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<b>Title:</b>	Naloxone
<b>Policy #:</b>	Rx.01.167

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***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

**▶ Intent:**

The intent of this policy is to communicate the medical necessity criteria for **naloxone auto-injector (Evzio®) and naloxone nasal spray (Kloxxado™)** as provided under the member's prescription drug benefit

**▶ Description:**

Drug overdose deaths, including those involving opioids, continue to increase in the United States. From 1999 to 2017, more than 700,000 people have died from a drug overdose. Around 68% of more than 70,200 drug overdose deaths in 2017 involved an opioid. In 2017, the number of overdose deaths involving opioids was six times higher than in 1999.

Naloxone is an opioid antagonist that competes for mu, kappa and sigma opiate sites in the central nervous system (CNS), with the strongest affinity for mu receptors. Naloxone is indicated for known or suspected opioid overdoses, manifested by respiratory and/or CNS depression in adults and pediatric patients. Naloxone is not a substitute for emergency medical care.

**▶ Policy:**

Naloxone auto-injector (Evzio®) or naloxone nasal spray (Kloxxado™) is approved when ALL of the following are met:

1. Brand Evzio® or naloxone (Kloxxado™) will be used for known or suspected opioid overdose; and
2. The prescription is written for the member to whom the medication will be administered; and
3. Documentation that the member's caregiver would be unable to utilize naloxone nasal spray (Narcan®)

Authorization duration: 2 years

**▶ Black Box Warning as shown in the drug Prescribing Information:**

None

**▶ Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed

in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**


Naloxone. Micromedex. Available from: <http://www.micromedexsolutions.com>. Accessed February 08, 2022.

Evzio® (naloxone auto injector) [package insert].Richmond, VA: Kaleo, Inc. October 2016. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=5f8e8d17-a72f-406d-a736-48e61620f9d8&type=display>. Accessed February 08, 2022.

Opioid Overdose. Centers for Disease Control and Prevention. Available at: <https://www.cdc.gov/drugoverdose/epidemic/index.html>. Accessed February 08, 2022.

Kloxxado™ (naloxone hydrochloride nasal spray) [package insert]. Columbus, OH: Hikma Pharmaceuticals USA Inc. April 2021. Available at: <https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=ebf0f833-c1c0-487c-8f29-01fa8c61b6cb&version=1>. Accessed February 08, 2022.

**Applicable Drugs:**

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

<b>Brand Name</b>	<b>Generic Name</b>
Evzio®	Naloxone auto-injector
Kloxxado™	Naloxone nasal spray

**Cross References:**

Off-Label Use Rx.01.33  
Quantity Level Limits for Pharmaceuticals Covered Under the Prescription Drug Benefit Rx.01.76

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<b>Policy Version Number:</b>	10.00
<b>P&amp;T Approval Date:</b>	December 09, 2021
<b>Policy Effective Date:</b>	April 01, 2022
<b>Next Required Review Date:</b>	December 09, 2022

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The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

