Pharmacy Medical Necessity Guidelines: Evzio™ (naloxone)

Effective: July 20, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Evzio (naloxone) is an opioid antagonist Food and Drug Administration (FDA)-approved for emergency treatment of known or suspected opioid overdose. Evzio (naloxone) is available as a single-use, pre-filled auto-injector for intramuscular or subcutaneous use.

FDA-APPROVED INDICATIONS

Evzio (naloxone) is indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.

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 GUIDELINES

The plan may authorize coverage of Evzio (naloxone) for Members, when the following criteria are met:

1. There is a Food and Drug Administration confirmed shortage of ALL preferred products for the emergency treatment of opioid overdose (naloxone vials and syringes and Narcan [naloxone] nasal spray).

LIMITATIONS

1. Coverage for Evzio (naloxone) will be limited to 2 units per prescription, with a maximum of 4 units per 30 days.
2. Approval duration will be limited to a one time fill.
3. Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception but will be considered on an individual basis for prior authorization.

CODES

None

REFERENCES

1. Evzio (naloxone) [prescribing information]. Richmond, VA: kaleo, Inc.; 2016 October.
2. Intranasal naloxone for treatment of opioid overdose. *The Medical Letter.* 2014;56:1438.
3. Boyer EW. Management of opioid analgesic overdose. *N Engl J Med.* 2012,367(2):146-55.

APPROVAL HISTORY

April 12, 2016: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- July 11, 2017: No changes
- August 7, 2018: No changes

- October 15, 2019: No changes
- July 14, 2020: Added the following limitation: Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception but will be considered on an individual basis for prior authorization.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services