

## STEP THERAPY POLICY

**POLICY:** Naloxone Injection Step Therapy Program

**DATE REVIEWED:** 04/22/2020

**DRUGS AFFECTED:** Evzio® Auto-Injector (naloxone hydrochloride 0.4 mg or 2 mg injection – Kaleo, authorized generic to the 2 mg injection)

### OVERVIEW

Generic naloxone HCl injection is indicated for the complete or partial reversal of narcotic depression, including respiratory depression, induced by opioids including natural and synthetic narcotics, propoxyphene, methadone and certain narcotic-antagonist analgesics (e.g., nalbuphine, pentazocine and butorphanol).<sup>1-2</sup> Dosing for naloxone HCl injection in adult with known or suspected overdose is 0.4 mg to 2 mg per dose, up to a total dose of 10 mg. If no response is observed after 10 mg of naloxone HCl, the diagnosis of opioid-induced or partial opioid-induced toxicity should be questioned. Naloxone HCl injection is also indicated for the diagnosis of suspected acute opioid overdosage and may be useful as an adjunctive agent to increase blood pressure in the management of septic shock. Naloxone HCl injection may be administered intravenously (IV), intramuscularly (IM), or subcutaneously (SC); additionally, naloxone injection has been used intranasally using a nasal atomizer. The most rapid onset of action is achieved by IV administration, and this route of administration is recommended in emergency situations when administered by trained healthcare professionals.

Evzio Auto-Injector (naloxone HCl 0.4 mg or 2 mg injection for SC or IM use, authorized generic to the 2 mg injection) is indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or CNS depression in adults and pediatric patients.<sup>3-4</sup> Evzio Auto-Injector provides electronic voice instructions to the user; if the electronic voice instructions do not work for any reason, the Evzio auto-injector will still work. Evzio is intended for immediate administration as emergency therapy in settings where opioids may be present, and it is not a substitute for emergency medical care.

All of the naloxone HCl injectable products are indicated for use in adults and pediatric patients.<sup>1-4</sup> Table 1 provides information on the available injectable naloxone strengths and dosage forms.

**Table 1. Available Dosage Forms and Strengths of Naloxone Injectable Products.**

Product	Strength(s)	Dosage Form	Additional Supplies Needed to Administer
Evzio®, authorized generic	0.4 mg/0.4 mL 2 mg/0.4 mL	Prefilled auto-injector with electronic voice instructions	None
Naloxone HCl	2 mg/2 mL	<ul style="list-style-type: none"><li>• 2 mL prefilled syringe with needle</li><li>• 2 mL prefilled syringe without needle</li></ul>	<ul style="list-style-type: none"><li>• None if using IM/IV</li><li>• Needle or MAD</li></ul>
Naloxone HCl	0.4 mg/mL	<ul style="list-style-type: none"><li>• Vial (1 mL and 10 mL)</li><li>• 1 mL carpuject cartridge</li></ul>	<ul style="list-style-type: none"><li>• Syringe and needle or MAD</li><li>• Carpuject syringe system</li></ul>

HCl – Hydrochloride; IM – Intramuscular; IV – Intravenous; MAD – Mucosal atomization device.

## **POLICY STATEMENT**

A step therapy program has been developed to encourage the use of a generic Step 1 product prior to the use of a Step 2 product. If the step therapy rule is not met for a Step 2 agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 1 year in duration.

**Automation:** None.

**Step 1:** naloxone 0.4 mg/mL vial, naloxone 0.4 mg/mL syringe, naloxone 2 mg/2 mL syringe

**Step 2:** Evzio, naloxone 2 mg/0.4 ml auto-injector (authorized generic to Evzio)

## **CRITERIA**

1. Approve Evzio or its authorized generic if the prescriber can confirm that the patient's caregiver is blind or significantly visually impaired. NOTE: If the prescriber does not know or cannot confirm that the patient's caregiver is blind or significantly visually impaired, the request should NOT be approved.

NOTE: Denial reason is: Coverage is provided in situations where the prescriber can confirm that the patient's caregiver is blind or significantly visually impaired. The patient should be prescribed naloxone syringe for injection or Narcan Nasal Spray.

2. No other exceptions are recommended.

## **REFERENCES**

1. Naloxone 0.4 mg/mL injection [prescribing information]. Rockford, IL: Mylan Institutional LLC; January 2018.
2. Naloxone 1 mg/mL injection [prescribing information]. So. El Monte, CA: International Medication Systems, Limited; March 2016.
3. Evzio<sup>®</sup> auto-injector [prescribing information]. Richmond, VA: kaleo, Inc.; April 2014.
4. Evzio<sup>®</sup> auto-injector [prescribing information]. Richmond, VA: kaleo, Inc.; October 2016.