# **PRIOR AUTHORIZATION CRITERIA**

BRAND NAME			
(generic) KLOXXADO NASAL SPRAY (naloxone hydrochloride nasal spray)   (naloxone hydrochloride nasal spray) (naloxone hydrochloride nasal spray)   NARCAN NASAL SPRAY (naloxone hydrochloride nasal spray) NARCAN NASAL SPRAY (naloxone hydrochloride nasal spray)   OPVEE (nalmefene nasal spray) REXTOVY (naloxone hydrochloride nasal spray)   REZENOPY (naloxone hydrochloride nasal spray) RIVIVE (naloxone hydrochloride nasal spray)   RIVIVE (naloxone hydrochloride nasal spray) ZIMHI (naloxone hydrochloride injection)   ZURNAI (nalmefene injection) ZURNAI (nalmefene injection)   Status: CVS Caremark® Criteria Kitelite injection	DRUG CLASS	OPIOID REVERSAL AGENTS (RX AND OTC)	
(naloxone hydrochloride nasal spray)(naloxone hydrochloride nasal spray)NARCAN NASAL SPRAY (naloxone hydrochloride nasal spray)OPVEE (nalmefene nasal spray)REXTOVY (naloxone hydrochloride nasal spray)REZENOPY (naloxone hydrochloride nasal spray)RIVIVE (naloxone hydrochloride nasal spray)ZIMHI (naloxone hydrochloride nasal spray)	BRAND NAME (generic)		
(naloxone hydrochloride nasal spray)(naloxone hydrochloride nasal spray)NARCAN NASAL SPRAY (naloxone hydrochloride nasal spray)OPVEE (nalmefene nasal spray)REXTOVY (naloxone hydrochloride nasal spray)REZENOPY 			
(naloxone hydrochloride nasal spray) NARCAN NASAL SPRAY (naloxone hydrochloride nasal spray) OPVEE (nalmefene nasal spray) REXTOVY (naloxone hydrochloride nasal spray) REZENOPY (naloxone hydrochloride nasal spray) RIVIVE (naloxone hydrochloride nasal spray) ZIMHI (naloxone hydrochloride injection) ZURNAI (nalmefene injection) Status: CVS Caremark <sup>®</sup> Criteria			
NARCAN NASAL SPRAY (naloxone hydrochloride nasal spray) OPVEE (nalmefene nasal spray) REXTOVY (naloxone hydrochloride nasal spray) REZENOPY (naloxone hydrochloride nasal spray) RIVIVE (naloxone hydrochloride nasal spray) ZIMHI (naloxone hydrochloride injection) ZURNAI (nalmefene injection) Status: CVS Caremark <sup>®</sup> Criteria		(naloxone hydrochioride hasal spray)	
(naloxone hydrochloride nasal spray)   OPVEE (nalmefene nasal spray)   REXTOVY (naloxone hydrochloride nasal spray)   REZENOPY (naloxone hydrochloride nasal spray)   RIVIVE (naloxone hydrochloride nasal spray)   ZIMHI (naloxone hydrochloride injection)   ZURNAI (nalmefene injection)   Status: CVS Caremark <sup>®</sup> Criteria		(naloxone hydrochloride nasal spray)	
OPVEE (nalmefene nasal spray) REXTOVY (naloxone hydrochloride nasal spray) REZENOPY (naloxone hydrochloride nasal spray) RIVIVE (naloxone hydrochloride nasal spray) ZIMHI (naloxone hydrochloride injection) ZURNAI (nalmefene injection) Status: CVS Caremark <sup>®</sup> Criteria		NARCAN NASAL SPRAY	
(nalmefene nasal spray)   REXTOVY (naloxone hydrochloride nasal spray)   REZENOPY (naloxone hydrochloride nasal spray)   RIVIVE (naloxone hydrochloride nasal spray)   ZIMHI (naloxone hydrochloride injection)   ZURNAI (nalmefene injection)   Status: CVS Caremark <sup>®</sup> Criteria		(naloxone hydrochloride nasal spray)	
REXTOVY (naloxone hydrochloride nasal spray)   REZENOPY (naloxone hydrochloride nasal spray)   RIVIVE (naloxone hydrochloride nasal spray)   ZIMHI (naloxone hydrochloride injection)   ZURNAI (nalmefene injection)   Status: CVS Caremark <sup>®</sup> Criteria		OPVEE	
(naloxone hydrochloride nasal spray)   REZENOPY (naloxone hydrochloride nasal spray)   RIVIVE (naloxone hydrochloride nasal spray)   ZIMHI (naloxone hydrochloride injection)   ZURNAI (nalmefene injection)   Status: CVS Caremark <sup>®</sup> Criteria		(nalmefene nasal spray)	
REZENOPY (naloxone hydrochloride nasal spray) RIVIVE (naloxone hydrochloride nasal spray) ZIMHI (naloxone hydrochloride injection) ZURNAI (nalmefene injection) Status: CVS Caremark <sup>®</sup> Criteria		REXTOVY	
(naloxone hydrochloride nasal spray) RIVIVE (naloxone hydrochloride nasal spray) ZIMHI (naloxone hydrochloride injection) ZURNAI (nalmefene injection) Status: CVS Caremark <sup>®</sup> Criteria		(naloxone hydrochloride nasal spray)	
RIVIVE (naloxone hydrochloride nasal spray) ZIMHI (naloxone hydrochloride injection) ZURNAI (nalmefene injection) Status: CVS Caremark <sup>®</sup> Criteria		REZENOPY	
(naloxone hydrochloride nasal spray) ZIMHI (naloxone hydrochloride injection) ZURNAI (nalmefene injection) Status: CVS Caremark <sup>®</sup> Criteria		(naloxone hydrochloride nasal spray)	
ZIMHI (naloxone hydrochloride injection) ZURNAI (nalmefene injection) Status: CVS Caremark <sup>®</sup> Criteria		RIVIVE	
(naloxone hydrochloride injection) ZURNAI (nalmefene injection) Status: CVS Caremark <sup>®</sup> Criteria		(naloxone hydrochloride nasal spray)	
ZURNAI (nalmefene injection) Status: CVS Caremark <sup>®</sup> Criteria		ZIMHI	
(nalmefene injection) Status: CVS Caremark <sup>®</sup> Criteria		(naloxone hydrochloride injection)	
Status: CVS Caremark <sup>®</sup> Criteria		ZURNAI	
		(nalmefene injection)	
	Status: CVS Caremark <sup>®</sup> Criteria		

