present. These auto-injectors are not a substitute for medical care. Both of these products provides a voice guided auto injection option. 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 (whose active ingredient is naloxone). Both the generic naloxone injections and the Narcan nasal spray are cheaper and equally efficacious as compared to the auto-injectors targeted by this policy. Given the clinical information regarding these naloxone auto-injectors and the availability of alternative products, the use of the alternative products (generic naloxone injection, Narcan nasal spray) is a clinically and economically sensible option.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Evzio was approved in 2014 for the emergency treatment of known or suspected opioid overdose. A branded Naloxone auto-injector was approved in late 2019 with the same indication and formulation as Evzio.

Rationale/Source

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 auto-injectors 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.

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Policy History

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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
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.

Next Scheduled Review Date: 06/2022

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety,

effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**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.