pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
September 4, 2019	January 1, 2020	*See below

SUBJECT

Prior Authorization of GI Motility, Chronic Agents – Pharmacy Services

BY

Sally A. Kozak, Deputy Secretary
Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for GI Motility, Chronic Agents submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to GI Motility, Chronic Agents to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed clinical literature and makes recommendations relating to the following:

*01-19-58	09-19-54	27-19-52	
02-19-52	11-19-51	30-19-50	
03-19-51	14-19-50	31-19-57	
08-19-60	24-19-52	32-19-50	33-19-54

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the June 21, 2019, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of GI Motility, Chronic Agents:

- Remove the guidelines specific to Lotronex (alosetron hydrochloride) as these elements are included in the U.S. Food and Drug Administration-approved package labeling and will be taken into account when evaluating whether the beneficiary is being treated for a diagnosis that is indicated in the FDA-approved package labeling or a medically accepted indication; and
- Update the guidelines for agents indicated for treatment of a diagnosis involving diarrhea to include therapeutic failure, contraindication, or intolerance of both loperamide and a bile acid sequestrant rather than loperamide and an antispasmodic prior to treatment with a GI Motility, Chronic Agent.

The revisions to the guidelines to determine medical necessity of GI Motility, Chronic Agents, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of GI Motility, Chronic Agents are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to GI Motility, Chronic Agents) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements
http://www.dhs.pa.gov/provider/pharmacyservices/pharmacypriorauthorizationgeneralrequirements/index.htm

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
http://www.dhs.pa.gov/provider/pharmacyservices/drugsrequiringclinicalpriorauthorization/index.htm

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. See the Preferred Drug List for the list of preferred GI Motility, Chronic Agents at: https://papdl.com/preferred-drug-list;

   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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

   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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

   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 up to 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 up to four (4) weeks.
   b. Renewal requests will be approved for up to 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.