

Initial Prior Authorization

Symproic

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Symproic	naldemedine

Indications

FDA-approved Indications

Symproic is 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.

Coverage Criteria

Opioid-Induced Constipation (OIC)

Authorization may be granted when the requested drug is being prescribed for the treatment of opioid-induced constipation (OIC) in an adult patient with chronic non-cancer pain, including chronic pain related to prior cancer or its treatment, who does NOT require frequent (e.g., weekly) opioid dosage escalation

Duration of Approval (DOA)

- 1713-A: DOA: 12 months

References

1. Symproic [package insert]. Raleigh, NC: BioDelivery Sciences International, Inc.; July 2021.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 12, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/12/2024).

Document History

Written by: UM Development (KM)

Date Written: 03/2017

Revised: (DS) 08/2017 (no clinical changes), 03/2018 (label update), 09/2018 (no clinical changes), 09/2019 (no clinical changes; removed MDC); (KC) 09/2020 (no clinical changes); (DS) 09/2021 (no clinical changes); (VLS) 09/2022 (no clinical changes); (SS) 09/2023 (no clinical changes); (ANB) 09/2024 (no clinical changes)

Reviewed: Medical Affairs (JG) 04/2017; (MC) 03/2018; (CHART) 09/26/2019, 09/24/20, 09/30/2021, 09/22/2022, 09/28/2023, 09/26/2024

External Review: 12/2017, 04/2018, 12/2018, 12/2019, 12/2020, 12/2021, 12/2022, 12/2023, 12/2024

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for the treatment of opioid-induced constipation (OIC) in an adult patient with chronic non-cancer pain, including chronic pain related to prior cancer or its treatment who does NOT require frequent (e.g., weekly) opioid dosage escalations? [No further questions]	Yes	No
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Mapping Instructions			
	Yes	No	DENIAL REASONS

1.	Approve, 12 Months	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for opioid-induced constipation (OIC) in an adult patient with specific types of pain who do not need frequent dose changes. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
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