These criteria apply to the fo	ollowing:		
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✓ ACFC	□ VF	☐ Marketplace (MF)	□ Aetna FI ACFC
✓ SF	□ VFC	Aetna SG ACA (Aetna Health Exchanges)	□ Aetna FI SOO
✓ SFC		□ Aetna IVL	

MEDICAL NECESSITY CRITERIA

DRUG CLASS MEDICAL NECESSITY CRITERIA

BRAND NAME* (generic)

EVZIO

(naloxone hydrochloride injection)

Status: CVS Caremark Criteria Type: Medical Necessity Criteria**

Ref # 2841-C

FDA-APPROVED INDICATIONS

Evzio 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 in adults and pediatric patients. Evzio is intended for immediate administration as emergency therapy in settings where opioids may be present. Evzio is not a substitute for emergency medical care.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient's treatment cannot be switched to a formulary drug [Available Formulary Alternatives: Narcan (naloxone hydrochloride) nasal spray, naloxone injection (excluding auto-injector)]
 AND
- The requested drug is being prescribed in the event that emergency treatment of opioid overdose may be needed AND
- The patient has factors that increase risk for opioid overdose
 [Note: Factors may include history of overdose, history of substance use disorder, higher opioid dosages (greater than or equal to 50 morphine milligram equivalents (MME)/day), or concurrent benzodiazepine use.]
 AND
 - The patient has a nasal condition, a nasal anatomical abnormality, or other valid anatomical medical reason where Narcan (naloxone hydrochloride) nasal spray is unable to be used. The prescriber must submit chart notes or other documentation supporting a nasal condition, a nasal anatomical abnormality, or other valid anatomical medical reason where Narcan (naloxone hydrochloride) nasal spray is unable to be used.

OR

There is a reason why the individual administering opioid overdose treatment cannot properly demonstrate appropriate and safe use or administration technique of Narcan (naloxone hydrochloride) nasal spray. The prescriber must submit chart notes or other documentation supporting a reason why the individual administering opioid overdose treatment cannot properly demonstrate appropriate and safe use or administration technique of Narcan (naloxone hydrochloride) nasal spray.

AND

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^{*} Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.

^{**} No Tech Approval; criteria requires a pharmacist to approve.

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✓ SFC		□ Aetna IVL		

There is a reason why the individual administering opioid overdose treatment cannot properly demonstrate appropriate and safe use or administration technique of naloxone injection (excluding autoinjector). The prescriber must submit chart notes or other documentation supporting a reason why the individual administering opioid overdose treatment cannot properly demonstrate appropriate and safe use or administration technique of naloxone injection (excluding auto-injector).

AND

- Chart notes or other documentation supporting all of the following have been submitted to CVS Health: A) The patient has a nasal condition or a nasal anatomical abnormality where Narcan (naloxone hydrochloride) nasal spray is unable to be used OR the individual administering opioid overdose treatment cannot properly demonstrate appropriate and safe use or administration technique of Narcan (naloxone hydrochloride) nasal spray, B) The individual administering opioid overdose treatment cannot properly demonstrate appropriate and safe use or administration technique of naloxone injection (excluding auto-injector)
- If requesting more than 2 cartons (4 auto-injectors) in a 6 month period, then the patient requires more than 2 cartons due to any of the following: A) The type of opioid that the patient is taking (e.g., buprenorphine, pentazocine, long-acting/extended-release opioids), B) The patient is living in an area that has a longer wait time for emergency medical assistance, C) The patient had an overdose episode that required the use of naloxone or the requested drug

Quantity Limits apply.

AND

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Evzio is indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression in adults and pediatric patients. Evzio is intended for immediate administration as emergency therapy in settings where opioids may be present. Evzio is not a substitute for emergency medical care.^{1,4,5}

In the event that opioid overdose emergency treatment may be needed by the patient, Evzio may be covered if the patient has factors that increase risk for opioid overdose. The Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain recommends before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should consider offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages [≥50 morphine milligram equivalents (MME)/day], or concurrent benzodiazepine use, are present.¹¹

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.² Naloxone hydrochloride injection (vial and pre-filled syringe) is indicated for the complete or partial reversal of opioid depression, including respiratory depression, induced by natural or synthetic opioids, including propoxyphene, methadone and certain mixed agonist-antagonist analgesics: nalbuphine, pentazocine, butorphanol, and cyclazocine. Naloxone hydrochloride injection is also indicated for diagnosis of suspected or known acute opioid overdosage.³ The request for Evzio will be approved if the patient's treatment cannot be switched to a formulary drug [Available Formulary Alternatives: Narcan (naloxone hydrochloride) nasal spray, naloxone injection (excluding auto-injector)] due to all of the following reasons: 1) The patient has a nasal condition or a nasal anatomical abnormality where Narcan (naloxone hydrochloride) nasal spray is unable to be used OR the individual administering opioid overdose treatment cannot properly demonstrate appropriate and safe use or administration technique of Narcan (naloxone hydrochloride) nasal spray AND 2) The individual administering opioid overdose treatment cannot properly demonstrate appropriate and safe use or administration technique of naloxone injection (excluding auto-injector).

