

NALOXONE HCL

Generic	Brand	HICL	GCN	Exception/Other
NALOXONE HCL	EVZIO		36342, 42502	

GUIDELINES FOR USE

1. Is there a FDA confirmed shortage of ALL other naloxone products for the emergency treatment of opioid overdose [naloxone vials and syringes (with or without a nasal adaptor) and naloxone nasal spray (Narcan)]?

If yes, **approve for 1 fill only.**

If no, continue to #2.

2. Is the caregiver unable to use alternative mechanisms of naloxone delivery (e.g., naloxone nasal spray, injectable naloxone pre-filled syringe or vial) due to deficits requiring the need for an auto-injector with audio cues for administration and precluding the use of nasally administered naloxone?

If yes, **approve for 1 fill only.**

If no, do not approve, but please ensure member receives one of the alternative mechanisms of delivery.

DENIAL TEXT: Our guideline for **NALOXONE HCL** auto-injector with audio cues (Evzio) requires either a Food and Drug Administration (FDA) confirmed shortage of all other naloxone products for the emergency treatment of opioid overdose [naloxone vials and syringes (with or without a nasal adaptor) and naloxone nasal spray (Narcan)], or the caregiver must be unable to use alternative mechanisms of naloxone delivery (e.g., naloxone nasal spray, injectable naloxone pre-filled syringe or vial) due to deficits requiring the need for an auto-injector with audio cues for administration and precluding the use of nasally administered naloxone.

RATIONALE

To prevent inappropriate utilization of naloxone auto-injector with audio cues when there are other preferred naloxone dosage forms.

FDA APPROVED INDICATIONS

Naloxone HCl is an opioid antagonist indicated for the emergency treatment of known or suspected opiate overdose, as manifested by respiratory and/or central nervous system depression.

REFERENCES

- Kaleo, Inc. Evzio package insert. Richmond, VA. April 2014.

Created: 04/17

Effective: 04/20/17

Client Approval: 03/20/17

P&T Approval: N/A