

Clinical Policy: Naloxone (Evzio, Narcan Nasal Spray)

Reference Number: CP.CPA.28

Effective Date: 11.16.16

Last Review Date: 08.17

Line of Business: Commercial

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

The following are naloxone requiring prior authorization: Naloxone (Evzio[®]), Naloxone (Narcan[®] Nasal Spray). Evzio is a prefilled, single use auto-injector. Narcan nasal spray is a prefilled, single dose intranasal spray. Naloxone is an opioid antagonist.

FDA approved indication

Evzio and Narcan Nasal Spray are indicated:

- For the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Evzio and Narcan Nasal Spray are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Emergency treatment of known or suspected opioid overdose (must meet all):

1. Patient may have access to opioids;
2. For Evzio requests: medical justification why patient cannot use Narcan (naloxone) nasal spray.

Approval duration:

Evzio: 6 months or to member's renewal period, whichever is longer [two boxes (4 autoinjectors) per prescription]

Narcan: Length of benefit [two cartons (4 single dose nasal sprays) per prescription]

B. Other diagnoses/indications

1. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Emergency treatment of known or suspected opioid overdose (must meet all):

1. Currently receiving medication via health plan benefit or member has previously met initial approval criteria.

Approval duration:

Evzio: 6 months or to member's renewal period, whichever is longer [two boxes (4 autoinjectors) per prescription]

Narcan: Length of benefit [two cartons (4 single dose nasal sprays) per prescription]

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviations/Acronym Key

- N/A

Appendix B: General Information

- Evzio is intended for immediate administration as emergency therapy in settings where opioids may be present.
- Evzio is not a substitute for emergency medical care. If the desired response is not obtained after 2 or 3 minutes, another Evzio dose may be administered. If there is still no response and additional doses are available, additional Evzio doses may be administered every 2 to 3 minutes until emergency medical assistance arrives. If no response is observed after 10 mg of naloxone hydrochloride have been administered, the diagnosis of narcotic-induced or partial narcotic induced toxicity should be questioned. Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.
- Clinical efficacy studies were not conducted for Evzio. In one pharmacokinetic study of 30 patients, a single Evzio injection provided equivalent naloxone compared to a single dose of naloxone injection using a standard syringe.

Appendix C: Therapeutic Alternatives

N/A

V. Dosage and Administration

Evzio		
Indication	Dosing Regimen	Maximum Dose
Known or Suspected Opioid Overdose	IM or SC only injection. Place the Black end of Evzio against the outer thigh, through clothing, if needed. Press firmly and hold in	N/A

	<p>place for 5 seconds. Repeat doses of Evzio may be required depending upon the amount, type, and route of administration of the opioid being antagonized. If there is still no response and additional doses are available, additional Evzio doses may be administered every 2 to 3 minutes until emergency medical assistance arrives.</p>	
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Narcan		
Indication	Dosing Regimen	Maximum Dose
Known or Suspected Opioid Overdose	4 mg intranasally as a single spray in one nostril. Repeat as needed every 2 to 3 minutes with a new nasal spray in alternate nostrils. Additional doses may be administered every 2 to 3 minutes until emergency medical assistance arrives	N/A

VI. Product Availability

Drug	Availability
Evzio	Prefilled autoinjector: 0.4 mg/0.4 ml, 2 mg/0.4 ml
Narcan	Nasal Spray: 4 mg in 0.1 ml. Supplied as a carton containing two blister packages, each with a single dose

VII. References

1. Evzio Prescribing Information. Richmond, VA: Kaleo Inc.; October 2016. Available at www.evzio.com. Accessed January 11, 2017.
2. Narcan Prescribing Information. Radnor, PA; Adapt Pharma; November 2015. Available at www.narcan.com. Accessed January 11, 2017.
3. FDA’s Summary Review for Regulatory Action for Evzio accessed at: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205787Orig1s000SumR.pdf. Accessed January 11, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template; minor changes to verbiage and grammar. References updated.	1.11.17	8.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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