

ALASKA MEDICAID
Prior Authorization Criteria

Symproic® (naldemedine)

FDA INDICATIONS AND USAGE¹

Symproic® is an opioid antagonist indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.

APPROVAL CRITERIA^{1,2}

1. Patient meets FDA labeled age; **AND**
2. Diagnosis of Opioid-induced constipation (OIC) in adults with chronic non-cancer pain; **AND**
3. Recipient has been taking opioids for a period longer than 4 weeks; **AND**
4. Recipient does not have or suspected mechanical gastrointestinal obstruction; **AND**
5. Submit dates of trial or inadequate response from at least 2 laxative therapies.

DENIAL CRITERIA^{1,2}

1. Recipient does not have a diagnosis of Opioid-induced constipation (OIC) in adults with chronic non-cancer pain; **OR**
2. Recipient has not taken opioids for a period longer than 4 weeks; **OR**
3. Recipient is at risk or has a suspected mechanical gastrointestinal obstruction; **OR**
4. Dates of trial or inadequate response from at least 2 laxative therapies has not been submitted.

CAUTIONS¹

- There is a potential for gastrointestinal perforation.
- May cause severe or persistent diarrhea.
- Patients should be monitored for symptoms of opioid withdrawal.

DURATION OF APPROVAL

- Approval: up to a maximum of 4 months

QUANTITY LIMITS

- 34 day supply at FDA approved dosage.

ALASKA MEDICAID
Prior Authorization Criteria

REFERENCES / FOOTNOTES:

1. Symproic® [prescribing information]. Raleigh, NC: BioDelivery Sciences International Inc, May 2020.
2. American Gastroenterological Association Technical Review on Constipation. Bharucha, Adil E.Pemberton, John H.Locke, G. Richard et al. Gastroenterology , Volume 144 , Issue 1 , 218 - 238