ALASKA MEDICAID Prior Authorization Criteria

Naloxone Opioid Overdose Treatment: Evzio[®] (naloxone HCl)

FDA Indications and Usage:

"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. 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

Dosage Form/Strength:

Evzio Injection: 0.4mg/0.4mL naloxone HCl auto-injector

Evzio Criteria for Approval:

- The patient has previously used and had experienced a documented intolerance to Narcan Nasal Spray OR
- 2. The patient has a documented clinical reason why Narcan Nasal Spray cannot be used.

Evzio Criteria for Denial:

- 1. The patient has not used and experienced a documented intolerance to Narcan Nasal Spray OR
- 2. The patient does not have a documented clinical reason why Narcan Nasal Spray cannot be used

Length of Authorization:

- 1. Initial authorization may be approved for up to 6 months.
- 2. Subsequent re-authorizations may be approved for up to 1 year.

Quantity Limit:

1. The Evzio dispensing limit is 1 box (2 auto-injectors) per fill.

Mechanism of Action:

"Naloxone hydrochloride is an opioid antagonist that antagonizes opioid effects by competing for the same receptor sites. Naloxone hydrochloride reverses the effects of opioids, including respiratory depression, sedation, and hypotension. It can also reverse the psychotomimetic and dysphoric effects of agonist-antagonists such as pentazocine."¹

Opioid Overdose Background Clinical Information^{1, 2, 3, 4}

Current clinical guidelines recommend that patients at high risk of opioid overdose have access to an opioid antagonist (reversal) agent to prevent death due to opioid overdose. Per the CDC guidelines, if an opioid reversal agent is warranted, prescribers should consider offering naloxone. For additional information about the guidelines, the management of an opioid overdose, and opioid overdose risk factors, please refer to the citations listed below.

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References:

 ¹ Evzio[®] Prescribing Information. kaleo, Inc. Richmond, VA. April 2014. <u>http://evzio.com/pdfs/Evzio%20PI.PDF</u>. Accessed 12/1/2015.
² Boyer EW, "Management of Opioid Analgesic Overdose," N Engl J Med, 2012, 367(2):146-55. <u>http://www.nejm.org/doi/full/10.1056/NEJMra1202561.</u> Accessed 12/2/2015.

³ "Injury Prevention and Control: Opioid Overdose." Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, Division of Unintentional Injury Prevention. Atlanta, GA. March 14, 2016. <u>http://www.cdc.gov/drugoverdose/epidemic/index.html</u>. Accessed 6/2/2016.

⁴ Dowell D, Haegerich TM, Chou R. CDC. "CDC Guidelines for Prescribing Opioids for Chronic Pain – United States, 2016." Morbidity and Mortality Weekly Report (MMWR). March 18, 2016 / 65(1);1–49. <u>https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm</u>