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✓ SFC		□ Aetna IVL		

Evzio automatically inserts the needle intramuscularly or subcutaneously and delivers 2 mg naloxone hydrochloride upon actuation. If the desired response is not obtained after 2 or 3 minutes, an additional dose of Evzio may be administered. If there is still no response and additional doses are available, additional doses of Evzio may be administered every 2 to 3 minutes until emergency medical assistance arrives. If the patient responds and relapses back into respiratory depression before emergency assistance arrives, an additional dose of Evzio may be administered. Each Evzio auto-injector contains a single dose of naloxone. Evzio is supplied in a carton containing two auto-injectors. ^{1,4,5} When the prior authorization criteria are met, patients will be eligible to receive a quantity of up to 2 cartons per 180 days.

If the request is for quantities in excess of 2 cartons per 180 days, then additional prior authorization criteria will need to be met. If the additional criteria are met, then the patient will be eligible to receive up to 4 cartons per 180 days.

The requirement for repeat doses of Evzio depends upon the amount, type, and route of administration of the opioid being antagonized. Reversal of respiratory depression by partial agonists or mixed agonist/antagonists, such as buprenorphine and pentazocine, may be incomplete or require higher doses of naloxone or repeated administration of Evzio. The duration of action of most opioids exceeds that of naloxone hydrochloride, and the suspected opioid overdose may occur outside of supervised medical settings.¹ The Substance Abuse and Mental Health Services Administration (SAMHSA) Opioid Overdose Prevention Toolkit states that most patients respond to naloxone generally within 2 to 3 minutes. Patients who have taken longer-acting opioids may require further doses or an infusion. Naloxone will continue to work for 20 to 90 minutes, but after that time, overdose symptoms may return. It is essential to get the person to an emergency department or other source of medical care as quickly as possible. ^{6,7,9} If the patient is living in an area of extended emergency response time or taking opioids that may require further dosing, then a total of 4 cartons per 180 days may be covered in a 6 month period.

The SAMHSA Medication-Assisted Treatment for Opioid Addiction Protocol supports opioid addiction as a chronic medical disorder where genetic, personal-choice, and environmental factors play a part in the etiology and course including relapse and adherence to treatment. The risk of relapse during and after tapering is significant and many patients who complete tapering from opioid medication continue to need support, especially during the first 3 to 12 months. ^{8,9} According to the World Health Organization (WHO), a reduction in tolerance, seen when opioid use is restarted after a period of abstinence, markedly increases the risk of an opioid overdose. ¹⁰ Most patients resume opioid use within six months of opioid withdrawal and are at increased risk of overdose during the first weeks of treatment. ⁷ Therefore, if the patient has previously had an overdose episode that required the use of naloxone, then a total of 4 cartons per 180 days may be covered in a 6 month period.

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✓ SFC		□ Aetna IVL		

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UM Development (CF/DS) Written by:

Date Written: 01/2019

Revised: (MAC) 11/2019 (added BF to title, no clinical changes); (DS) 01/2020 (no clinical changes), 01/2021 (no clinical changes), 09/2021

(updated title); (RZ) 01/2022 (no clinical changes)

Medical Affairs: (DNC) 01/2019; (CHART) 1/30/2020, 01/28/2021, 02/03/2022 Reviewed:

External Review: 04/2019, 12/2019 (FYI), 04/2020, 04/2021, 04/2022

CRITERIA FOR APPROVAL

1 The patient's drug benefit plan provides coverage for other drugs which may be considered for treating your patient. Can your patient's treatment be switched to a formulary drug?

Yes No

Available Formulary Alternatives:

Narcan (naloxone hydrochloride) nasal spray, naloxone injection (excluding auto-injector)

Ilf yes, then provide your patient with a new prescription for a preferred product: Narcan (naloxone hydrochloride) nasal spray, naloxone injection (excluding auto-injector).]

[If yes, then no further questions.]

2 Is the requested drug being prescribed in the event that emergency treatment of opioid overdose may be needed?

Yes No

[If no, then no further questions.]

