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Section:	Prescription Drugs	**Effective Date:**	July 1, 2022
Subsection:	Miscellaneous Products	**Original Policy Date:**	March 12, 2021
Subject:	LifEMS Naloxone	**Page:**	1 of 4

Last Review Date: June 16, 2022

LifEMS Naloxone

Description

LifEMS Naloxone (Naloxone Convenience Kit)

Background
Naloxone hydrochloride antagonizes opioid effects by competing for the μ, κ, and σ opiate receptor sites in the central nervous system, with the greatest affinity for the μ receptor. Naloxone hydrochloride prevents or reverses the effects of opioids including respiratory depression, sedation, and hypotension. When administered intravenously, the onset of action is generally apparent within two minutes (1).

Regulatory Status
FDA approved indication: LifEMS Naloxone (Naloxone Convenience Kit) is indicated for the complete or partial reversal of opioid depression, including respiratory depression, induced by natural and synthetic opioids including, propoxyphene, methadone and certain mixed agonist-antagonist analgesics: nalbuphine, pentazocine, butorphanol and cyclazocine. LifEMS Naloxone is also indicated for the diagnosis of suspected or known acute opioid overdosage (1).

LifEMS Naloxone is not effective against respiratory depression due to non-opioid drugs and in the management of acute toxicity caused by levopropoxyphene. Reversal of respiratory depression by partial agonists of mixed agonist/antagonists, such as buprenorphine and pentazocine, may be incomplete or require higher doses of naloxone (1).

LifEMS Naloxone is a naloxone convenience kit designed to treat a single episode of an opioid overdose. The naloxone provided in this kit must be used on the patient experiencing signs and

symptoms of an overdose. Each LifEMS Naloxone kit contains: 1 Naloxone Hydrochloride USP injection (1 mg/mL) 2mL single dose disposable prefilled syringe in a MINI-I-JET® syringe with a 21 G. x 1-1/2 needle; 2 alcohol pads for administration; 1 Naloxone package insert; and 1 instructions for use card (1).

Related policies

Evzio

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

LifEMS Naloxone (Naloxone Convenience Kit) may be considered **medically necessary** for the treatment of patients with suspected or known opioid overdose or high risk of suspected opioid overdose and if the conditions indicated below are met.

LifEMS Naloxone (Naloxone Convenience Kit) may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Emergency treatment for suspected or confirmed opioid overdose
2. High risk of suspected opioid overdose

AND ALL of the following:

a. Inadequate treatment response, intolerance, or contraindication to **ALL** of the following:
    a. Narcan nasal spray
    b. Generic naloxone (vials)
    c. Generic naloxone (auto-injector, prefilled syringe, or solution cartridge)

Prior – Approval Renewal Requirements

Same as Above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 2 Kits

Duration 6 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Naloxone hydrochloride antagonizes opioid effects by competing for the μ, κ, and σ opiate receptor sites in the central nervous system, with the greatest affinity for the μ receptor. Naloxone hydrochloride prevents or reverses the effects of opioids including respiratory depression, sedation, and hypotension. When administered intravenously, the onset of action is generally apparent within two minutes. LifEMS Naloxone is a naloxone convenience kit designed to treat a single episode of opioid overdose (1).

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

References

1. LifEMS Naloxone [package insert]. El Monte, CA: International Medication Systems, Limited; February 2022.

Policy History

Date	Action
March 2021	Addition to PA

June 2021	Annual review
December 2021	Annual review. Per FEP, addition of prefilled syringe and solution cartridge to generic naloxone formulations the patient must have inadequate response, intolerance, or contraindication to.
June 2022	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.