Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: N/A**
Policy Number: PHW.PDL.534	**Effective Date: 01/01/2020** **Revision Date: 01/2021**
Policy Name: GI Motility, Chronic Agents	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q1 2021 annual review: no changes.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: GI Motility, Chronic Agents

Reference Number: PHW.PDL.534
Effective Date: 01/01/2020
Last Review Date: 01/2021

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Chronic GI Motility Agents are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of GI Motility, Chronic Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for GI Motility, Chronic Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a GI Motility, Chronic Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact); **AND**

5. Does not have a history of a contraindication to the prescribed medication; **AND**

6. **One** of the following:

    a. For an agent indicated for treatment of a diagnosis involving constipation, has a documented history of therapeutic failure, contraindication, or intolerance of **all** of the following:

i. Laxatives,
ii. Fiber supplementation,
iii. Osmotic agents,
iv. Bulk forming agents,
v. Glycerin or bisacodyl suppositories

b. For an agent indicated for treatment of a diagnosis involving diarrhea, **all** of the following:

i. Has a documented history of therapeutic failure, contraindication, or intolerance of **both** of the following:

a) Loperamide
b) A bile acid sequestrant,

ii. Has a documented history of therapeutic failure of **both** of the following:

a) Lactose, gluten, and artificial sweetener avoidance
b) A low fermentable oligo-, di-, and monosaccharides and polyols (FODMAP) diet,

iii. Is prescribed the requested medication by or in consultation with a gastroenterologist;

AND

7. For a non-preferred GI Motility, Chronic Agent, has a history of therapeutic failure, contraindication, or intolerance to the preferred GI Motility, Chronic Agents approved or medically accepted for the beneficiary's diagnosis.

AND

8. If a prescription for a GI Motility, Chronic Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR GI MOTILITY, CHRONIC AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for a GI Motility, Chronic Agent that was previously approved

will take into account whether the beneficiary:

1. Has documentation of tolerability and a positive clinical response to the medication; **AND**

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact); **AND**

4. Does not have a history of a contraindication to the prescribed medication; **AND**

5. For an agent indicated for treatment of a diagnosis involving diarrhea, is prescribed the requested medication by or in consultation with a gastroenterologist; **AND**

6. If a prescription for a GI Motility, Chronic Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a GI Motility, Chronic Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. **Dose and Duration of Therapy**

1. Initial and renewal requests for prior authorization of GI Motility, Chronic agents will be approved for 6 months unless otherwise indicated below.

2. Requests for prior authorization of Lotronex (alosetron hydrochloride) will be approved as follows:

a. Initial requests will be approved for four (4) weeks.
b. Renewal requests will be approved for three (3) months.

E. References

1. Amitiza [package insert]. Sucampo Pharma Americas, LLC. Bedminster, NJ. October 2018.
2. Linzess [package insert]. Allergan USA, Inc. Madison, NJ. October 2018.
3. World Gastroenterology Organization Global Guideline: Irritable bowel syndrome: a global perspective. 2009, April 20.
4. American Gastroenterological Association Institute Guideline on the Pharmacological Management of Irritable Bowel Syndrome. Gastroenterology 2014;147:1146–1148.
5. Management of chronic constipation in adults. UpToDate, accessed May 6, 2015.
6. Cancer pain management with opioids: Prevention and management of side effects. UpToDate, accessed May 6, 2015.
7. Lotronex [package insert]. Sebela Pharmaceuticals, Inc. Roswell, GA. January 2016.
8. Viberzi [package insert]. Allergan USA, Inc. Madison, NJ. June 2018.
9. Wald A. Treatment of irritable bowel syndrome in adults. Talley NJ and Grover S, eds. Waltham MA: UpToDate Inc. Updated May 23, 2019. Accessed June 4, 2019.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021