

EPINEPHRINE

Generic	Brand	HICL	GCN	Exception/Other
EPINEPHRINE	AUVI-Q			NDC-00024583102 NDC-00024583302 NDC-60842002201 NDC-60842002301

GUIDELINES FOR USE

1. Is there a FDA confirmed shortage of ALL other epinephrine auto-injector products for the emergency treatment of anaphylaxis [Adrenaclick, epinephrine auto-injector (generic Adrenaclick), EpiPen, EpiPen Jr.]?

If yes, **approve for 1 fill only.**
If no, continue to #2.

2. Is the patient unable to use alternative mechanisms of epinephrine delivery [e.g., Adrenaclick, epinephrine auto-injector (generic Adrenaclick), EpiPen, EpiPen Jr.] despite documented training with a healthcare professional, due to significant functional impairment requiring the need for an auto-injector with audio cues for self-administration?

If yes, **approve for 1 fill only.**
If no, continue to #3.

3. Is the patient caregiver unable to use alternative mechanisms of epinephrine delivery [e.g., Adrenaclick, epinephrine auto-injector (generic Adrenaclick), EpiPen, EpiPen Jr.] despite documented training with a healthcare professional, due to significant functional impairment and requires an auto-injector with audio cues for appropriate administration?

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 **EPINEPHRINE** requires either a Food and Drug Administration (FDA) confirmed shortage of all other epinephrine auto-injector products for the emergency treatment of anaphylaxis [Adrenaclick, epinephrine auto-injector (generic Adrenaclick), EpiPen, EpiPen Jr.], or despite documented training with a healthcare professional the patient or patients' caregiver must be unable to use alternative mechanisms of epinephrine delivery [Adrenaclick, epinephrine auto-injector (generic Adrenaclick), EpiPen, EpiPen Jr.] due to significant functional impairment and requires an auto-injector with audio cues for appropriate administration.

RATIONALE

To prevent inappropriate utilization of epinephrine auto-injectors when there are other preferred epinephrine auto-injector dosage forms.

FDA APPROVED INDICATIONS

Epinephrine auto-injectors contain epinephrine, which is vasopressor indicated for the emergency treatment of type I allergic reactions, including anaphylaxis.

CONTINUED ON NEXT PAGE

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REFERENCES

- Kaléo, Inc. Auvi-Q package insert. Richmond, VA. May 2016.

Created: 04/17

Effective: 04/20/17

Client Approval: 03/20/17

P&T Approval: N/A