Gateway Health Plan
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, 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

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

      ~~i.~~ Has a documented history of therapeutic failure of a low fermentable oligo-, di-, and monosaccharides and polyols (FODMAP) diet
      ii. 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, contraindication, or 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 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. 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 four (4) weeks.
2. Renewal requests will be approved for up to three (3) months.

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GI MOTILITY, CHRONIC – CONSTIPATION-RELATED DIAGNOSES PRIOR AUTHORIZATION FORM

☐New request ☐Renewal request	# of pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:
Medication will be billed via: ☐ Pharmacy ☐ Medical (Jcode:)		Place of Service: ☐ Hospital ☐ Provider's Office ☐ Home ☐ Other	

CLINICAL INFORMATION

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

INITIAL requests

Indicate all other medications and diets the beneficiary has tried or cannot try for the treatment of constipation. *Check all that apply and SUBMIT DOCUMENTATION for each.*

☐fiber supplementation/high fiber diet (20-35 grams per day): _____ grams fiber/day

☐bulk-forming agents:	☐psyllium ☐wheat dextran	☐methylcellulose ☐calcium polycarbophil	
☐osmotic agents:	☐glycerin ☐lactulose	☐sorbitol ☐magnesium citrate	☐magnesium hydroxide ☐polyethylene glycol (PEG)
☐oral stimulant laxatives:	☐bisacodyl	☐sennosides	
☐suppositories:	☐bisacodyl	☐glycerin	
☐other (list):			

Requests for a non-preferred medication: Does the beneficiary have a history of trial and failure, contraindication, or intolerance of 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.*	☐Yes ☐No	*Submit documentation of all agents tried and treatment outcomes, contraindications, or intolerances.*

RENEWAL requests

Did the beneficiary experience a positive clinical response since starting the requested medication?	☐Yes ☐No	*Submit documentation.*

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Prescriber Signature:	Date:

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GI MOTILITY, CHRONIC – DIARRHEA-RELATED DIAGNOSES PRIOR AUTHORIZATION FORM

☐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:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:	Strength:	
Dose/directions:	Quantity:	Refills:
Diagnosis *(submit documentation)*:	Dx code (*required*):	
Is the requested medication being prescribed by or in consultation with a gastroenterologist?	☐Yes ☐No	*If prescriber is not a gastroenterologist, submit documentation of consultation.*

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

All INITIAL requests

- ☐Tried and failed a low fermentable oligo-, di-, and monosaccharides and polyols (FODMAP) diet
- ☐For Lotronex (alosetron) INITIAL requests:
  - ☐Has chronic IBS symptoms generally lasting 6 months or longer
  - ☐Had anatomic or biochemical abnormalities of the GI tract excluded
  - ☐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
- ☐For Viberzi (eluxadoline) INITIAL requests:
  - ☐Has results of recent liver function tests (LFTs)

All RENEWAL requests

- ☐Experienced a positive clinical response since starting the requested medication

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Prescriber Signature:	Date: