Clinical Policy: GI Motility, Chronic Agents

Reference Number: PHW.PDL.534
Effective Date: 01/01/2020
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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 PA Health & 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 member:

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

5. **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 **two** of the following:

        i. Laxatives,
        ii. Fiber supplementation,
        iii. Osmotic agents,
        iv. Bulk forming agents,

v. Glycerin or bisacodyl suppositories,

6. For an agent indicated for treatment of a diagnosis involving diarrhea:
   a. 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 member'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 member 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 member, 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 member:

1. Has documentation of 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. Does not have a contraindication to the prescribed medication; **AND**

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

5. 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 member 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 member, 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 member.

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. November 2020.
2. Linzess [package insert]. Allergan USA, Inc. Madison, NJ. April 2021.
3. American Gastroenterological Association Institute Guideline on the Pharmacological Management of Irritable Bowel Syndrome. Gastroenterology 2014;147:1146–1148.
4. Wald A. Management of chronic constipation in adults: UpToDate Inc. Updated March 4, 2021. Accessed July 22, 2021.
5. Lotronex [package insert]. Sebela Pharmaceuticals, Inc. Roswell, GA. April 2019.
6. Viberzi [package insert]. Allergan USA, Inc. Madison, NJ. June 2020.
7. Wald A. Treatment of irritable bowel syndrome in adults. Talley NJ and Grover S, eds. Waltham MA: UpToDate Inc. Updated July 15, 2020. Accessed July 20, 2021.
8. American Gastroenterological Association Institute Guideline on the Medical Management of Opioid-Induced Constipation. Gastroenterology 2019;156:216-226.
9. Lacy, BE, Pimentel M, Brenner DM, et al. ACG Clinical Guideline: Management of Irritable Bowel Syndrome. Am J.Gastroenterol. 2021;116:17-44.
10. Motegrity [package insert]. Takeda Pharmaceuticals U.S.A. Lexington, MA. November 2020.
11. Movantik [package insert]. RedHill Biopharma Inc. Raleigh, NC. April 2020.

12. Relistor [package insert]. Progenics Pharmaceuticals, Inc. Tarrytown, NY. April 2020.
13. Symproic [package insert]. Shionogi & Co., Ltd. Raleigh, NC. May 2020.
14. Trulance [package insert]. Salix Pharmaceuticals, Inc. Bridgewater, NJ. April 2021.

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
Q1 2022: policy revised according to DHS revisions effective 01/03/2022.	10/2021
Q1 2023: policy revised according to DHS revisions effective 01/09/2023.	10/2022