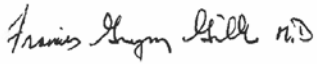




Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	Submission Date: 11/1/2018
Policy Number: PA.CP.PMN.139	Effective Date: 10/17/2018 Revision Date: 10/17/2018
Policy Name: Naloxone (Evzio)	HC Approval Date:
Type of Submission – Check all that apply: <input checked="" type="checkbox"/> New Policy <input type="checkbox"/> Revised Policy* <input type="checkbox"/> Annual Review – No Revisions <input type="checkbox"/> Attestation of HC PARP Policy – <i>This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term “Community HealthChoices” to the policy.</i>	
*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document. Please provide any changes or clarifying information for the policy below: New Policy created.	
Name of Authorized Individual (Please type or print): Francis G. Grillo, MD	Signature of Authorized Individual: 

Commented [HK1]: Please be aware that per CMS, Labeler 60842 has a labeler termination effective date of 4/1/2017. Products include Evzio. After this date, this product will no longer be a Medicaid covered outpatient drug per CMS unless the agreement is reinstated. To date, Evzio is still not eligible for coverage.
Recommend withdrawal of this policy.

CLINICAL POLICY

Fusilev

Clinical Policy: Naloxone (Evzio)

Reference Number: PA.CP.PMN.139

Effective Date: 10.17.18

Last Review Date: 10.17.18



[Revision Log](#)

Description

Naloxone (Evzio®) is an opioid antagonist.

FDA Approved Indication(s)

Evzio is indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression in adults and pediatric patients.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Evzio is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Opioid overdose (must meet all):

1. Patient may have access to opioids;
2. Medical justification supports inability to use naloxone (Narcan®) nasal spray and naloxone solution for injection (example: contraindication to excipients in these agents) ;
3. Requested quantity does not exceed two boxes (4 autoinjectors) per prescription.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

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

1. Previously received medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. If request is for a dose increase, the requested quantity does not exceed two boxes (4 autoinjectors) per prescription.

Approval duration: 12 months

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 12 months (whichever is less); or

CLINICAL POLICY

Naloxone Autoinjector



2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

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 policies – PA.CP.PMN.53.

IV. Appendices/General Information

Appendix A: Abbreviations/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Narcan [®] nasal spray (naloxone)	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	Not applicable
naloxone 0.4 mg/mL solution	Adults: 0.4 to 2 mg IV, repeat every 2 to 3 minutes as needed; if no response after 10 mg, reconsider diagnosis of opioid toxicity; may administer IM or SC if IV route is unavailable Pediatrics: 0.01 mg/kg IV followed by 0.1 mg/kg IV if desired clinical response has not been achieved; divided doses may be given via IM or SC route if IV route is not available	Not applicable

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications

Not applicable

Appendix D: 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

CLINICAL POLICY

Naloxone Autoinjector



narcotic-induced or partial narcotic induced toxicity should be questioned. Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Known or Suspected Opioid Overdose	IM or SC only injection. 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.	N/A

VI. Product Availability

Auto-injector containing a single dose of naloxone 0.4 mg/0.4 mL or 2 mg/0.4 mL; each carton contains two auto-injectors

VII. References

1. Evzio Prescribing Information. Richmond, VA: Kaleo Inc.; October 2016. Available at www.evzio.com. Accessed May 21, 2018.
2. FDA's Summary Review for Regulatory Action for Evzio accessed at: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205787Orig1s000SumR.pdf.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 21, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy Created	10/18	