Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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 prescribed the GI Motility, Chronic Agent for the treatment of 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 of or a contraindication or an intolerance to **two** 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, is prescribed the requested medication by or in consultation with a gastroenterologist;
    AND

6. For a non-preferred GI Motility, Chronic Agent, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred GI Motility, Chronic Agents approved or medically accepted for the beneficiary's diagnosis. See the Preferred Drug List for the list of preferred GI Motility, Chronic Agents at: https://papdl.com/preferred-drug-list

    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 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

   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

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

1. Initial requests will be approved for up to 4 weeks.
2. Renewal requests will be approved for up to 3 months.

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GI MOTILITY, CHRONIC AGENTS PRIOR AUTHORIZATION FORM *(form effective 1/9/2023)*

☐New request ☐Renewal request	Total pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		City/state/zip:	
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:	Strength:	
Dose/directions:	Quantity:	Refills:
Diagnosis *(submit documentation)*:	Dx code (*required*):	

Complete all sections that apply to the beneficiary and this request. *Check all that apply and submit documentation for each item.*

INITIAL requests

1. **For treatment of a CONSTIPATION-related diagnosis (eg, opioid-induced constipation, IBS with constipation, chronic idiopathic constipation):**
   - ☐Tried and failed or has a contraindication or an intolerance to at least 2 of the following *(check all that apply)*:
     - ☐Bulk-forming agents (eg, calcium polycarbophil, methylcellulose, psyllium, wheat dextran)
     - ☐Fiber supplementation/high fiber diet
     - ☐Glycerin or bisacodyl suppositories
     - ☐Osmotic agents (eg, lactulose, magnesium citrate, magnesium hydroxide, polyethylene glycol [PEG], sorbitol)
     - ☐Stimulant laxatives (eg, oral bisacodyl, sennosides)
   - ☐**For a non-preferred GI Motility, Chronic Agent for the treatment of constipation:**
     - ☐Tried and failed or has a contraindication or an intolerance to the preferred GI Motility, Chronic Agents for the treatment of constipation (*Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.)*
2. **For treatment of a DIARRHEA-related diagnosis (eg, IBS with diarrhea):**
   - ☐Is prescribed the requested medication by or in consultation with a gastroenterologist *(submit documentation of consultation, if applicable)*
   - ☐**For Lotronex (alosetron) *(check all that apply)*:**
     - ☐Has severe diarrhea-predominant IBS that includes at least one of the following:
       - ☐Frequent and severe abdominal pain/discomfort
       - ☐Frequent bowel urgency or fecal incontinence
       - ☐Disability or restriction of daily activities due to IBS
     - ☐Has chronic IBS symptoms generally lasting 6 months or longer
     - ☐Had anatomic or biochemical abnormalities of the GI tract excluded
     - ☐Has not responded adequately to conventional therapy

RENEWAL requests

- ☐Experienced a positive clinical response since starting the requested medication
- ☐**For treatment of a diarrhea-related diagnosis (eg, IBS with diarrhea):**
  - ☐Is prescribed the requested medication by or in consultation with a gastroenterologist *(submit documentation of consultation, if applicable)*

PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

Prescriber Signature:	**Date**: