

Drug Policy

Policy:	Symproic (naldemedine)	Annual Review Date: 05/19/2022 Last Revised Date: 05/19/2022
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OVERVIEW

Symproic is a mu-opioid receptor antagonist that acts peripherally in tissues such as the GI tract, thereby decreasing the constipating effects of opioids. Symproic is indicated for the treatment of 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.

POLICY STATEMENT

This policy involves the use of Symproic. Prior authorization is recommended for pharmacy benefit coverage of Symproic. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Symproic is recommended in those who meet the following criteria:

1. Opioid Induced Constipation (OIC), Initial Therapy

Criteria. Patient must meet the following criteria (A, B, C, D, E, and F):

- A. The patient is 18 years of age or older; AND
- B. The patient has a documented diagnosis of chronic non-cancer pain, including chronic pain related to prior cancer if the patient does not require frequent dosage escalations; AND
- C. The patient has been taking opioids for 4 weeks or more; AND
- D. The patient has attempted lifestyle changes, including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; AND
- E. The patient has failed on or is intolerant to at least 2 of the following with or without a stool softener in the past 3 months (a, b, or c):
 - a. At least one stimulant laxative (e.g. bisacodyl); OR
 - b. At least one osmotic laxative (e.g. PEG 3350); OR
 - c. At least one saline laxative (e.g. magnesium citrate); AND

Drug Policy

- F. The patient does not have a known or suspected gastrointestinal obstruction and is not at increased risk for recurrent obstruction.

2. **Continuation of Therapy (Renewal)**

Criteria. *Patient must meet the following criteria (A, B, and C):*

- A. The patient is 18 years of age or older; AND
- B. The patient has demonstrated a beneficial response to Symproic, per the prescribing physician (e.g. increased number of bowel movements from baseline); AND
- C. The patient is still on opioid therapy; AND
- D. The patient has no contraindications to therapy with Symproic.

Initial Approval/ Extended Approval.

A) *Initial Approval:* 365 days

B) *Extended Approval:* 365 days

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Symproic has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Symproic (naldemedine) [prescribing information]. Stamford, CT: Purdue Pharma L.P.; March 2017

Drug Policy

2. Ford AC, Moayyedi P, Lacy BE, et al; Task Force on the Management of Functional Bowel Disorders. American College of Gastroenterology monograph on the management of irritable bowel syndrome and chronic idiopathic constipation. *Am J Gastroenterol*. 2014 Aug;109 Suppl 1:S2-26
3. Pare P, Bridges R, Champion MC, et al. Recommendations on chronic constipation (including constipation associated with irritable bowel syndrome) treatment. *Can J Gastroenterol*. 2007 Apr;21 Suppl B:3B-22B
4. Bove A, Bellini M, Battaglia E, et al. Consensus statement AIGO/SICCR diagnosis and treatment of chronic constipation and obstructed defecation (part II: treatment). *World J Gastroenterol*. 2012 Sep 28;18(36):4994-5013
5. Bharucha A, Dorn S, Lembo A. 'American Gastroenterological Association medical position statement on constipation. *Gastroenterology*. 2013 Jan;144(1):211-7
6. 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
7. Tarumi Y, Wilson MP, Szafran O, Spooner GR. Randomized, double-blind, placebo-controlled trial of oral docusate in the management of constipation in hospice patients. *J Pain Symptom Manage* 2013;45:2-13.
8. Weitzel KW, Goode JR. Constipation. In Krinsky DL, Ferreri SP, Hemstreet B, et al, Eds. *Handbook of Nonprescription Drugs*. 18th ed. Washington, DC: American Pharmaceutical Association, 2015.
9. Naldemedine. In: DRUGDEX (online database). Truven Health Analytics; Greenwood Village, CO. Last updated 5 Dec 2018. Accessed on 9 May 2019.