

**Pharmacy Policy**

---

**Gastrointestinal Agents**

**Policy Number:** 9.804

**Revision Number:** R0

**Version Effective Date:** 1/1/2021

Product Applicability  All Plan+ Products

**Well Sense Health Plan**

New Hampshire Medicaid

**Boston Medical Center HealthNet Plan**

MassHealth - MCO

MassHealth - ACO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

**Prior Authorization Policy**

---

**Products Affected:**

- alosetron
- Amitiza® (lubiprostone)
- Linzess® (linaclotide)
- Lotronex® (alosetron)
- Movantik® (naloxegol)

The Plan may authorize coverage of the above products for members meeting the following criteria:

<b>Covered Use</b>	All FDA approved indications not otherwise excluded
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	<p><b>Alosetron and Lotronex</b></p> <ol style="list-style-type: none"> <li>1. A diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS) in women; <b>AND</b></li> <li>2. Chronic IBS symptoms; <b>AND</b></li> </ol>

\* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

3. An inadequate response to at least one agent from within each of the following laxative types:

- a. fiber laxatives (e.g., psyllium, methylcellulose, calcium polycarbophil)
- b. stimulant laxatives (e.g., bisacodyl, senna)
- c. osmotic laxatives (e.g., Polyethylene glycol, magnesium citrate, milk of magnesia, sorbitol, lactulose);

**Amitiza**

1. One of the following diagnoses:

- a. chronic idiopathic constipation (CIC);
- b. irritable bowel syndrome with constipation (IBS-C) in women;
- c. opioid-induced constipation (OIC) in patients with chronic, non-cancer pain;
- d. opioid-induced constipation (OIC) in patient with chronic pain related to prior cancer or its treatment who do not require frequent (e.g. weekly) opioid dose escalations;

**AND**

2. An inadequate response to at least one agent from within each of the following laxative types:

- d. fiber laxatives (e.g., psyllium, methylcellulose, calcium polycarbophil)
- e. stimulant laxatives (e.g., bisacodyl, senna)
- f. osmotic laxatives (e.g., Polyethylene glycol, magnesium citrate, milk of magnesia, sorbitol, lactulose); **AND**

3. An inadequate response to two of the following preferred gastrointestinal agents: alonestron, Linzess, Lotronex, Movantik; **AND**

4. For diagnosis of opioid induced constipation (OIC) patient is not currently taking methadone

**Linzess**

1. One of the following diagnoses:

- a. chronic idiopathic constipation (CIC)
- b. irritable bowel syndrome with constipation (IBS-C); **AND**

2. An inadequate response to at least one agent from within each of the following laxative types:

- a. fiber laxatives (e.g., psyllium, methylcellulose, calcium polycarbophil)
- b. stimulant laxatives (e.g., bisacodyl, senna)
- c. osmotic laxatives (e.g., Polyethylene glycol, magnesium citrate, milk of magnesia, sorbitol, lactulose)

**Movantik**

1. Diagnosis of opioid-induced constipation (OIC) in patients with either:

- a. chronic non-cancer pain; **OR**
- b. chronic pain related to prior cancer or its treatment who do not require frequent (e.g. weekly) opioid dose escalations; **AND**

2. Member has been taking an opioid analgesic for at least 4 weeks immediately prior to the request; **AND**

3. An inadequate response or intolerance to at least one agent from within each of the following laxative types:

\* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	<ul style="list-style-type: none"> <li>a. fiber laxative (e.g., psyllium, methylcellulose, calcium polycarbophil)</li> <li>b. stimulant laxative (e.g., bisacodyl, senna)</li> <li>c. osmotic laxative (e.g., polyethylene glycol, magnesium citrate, milk of magnesia, sorbitol, lactulose)</li> </ul>
<b>Age Restriction</b>	18 years of age or older
<b>Prescriber Restriction</b>	None
<b>Coverage Duration</b>	12 months
<b>Other criteria</b>	Reauthorization: <ul style="list-style-type: none"> <li>1. Initial criteria are met; <b>AND</b></li> <li>2. Continuation of therapy is clinically appropriate; <b>AND</b></li> <li>3. The treatment has been effective and well tolerated</li> </ul>

### Applicable Coding:

None

### Clinical Background Information and References

1. American College of Gastroenterology IBS Task Force. Evidence-based position statement on the management of irritable bowel syndrome in North America. *Am J Gastroenterol.* 2009;104 (suppl 1):S1-S35
2. Bharucha AE, et al. American Gastroenterological Association Technical Review on Constipation. *Gastroenterology* - January 2013 (Vol. 144, Issue 1, Pages 218-238).
3. Brandt LJ. et al. An evidence-based position statement on the management of irritable bowel syndrome. American College of Gastroenterology Task Force on Irritable Bowel Syndrome. *Am J Gastroenterol.* 2009;104 Suppl 1:S1.
4. Chapelle, R. FDA News; FDA approves Relistor<sup>®</sup> for opioid-induced constipation; April 24, 2008. <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01826.html> Accessed January 21, 2009.
5. Crockett, Seth D.. et al. American Gastroenterological Association Institute Guideline on the Medical Management of Opioid-Induced Constipation. *Gastroenterology* , Volume 0 , Issue 0.
6. Ford AC, Moayyedi P, Lacy BE, Lembo AJ, Saito YA, Schiller LR, et al. American College of Gastroenterology monograph on the management of irritable bowel syndrome and chronic idiopathic constipation. *Amer J of Gastro.* 2014;109(S1):S2-S26.
7. Lexi-Comp Inc. Lexi-Drugs (comp + Specialties) Reader v. 2.4080428; 2008.
8. Movantik<sup>™</sup> [package insert]. Wilmington, DE. AstraZeneca.; August 2016. American Gastroenterological Association medical position statement: Irritable Bowel Syndrome. *Gastroenterol* 2002; 123:2105-7.
9. Product Information. Amitiza<sup>®</sup>, lubiprostone capsules. Sucampo Pharmaceuticals, Inc., Bethesda, MD 20814. April 2013.
10. Product Information. Linzess<sup>®</sup>, linaclotide capsules. Forest Pharmaceuticals, Inc., St. Louis, MS 63045. August 2012.
11. Wald, A. Management of chronic constipation in adults. Up to Date<sup>®</sup>, accessed May 2013; available from: <http://www.uptodate.com>.
12. Wald, A. Treatment of irritable bowel syndrome. Up to Date<sup>®</sup>, accessed May 2013; available from: <http://www.uptodate.com>.

\* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.122 Gastrointestinal Agents Policy retired, new policy created	1/1/2021	P&T Committee, NH DHHS

### Next Review Date

2021

### Other Applicable Policies

### Reference to Applicable Laws and Regulations, If Any

#### Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

\* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.