BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Gastrointestinal Agents

Policy Number: 9.804
Version Number: 2.0
Version Effective Date: 3/1/2022

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:

- Linzess (linaclotide)
- lubiprostone
- Movantik (naloxegol)

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

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None
Required Medical Information	**lubiprostone** 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;

+ *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.

	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. If the diagnosis is opioid induced constipation (OIC), the member 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) **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: a. fiber laxative (e.g., psyllium, methylcellulose, calcium polycarbophil) b. stimulant laxative (e.g., bisacodyl, senna) c. osmotic laxative (e.g., polyethylene glycol, magnesium citrate, milk of magnesia, sorbitol, lactulose); ***AND*** 2. The member has had an inadequate response, intolerance, or contraindication to lubiprostone
Age Restriction	18 years of age or older
Prescriber Restriction	None
Coverage Duration	12 months
Other criteria	**Reauthorization:** 1. Initial criteria are met; ***AND*** 2. Continuation of therapy is clinically appropriate; ***AND*** 3. The treatment has been effective and well tolerated

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 (supp 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® 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™ [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®, lubiprostone capsules. Sucampo Pharmaceuticals, Inc., Bethesda, MD 20814. April 2013.
10. Product Information. Linzess®, linaclotide capsules. Forest Pharmaceuticals, Inc., St. Louis, MS 63045. August 2012.
11. Wald, A. Management of chronic constipation in adults. Up to Date®, accessed May 2013; available from: http://www.uptodate.com.
12. Wald, A. Treatment of irritable bowel syndrome. Up to Date®, accessed May 2013; available from: http://www.uptodate.com.

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

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
11/11/20211	P&T Annual Review. Replace Amitiza with lubiprostone. Remove trial/failure requirements from lubiprostone & Linzess (to match label). Prefer lubiprostone over Movantik.	3/1/2022	P&T Committee

Next Review Date

11/2022

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.