# POLICY

## FDA-APPROVED INDICATIONS

## Kloxxado Nasal Spray

Kloxxado is indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult and pediatric patients. Kloxxado is intended for immediate administration as emergency therapy in settings where opioids may be present. Kloxxado is not a substitute for emergency medical care.

Opioid Reversal Agents Post Limit PA Policy UDR 02-2024 v3.docx

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

# Naloxone Nasal Spray (OTC)

Uses

- to "revive" someone during an overdose from many prescription pain medications or street drugs such as heroin
- this medicine can save a life

## Narcan Nasal Spray (naloxone nasal spray)

Narcan Nasal Spray is indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.

Narcan Nasal Spray is intended for immediate administration as emergency therapy in settings where opioids may be present.

Narcan Nasal Spray is not a substitute for emergency medical care.

#### Narcan Nasal Spray (OTC)

Uses

- to "revive" someone during an overdose from many prescription pain medications or street drugs such as heroin
- this medicine can save a life

#### **Opvee Nasal Spray**

Opvee Nasal Spray is indicated for the emergency treatment of known or suspected overdose induced by natural or synthetic opioids in adults and pediatric patients aged 12 years and older, as manifested by respiratory and/or central nervous system depression.

Opvee Nasal Spray is intended for immediate administration as emergency therapy in settings where opioids may be present.

Opvee Nasal Spray is not a substitute for emergency medical care.

#### **Rextovy Nasal Spray**

Rextovy Nasal Spray is indicated for emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult and pediatric patients.

Rextovy Nasal Spray is intended for immediate administration as emergency therapy in settings where opioids may be present.

Rextovy Nasal Spray is not a substitute for emergency medical care.

#### **Rezenopy Nasal Spray**

Rezenopy nasal spray is indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression in adult and pediatric patients.

Rezenopy nasal spray is intended for immediate administration as emergency therapy in settings where opioids may be present.

Rezenopy nasal spray is not a substitute for emergency medical care.

#### **RiVive Nasal Spray**

Uses

- to "revive" someone during an overdose from many prescription pain medications or street drugs such as heroin
- this medicine can save a life

#### Zimhi

Zimhi is indicated in adults and pediatric patients for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.

Zimhi is intended for immediate administration as emergency therapy in settings where opioids may be present. Zimhi is not a substitute for emergency medical care.

## Zurnai

Opioid Reversal Agents Post Limit PA Policy UDR 02-2024 v3.docx

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

Zurnai is indicated for the emergency treatment of known or suspected opioid overdose induced by natural or synthetic opioids in adults and pediatric patients aged 12 years and older, as manifested by respiratory and/or central nervous system depression.

Zurnai is intended for immediate administration as emergency therapy in settings where opioids may be present. Zurnai is not a substitute for emergency medical care.

## **COVERAGE CRITERIA**

## **Emergency Treatment of Opioid Overdose**

Authorization may be granted when the requested drug is being prescribed in the event that emergency treatment of opioid overdose may be needed when the following criteria is met:

The patient requires MORE than 2 nasal spray cartons (4 nasal sprays) OR 2 pre-filled syringe cartons (4 pre-filled syringes) OR 4 auto-injector cartons (4 auto-injectors) of the requested drug per month due to ANY of the following: the type of opioid that the patient is taking (e.g., buprenorphine, pentazocine, long-acting/extended-release opioids), the patient is living in an area that has a longer wait time for emergency medical assistance, the patient had an overdose episode that required the use of the requested drug

[NOTE: An initial quantity of 2 nasal spray cartons (4 nasal sprays) OR 2 pre-filled syringe cartons (4 pre-filled syringes) OR 4 auto-injector cartons (4 auto-injectors) per month of the requested drug will be covered without prior authorization.]