3 Does the patient have any factors that increase risk for opioid overdose? [Note: Factors may include history of overdose, history of substance use disorder, higher opioid dosages (greater than or equal to 50 morphine milligram equivalents (MME)/day). or concurrent benzodiazepine use.]

Yes No

[If no, then no further questions.]

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✓ SFC		□ Δetna IVI			

4	Does the patient have a nasal condition, a nasal anatomical abnormality, or other valid anatomical medical reason where Narcan (naloxone hydrochloride) nasal spray is unable to be used?	Yes	No
	[If yes, then prescriber MUST submit chart notes or other documentation supporting a nasal condition, a nasal anatomical abnormality, or other valid anatomical medical reason where Narcan (naloxone hydrochloride) nasal spray is unable to be used.]		
	[If yes, then skip to question 6.]		
5	Is there a reason why the individual administering opioid overdose treatment cannot properly demonstrate appropriate and safe use or administration technique of Narcan (naloxone hydrochloride) nasal spray?	Yes	No
	[If yes, then prescriber MUST submit chart notes or other documentation supporting a reason why the individual administering opioid overdose treatment cannot properly demonstrate appropriate and safe use or administration technique of Narcan nasal spray (naloxone nasal spray).]		
	[If no, then provide your patient with a new prescription for a preferred product: Narcan (naloxone hydrochloride) nasal spray, naloxone injection (excluding auto-injector).]		
	[RPh Note: Leave response as answered by prescriber. Verification of chart note by RPh will be addressed in question 7.]		
	[If no, then no further questions.]		
6	Is there a reason why the individual administering opioid overdose treatment cannot properly demonstrate appropriate and safe use or administration technique of naloxone injection (excluding auto-injector)?	Yes	No
	[If yes, then prescriber MUST submit chart notes or other documentation supporting a reason why the individual administering opioid overdose treatment cannot properly demonstrate appropriate and safe use or administration technique of naloxone injection (excluding auto-injector).]		
	[If no, then provide your patient with a new prescription for a preferred product: naloxone injection (excluding auto-injector).]		
	[RPh Note: Leave response as answered by prescriber. Verification of chart note by RPh will be addressed in question 7.]		
	[If no, then no further questions.]		
7	Have chart notes or other documentation supporting all of the following been submitted to CVS Health: A) The patient has a nasal condition or a nasal anatomical abnormality where Narcan (naloxone hydrochloride) nasal spray is unable to be used OR the individual administering opioid overdose treatment cannot properly demonstrate	Yes	No

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✓ SF		VFC		Aetna SG ACA (Aetna Health Exchanges)		Aetna FI SOO
✓ SFC				Aetna IVL		

appropriate and safe use or administration technique of Narcan (naloxone hydrochloride) nasal spray, B) The individual administering opioid overdose treatment cannot properly demonstrate appropriate and safe use or administration technique of naloxone injection (excluding auto-injector)?

[Tech Note: If the PA is worked over the phone, then the prescriber still MUST submit physical chart notes or other documentation.]

[RPh Note: MUST obtain a physical copy of chart notes or other documentation supporting ALL of the following: A) The patient has a nasal condition or a nasal anatomical abnormality where Narcan (naloxone hydrochloride) nasal spray is unable to be used OR the individual administering opioid overdose treatment cannot properly demonstrate appropriate and safe use or administration technique of Narcan (naloxone hydrochloride) nasal spray, B) The individual administering opioid overdose treatment cannot properly demonstrate appropriate and safe use or administration technique of naloxone injection (excluding auto-injector).

[If a physical copy of documentation supporting why Narcan (naloxone hydrochloride) nasal spray and naloxone injection (excluding auto-injector) are unable to be used is not received, then the PA should be denied.]

[If no, then no further questions.]

- Does the patient require more than 2 cartons (4 auto-injectors) per 6 months?

 [Note: Coverage is provided for up to an initial quantity of 2 cartons per 6 months. If higher quantities are needed, then additional questions are required.]

 [If no, then no further questions.]
- Does the patient require more than 2 cartons (4 auto-injectors) in a 6 month period due to any of the following: A) The type of opioid that the patient is taking (e.g., buprenorphine, pentazocine, long-acting/extended-release opioids), B) The patient is living in an area that has a longer wait time for emergency medical assistance, C) The patient had an overdose episode that required the use of naloxone or the requested drug?

 [If no, then no further questions.]

[RPh Note: If no, then deny and enter a partial approval for 2 cartons (4 auto-injectors) per 180 days.]

