

EVZIO (naloxone injection)

Federal Employee Program.

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Evzio (naloxone) is a single-use auto-injector that contains naloxone hydrochloride. Naloxone is an opioid antagonist that directly counteracts the effect of opioid medications by competing for the same drug receptors. In cases of opioid drug overdose, this competitive inhibition helps reverse the depressant effects of opioid agonists. Opioid reversal is key in turning back the respiratory depression, CNS sedation, and low blood pressure associated with opioid overdose (1-2).

Regulatory Status

FDA approved indication: Evzio 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.

- 1. Evzio is intended for immediate administration as emergency therapy in settings where opioids may be present.
- 2. Evzio is not a substitute for emergency medical care (1-2).

Evzio is approved to use in anyone of any age that is suffering from suspected or known opioid overdose with slight differences in the technique used for administration based on the age of the patient (1-2).

Summary

Opioid receptor antagonists have respiratory and CNS depression reversal properties for opioid overdose. Evzio is FDA-approved for the reversal of known or suspected opioid overdose by competitive antagonism of key receptors in patients of any age. Naloxone is a pregnancy category B drug that should be used only in cases of clear benefit. The safety and efficacy of naloxone have been established in pediatric patients with numerous clinical studies as well as post-marketing data and clinical practice guidelines (1-2).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Evzio while maintaining optimal therapeutic outcomes.



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References

- 1. Evzio 0.4mg [package insert]. Richmond, VA, Kaleo Inc.; April 2014.
- 2. Evzio 2.0mg [package insert]. Richmond, VA, Kaleo Inc.; October 2016.