

### Clinical Pharmacy Program Guidelines for Evzio

Program	Prior Authorization
Medication	Evzio (naloxone hydrochloride)
Issue Date	9/2014
Pharmacy and Therapeutics Approval Date	12/2017
Effective Date	2/2018

**1. Background:**

Evzio (naloxone hydrochloride injection) 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 will be approved based on the following criteria:

**NOTE: This policy does not apply to Washington, please refer to global criteria.**

**2. Coverage Criteria:**

<p><b>A. Evzio</b> will be approved based on all of the following criteria:</p> <ol style="list-style-type: none"> <li>1. Patient is currently using an opioid</li> </ol> <p style="text-align: center;"><b>-AND-</b></p> <ol style="list-style-type: none"> <li>2. <b>One</b> of the following risk factors for overdose:             <ol style="list-style-type: none"> <li>a. History of emergency medical care involving opioid overdose</li> <li>b. History of substance abuse</li> <li>c. Receiving higher dose (&gt; 50mg morphine equivalent/day) opioid prescription</li> <li>d. Concomitant use with benzodiazepines, antidepressants, alcohol, or muscle relaxants</li> <li>e. Chronic pulmonary disease (e.g. emphysema, chronic bronchitis, asthma)</li> <li>f. Sleep apnea</li> <li>g. Renal impairment</li> <li>h. Chronic cirrhosis or hepatitis</li> <li>i. Mental illness (e.g. bipolar disorder, schizophrenia)</li> <li>j. Cognitive impairment</li> </ol> </li> </ol> <p style="text-align: center;"><b>-AND-</b></p>
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3. Both of the following:

(1) Documentation that the member is unable to obtain generic naloxone injection, used with or without the nasal atomizer

**-AND-**

(2) Reason or special circumstance that the patient cannot be treated with Narcan nasal spray

**Authorization will be issued for 12 months.**

**3. References:**

1. Substance Abuse and Mental Health Services Administration (SAMHSA) Opioid Overdose Toolkit. Accessed 9 Sept 2015. <<http://prescribetoprevent.org>>.
2. Evzio Prescribing Information. Kaleo Inc. Richmond, VA. October 2016.
3. Paulozzi L, et al; Centers for Disease Control and Prevention. MMWR Morb Mortal Wkly Rep. 2011;60:1487-1492.
4. Dunn KM, Saunders KW, Rutter CM. Opioid Prescriptions for Chronic Pain and Overdose. *Ann Intern Med.* 2010;152:85-92.
5. Bohnert AS, Valenstein M, Bair MJ, et al. Associate Between Opioid Prescribing Patterns and Opioid Overdose-related Deaths. *JAMA.* 2011;305:1315-1321.
6. Madadi P, Hildebrandt D, Lauwers AE, Koren G (2013) Characteristics of Opioid-Users Whose Death Was Related to Opioid-Toxicity: A Population-Based Study in Ontario, Canada. *PLoS ONE* 8(4): e60600.
7. Paulozzi LJ, Logan JE, Hall AJ, McKinstry E, Kaplan JA. A comparison of drug overdose deaths involving methadone and other opioid analgesics in West Virginia. *Addiction* 2009; 104:1541-1548.
8. Paulozzi LJ, Budnitz DS, Xi Y. Increasing deaths from opioid analgesics in the United States. *Pharmacoepidemiology and Drug Safety* 2006; 15:618-627.
9. Paulozzi L, Zhang K, Jones C, Mack K. Risk of adverse health outcomes with increasing duration and regularity of opioid therapy. *J Am Board Fam Med* 2014;27:329-338.
10. Baily AM, Wrmeling DP. Naloxone for opioid overdose prevention: pharmacists' role in community-based practice settings. *Ann Pharmacother.* 2014 May;48(5):601-6
11. Howe CQ, Sullivan MD, Saunders KW. Depression and Ambivalence toward Chronic Opioid Therapy for Chronic Non-cancer Pain. *Clin J Pain.* Sept 2012; 28(7):551-566.
12. Zedler B, Xie L, Wang L, et al. Risk factors for serious prescription opioid-related toxicity or overdose among veterans health administration patients. *Pain Med* 2014. Published online: 14 Jun 2014.

Program	Prior Authorization –Evzio (naloxone hydrochloride)
<b>Change Control</b>	
Date	Change
9/18/2014	New policy
12/17/2015	Annual review, no change
11/2016	Updated policy to align with E&I, added reason patient cannot take Narcan nasal spray to criteria
3/2017	Clarified that naloxone injection can be used with or without a nasal atomizer
12/2017	Updated references.