

SmartPA Criteria Proposal

Drug/Drug Class:	Opioid Emergency Reversal Agents PDL Edit
First Implementation Date:	April 6, 2017
Proposed Date:	December 16, 2021
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: According to the U.S. Department of Health and Human Services (HHS), in 2019, 10.1 million people misused prescription opioids. Of those, 1.6 million were diagnosed with an opioid use disorder; 48,006 deaths were attributed to overdosing on synthetic opioids other than methadone. In Missouri in 2018, nearly 3.1 persons died each day from an opioid overdose.

Naloxone 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. Historically, naloxone has only been available in a 0.4 mg single dose vial for intramuscular (IM) injection. A 2 mg/2 mL prefilled syringe is also available and has been used with an atomizer device to administer naloxone intranasally.

In April 2021 Kloxxado™, an 8 mg/0.1 mL nasal spray, received FDA approval based on safety and efficacy data from naloxone hydrochloride (Narcan® injection). The need for a higher dosed naloxone product stems from the increased potency of synthetic opioids, for which a higher dose may be required to revive a patient. The product is available in a carton containing 2 single dose nasal spray devices, each containing 8 mg naloxone.

Narcan® Nasal Spray delivers a 4 mg dose of naloxone and is available as a two-pack. All products reviewed within this PDL class will be available without restriction as “preferred” products for MO HealthNet participants at risk of harm from an opiate overdose. Pharmacists in Missouri are able to dispense naloxone according to protocol upon request or upon presentation of a valid prescription. A statewide Standing Order issued by the Missouri Department of Health and Senior Services is available at <https://pr.mo.gov/boards/pharmacy/NaloxoneStandingOrder.pdf>.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> Kloxxado™ Naloxone Narcan® 	<ul style="list-style-type: none"> N/A

- Type of Criteria: Increased risk of ADE Preferred Drug List
 Appropriate Indications Clinical Edit
- Data Sources: Only Administrative Databases Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Opioid Emergency Reversal Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Claim is for a preferred product

Denial Criteria

- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:
 MedWatch Form:

Progress Notes:
 Other:

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List Edit)
 Rule Type: PDL

Default Approval Period

3 months

References

- Evidence-Based Medicine and Fiscal Analysis: "Opiate Emergency Reversal Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; November 2021.
- Evidence-Based Medicine Analysis: "Opiate Emergency Reversal Agents", UMKC-DIC; September 2021.
- Missouri Opioid State Target Response (STR) Project. <https://missouriopioidstr.org/> Website accessed December 2018.
- Revised Statutes of State of MO (RSMO) 195.206. Title XII – Public Health and Welfare; Chapter 195 – Drug Regulations Chapter 195. Opioid antagonist, sale and dispensing of by pharmacists, possession of — administration of, contacting emergency personnel — immunity from liability, when. Accessed December 2018.
- Centers for Disease Control and Prevention (CDC) – Morbidity and Mortality Weekly Report: "CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016"; Volume 65 - March 15, 2016.
- Centers for Disease Control (CDC): "Understanding the Epidemic" – Data Overview: Deaths from Prescription Opioid Overdose. <http://www.cdc.gov/nchs/deaths.htm>. Accessed December 2018.

- U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA). “Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health.” September 2020. <https://www.samhsa.gov/data/sites/default/files/reports/rpt29393/2019NSDUHFFR1PDFW090120.pdf>.
- USPDI, Micromedex; 2021.
- Drug Facts and Comparisons On-line; 2021.

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