



Louisiana

Evzio[®] (naloxone auto-injector)

Policy # 00533

Original Effective Date: 01/01/2017

Current Effective Date: 10/17/2018

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 Evzio^{®‡} (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 Evzio (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 Evzio (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.****

Background/Overview

Evzio is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. Evzio is intended for immediate administration as emergency therapy in settings where opioids may be present. Evzio is not a substitute for medical care. Evzio 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 Evzio auto injector. Given the clinical information regarding Evzio 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.

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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 Evzio (naloxone auto-injector) over the other available naloxone products (e.g., generic injection, nasal spray).

References

1. Evzio [package insert]. Kaleo, Inc. Richmond, Virginia. Updated April 2014.

Policy History

Original Effective Date: 01/01/2017

Current Effective Date: 10/17/2018

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.

Next Scheduled Review Date: 10/2019

****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: 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.

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