# **QUANTITY LIMITS APPLY**

POST LIMIT OLIANTITY

Drug (RX and OTC)**	1 Month Limit*	3 Month Limit*
Kloxxado Nasal Spray	4 cartons (8 nasal sprays) / 25	12 cartons (24 nasal sprays) /
(naloxone hydrochloride nasal spray)	days	75 days
naloxone hydrochloride nasal spray	4 cartons (8 nasal sprays) / 25 days	12 cartons (24 nasal sprays) / 75 days
Narcan Nasal Spray	4 cartons (8 nasal sprays) / 25	12 cartons (24 nasal sprays) /
(naloxone hydrochloride nasal spray)	days	75 days
Opvee	4 cartons (8 nasal sprays) / 25	12 cartons (24 nasal sprays) /
(nalmefene nasal spray)	days	75 days
Rextovy	4 cartons (8 nasal sprays) / 25	12 cartons (24 nasal sprays) /
(naloxone hydrochloride nasal spray)	days	75 days
Rezenopy	4 cartons (8 nasal sprays) / 25	12 cartons (24 nasal sprays) /
(naloxone hydrochloride nasal spray)	days	75 days
RiVive	4 cartons (8 nasal sprays) / 25	12 cartons (24 nasal sprays) /
(naloxone hydrochloride nasal spray)	days	75 days
Zimhi (naloxone hydrochloride injection)	4 cartons (8 pre-filled syringes) / 25 days	12 cartons (24 pre-filled syringes) / 75 days
Zurnai	8 cartons (8 auto-injectors) / 25	24 cartons (24 auto-injectors) /
(nalmefene injection)	days	75 days

Opioid Reversal Agents Post Limit PA Policy UDR 02-2024 v3.docx

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

\*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing. \*\*Some products may only be available only by prescription, some may only be available over-the-counter (OTC), and others may be available both by prescription and over-the-counter (OTC). The limits apply to all listed products, both prescription and over-the-counter (OTC), as available.

## **DURATION OF APPROVAL (DOA)**

1138-J: DOA: 6 months

## **REFERENCES**

- 1. Kloxxado Nasal Spray [package insert]. Columbus, OH: Hikma Specialty USA Inc.; May 2022.
- 2. Naloxone Nasal Spray RX [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; October 2023.
- 3. Naloxone Nasal Spray OTC [package insert]. Yeruham, Israel: Padagis Israel Pharmaceuticals Ltd; July 2023.
- 4. Narcan Nasal Spray RX [package insert]. Plymouth Meeting, PA: Emergent Devices Inc.; November 2020.
- 5. Narcan Nasal Spray OTC [package insert]. Plymouth Meeting, PA: Emergent Devices Inc.; August 2023.
- 6. Opvee Nasal Spray [package insert]. North Chesterfield, VA: Indivior Inc.; June 2023.
- 7. Rextovy Nasal Spray [package insert]. So. El Monte, CA: International Medication Systems, Limited.; June 2023.
- 8. Rezenopy Nasal Spray [package insert]. Lexington, KY: Summit Biosciences Inc., April 2024.
- 9. RiVive Nasal Spray [package insert]. Bethesda, MD: Harm Reduction Therapeutics, Inc.; June 2023.
- 10. Zimhi [package insert]. San Diego, CA: Adamis Pharmaceuticals Corporation; October 2021.
- 11. Zurnai [package insert]. Stamford, CT: Purdue Pharm L.P.; August 2024.
- 12. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed December 8, 2023.
- 13. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed December 8, 2023.
- 14. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 12.8.2023).
- Substance Abuse and Mental Health Services Administration. SAMHSA Opioid Overdose Prevention Toolkit. HHS Publication No. (SMA) 18-4742. Rockville, MD: Substance Abuse and Mental Health Services Administration, First printed 2013. Revised 2014, 2016, 2018. https://store.samhsa.gov/sites/default/files/d7/priv/sma18-4742.pdf. Accessed December 8, 2023.
- Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence. World Health Organization. 2009. Available at: https://www.who.int/publications/i/item/9789241547543.. Accessed December 14, 2022.
- U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration (SAMHSA). Treatment Improvement Protocol (TIP) Series 43. Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs. Available at: https://www.hrsa.gov/behavioral-health/tip-43-medication-assistedtreatment-opioid-addiction-opioid-treatment-programs. Accessed December 8, 2023.
- U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration (SAMHSA). Treatment Improvement Protocol (TIP) Series 63: Medications for Opioid Use Disorder. Available at: https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP21-02-01-002. Accessed December 8, 2023.
- 19. Substance Use Community Management of Opioid Overdose. World Health Organization. 2014. https://apps.who.int/iris/bitstream/handle/10665/137462/9789241548816\_eng.pdf. Accessed December 8, 2023.

Opioid Reversal Agents Post Limit PA Policy UDR 02-2024 v3.docx

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.