



**Medication Policy Manual**

**Policy No:** dru483

**Topic:** Evzio®, naloxone hydrochloride autoinjector **Date of Origin:** January 13, 2017

**Committee Approval Date:** January 13, 2017 **Next Review Date:** January 2018

**Effective Date:** January 13, 2017

### **IMPORTANT REMINDER**

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of Medication Policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

### **Description**

Naloxone HCl autoinjector (Evzio) is an opioid antagonist used for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression.

## Policy/Criteria

- I. Most contracts require prior authorization approval of naloxone HCl autoinjector (Evzio) prior to coverage. Naloxone HCl autoinjector (Evzio) may be considered medically necessary when there is clinical documentation of visual or functional impairment which makes the patient or patient's caretaker unable to use alternative mechanisms of naloxone delivery (as specified in Table 1).

**Please note:** No prior authorization is required for the naloxone formulations in Table 1.

- II. OmedaRx considers naloxone HCl injection (Evzio) to be a self-administered medication.
- III. Use of naloxone HCl autoinjectors (Evzio) is considered investigational when used for all other conditions other than the immediate reversal of suspected or known opioid overdose.

## Position Statement

### *Summary*

- Naloxone HCl blocks the actions of opioid medications thereby reversing the effects, including respiratory depression.
- Since its approval, naloxone HCl has been used widely by hospitals and first responder personnel. Although there are no high quality randomized, controlled trials with this medication, there is vast clinical experience with naloxone HCl as a narcotic reversal agent.<sup>[1]</sup>
- The Centers for Disease Control and Prevention (CDC) Guidelines for Prescribing Opioids for Chronic Pain, recommend that clinicians offer naloxone and overdose prevention education to both patients and their household members if they have risk factors for opioid overdose. These risk factors include:<sup>[2]</sup>
  - \* Opioid dosage exceeding 50 morphine milligram equivalents per day
  - \* History of overdose
  - \* History of substance use disorder
  - \* Concurrent benzodiazepine use.
- The World Health Organization guidelines concluded that naloxone is effective when delivered through intravenous, intramuscular, subcutaneous, and intranasal routes of administration. These guidelines did not find evidence of differences between the intranasal naloxone and intramuscular naloxone for the treatment of opioid overdose. <sup>[3]</sup>
- Formulations such as intramuscular/subcutaneous naloxone injectable solution and naloxone HCl nasal spray (Narcan, others), provide the best value. Naloxone HCl autoinjector (Evzio) has not been proven to be safer or more effective than naloxone HCl through other routes of administration including intramuscular/subcutaneous injections or as an intranasal spray, but is more costly. <sup>[3]</sup>

- The recommended dose of naloxone HCl autoinjector (Evzio) is one prefilled injection immediately at the time of emergency therapy. Additional doses can be administered every 2 to 3 minutes following the initial injection until emergency medical assistance arrives.<sup>[4]</sup>
- Naloxone HCl autoinjector (Evzio) should not be used as a substitute for seeking immediate emergency care in the setting of an opioid overdose.

*Clinical Efficacy*

- Naloxone HCl has been widely used in its intravenous, injectable, and intranasal form since its approval and there is extensive experience with this medication in clinical practice. Naloxone HCl autoinjector (Evzio) was approved by demonstrating that it produced similar drug levels in patients as injectable naloxone.<sup>[1]</sup>

*Investigational Uses*

- There are no high-quality published clinical trials evaluating the safety or efficacy of naloxone HCl for indications other than the immediate reversal of opioid withdrawal.

<b>Table 1. Alternative forms of naloxone HCl</b>
Naloxone HCl nasal spray (Narcan, others)
Naloxone HCl intramuscular/subcutaneous injectable solution [generic]

<b>Cross References</b>
None

<b>Codes</b>	<b>Number</b>	<b>Description</b>
N/A		None

## References

1. Senchyna, M, Wax, MB. Quantitative assessment of tear production: A review of methods and utility in dry eye drug discovery. *Journal of ocular biology, diseases, and informatics*. 2008 Mar;1(1):1-6. PMID: 20072630
2. Dowell, D, Haegerich, T, Chou, R. CDC Guideline for Prescribing Opioids for Chronic Pain - United States. *MMWR Recomm Rep*. 2016;65(RR-1):1-49. PMID:
3. World Health Organization. Community Management of opioid overdose. Geneva, Switzerland: WHO; 2014
4. Donnenfeld, ED, Karpecki, PM, Majmudar, PA, et al. Safety of Lifitegrast Ophthalmic Solution 5.0% in Patients With Dry Eye Disease: A 1-Year, Multicenter, Randomized, Placebo-Controlled Study. *Cornea*. 2016 Jun;35(6):741-8. PMID: 27055211

## Revision History

Revision Date	Revision Summary
01/13/2017	New policy (effective 1/13/17)