Does the patient require more than the plan allowance of 4 cartons (8 auto-injectors) per 6 months?

[RPh Note: If yes, then deny and enter a partial approval for up to a total of 4 cartons (8 auto-injectors) per 180 days.]

Mapping Instructions			
	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D

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Yes

Yes

Yes

No

No

Nο

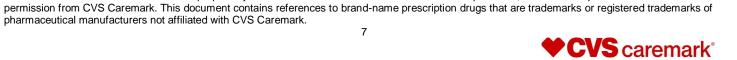
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✓ SFC		□ Aetna IVI			

1.	Deny, Inform	Go to 2	You do not meet the requirements of your plan.
1.	prescriber to	G0 10 2	Your plan covers this drug when your treatment cannot be switched
	provide patient		to any of the following:
	with a new		-Narcan (naloxone hydrochloride) nasal spray
	prescription for a		-Naloxone injection (excluding auto-injector)
	preferred		Your request has been denied based on the information we have.
	product.		Tour request has been defined based on the information we have.
	p. 64.64.		[Short Description: Therapy can be switched]
2.	Go to 3	Deny	You do not meet the requirements of your plan.
			Your plan covers this drug if you may need urgent opioid overdose
			treatment.
			Your request has been denied based on the information we have.
			[Short Description: No approvable diagnosis]
3.	Go to 4	Deny	You do not meet the requirements of your plan.
J.	00104	Deriy	Your plan covers this drug when you have factors that increase the
			risk for opioid overdose.
			Your request has been denied based on the information we have.
			Tour request has been defined based on the information we have.
			[Short Description: No risk factors that increase risk for opioid
			overdose]
4.	Go to 6	Go to 5	-
5.	Go to 6	Deny, Inform	You do not meet the requirements of your plan.
		prescriber to	Your plan covers this drug when you meet all of these conditions:
		provide patient with	-You have a nasal issue or other medical reason where you cannot
		a new prescription	use Narcan (naloxone hydrochloride) nasal spray or the person
		for a preferred	giving you urgent opioid overdose treatment cannot properly use
		product.	Narcan (naloxone hydrochloride) nasal spray
			-The person giving you urgent opioid overdose treatment cannot
			properly use naloxone injection (excluding auto-injector)
			Your request has been denied based on the information we have.
			[Short Description: No reason to avoid formulary alternatives
			(Narcan)]
6.	Go to 7	Deny, Inform	You do not meet the requirements of your plan.
		prescriber to	Your plan covers this drug when you meet all of these conditions:
		provide patient with	-The person giving you urgent opioid overdose treatment cannot
		a new prescription	properly use naloxone injection (excluding auto-injector)
		for a preferred	Your request has been denied based on the information we have.
		product.	
			[Short Description: No reason to avoid formulary alternatives]
7.	Go to 8	Deny	You do not meet the requirements of your plan.
			Your plan covers this drug when your prescriber submits your chart
			notes or other documentation to CVS Health that supports that you
			have all of these conditions:
			-You have a nasal issue or other medical reason where you cannot
			use Narcan (naloxone hydrochloride) nasal spray or the person

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✓ SFC		□ Aetna IVI			

			giving you urgent opioid overdose treatment cannot properly use Narcan (naloxone hydrochloride) nasal spray -The person giving you urgent opioid overdose treatment cannot properly use naloxone injection (excluding auto-injector) Your request has been denied based on the information we have. [Short Description: Prescriber did not submit documentation to
8.	Go to 9	Approve, 6 months	confirm a reason to avoid formulary alternatives]
0.	G0 10 9	2 cartons (4 auto- injectors [1.6 mL]) per 180 days	
9.	Go to 10	Deny	You have requested more than the quantity allowed by your plan. Current plan approved criteria cover up to 2 cartons (4 auto-injectors) in a 6 month period. Your request has been partially approved. You have been approved for the quantity your plan covers for a duration of 6 months. Your request for additional quantities of the requested drug and strength has been denied. Your plan covers additional quantities of this drug when you meet any of these conditions: You are taking a certain type of opioid (examples are buprenorphine, pentazocine, long-acting/extended-release opioids) You live in an area that has a longer wait time for emergency medical assistance You had an overdose episode that required the use of naloxone or the requested drug Your use of this drug does not meet the requirement. This is based on the information we have. [Short Description: Over max quantity and patient does not meet requirements for additional quantities]
10.	Deny	Approve, 6 months 4 cartons (8 auto- injectors [3.2 mL]) per 180 days No Tech Approval	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to a total of 4 cartons (8 auto-injectors) in a 6 month period. Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 6 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]

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