pennsylvania
DEPARTMENT OF HUMAN SERVICES

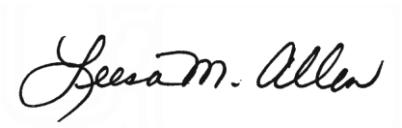
MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 13, 2015	October 26, 2015	*See below

SUBJECT

Prior Authorization of GI Motility, Chronic Agents - Pharmacy Service

BY



Leesa M. Allen, Deputy Secretary
Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers (including all associated service locations - 13 digits) who enrolled on or before **March 25, 2011** must revalidate their enrollment information no later than **March 24, 2016.** New enrollment application including all revalidation requirements may be found at http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994. Please send in your application(s) as soon as possible.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include instructions on how to request prior authorization of GI Motility, Chronic Agents, including the type of medical information needed to evaluate requests for medical necessity.

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 (FFS) delivery system, including pharmacy services to residents of long term care facilities.

BACKGROUND:

The Department of Human Services (Department) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective Drug Use Review (ProDUR) and Retrospective Drug Use Review (RetroDUR) programs.

*01-15-35	09-15-33	27-15-27	
02-15-27	11-15-26	30-15-26	
03-15-27	14-15-28	31-15-34	
08-15-33	24-15-28	32-15-27	33-15-32

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

DISCUSSION:

During the September 10, 2015 meeting, the DUR Board recommended updates to the guidelines to determine medical necessity of GI Motility, Chronic Agents to allow for an appropriate medical necessity determination of Lotronex (alosetron hydrochloride). Lotronex (alosetron hydrochloride) is designated as non-preferred on the Preferred Drug List (PDL) and is the only agent in the class of GI Motility, Chronic Agents with an indication for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). The guidelines to determine medical necessity, as recommended by the DUR Board, were subject to public review and comment, and subsequently approved for implementation by the Department. The requirements for prior authorization and clinical review guidelines to determine the medical necessity of GI Motility, Chronic Agents are included in the attached updated provider handbook pages.

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 chapters 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

SECTION II
GI Motility, Chronic Agents

I. Requirements for Prior Authorization of GI Motility, Chronic Agents (Formerly Irritable Bowel Syndrome Agents)

A. Prescriptions That Require Prior Authorization

Prescriptions for GI Motility, Chronic Agents that meet any of the following conditions must be prior authorized:

1. A prescription for a preferred or non-preferred GI Motility, Chronic Agent regardless of the quantity prescribed. See the Preferred Drug List (PDL) for the list of preferred and non-preferred GI Motility, Chronic Agents at: www.providersynergies.com/services/documents/PAM_PDL.pdf

2. A prescription for a GI Motility, Chronic Agent with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at: http://www.dhs.pa.gov/cs/groups/webcontent/documents/document/s_002077.pdf

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 recipient:

1. Is being treated for a condition that is U.S. Food and Drug Administration (FDA) approved, or a medically accepted indication

AND

2. Does not have a contraindication to the prescribed GI Motility, Chronic agent

AND

3. Is prescribed a dose consistent with package labeling

AND

4. Had all potential drug interactions addressed by the prescriber

AND

5. For the treatment of a diagnosis involving constipation, has a history of therapeutic failure, contraindication or intolerance to laxatives, fiber supplementation, osmotic agents, bulk forming agents, and glycerin or bisacodyl suppositories

OR

6. For the treatment of a diagnosis involving diarrhea, has a documented history of therapeutic failure, contraindication, of intolerance to loperamide and an antispasmodic

AND

7. For Lotronex (alosetron hydrochloride)

    a. Is prescribed Lotronex (alosetron hydrochloride) by a prescriber enrolled in the Prescribing Program for Lotronex/alosetron

    AND

    b. Had other etiologies for chronic diarrhea ruled out

    AND

    c. A documented therapeutic failure of lactose, gluten and artificial sweetener avoidance and a low fermentable oligo-, di-, and monosaccharides and polyols (FODMAP) diet

AND

8. For a non-preferred GI Motility, Chronic Agent, has a history of therapeutic failure, contraindication or intolerance to the preferred GI Motility, Chronic Agents used for the same indication

AND

9. In addition, if a prescription for either a preferred or non-preferred GI Motility, Chronic Agent is in 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

OR

10. 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 recipient.

FOR RENEWALS OF PRESCRIPITONS FOR A GI MOTILITY, CHRONIC AGENT: The determination of medical necessity of requests for prior authorization of renewals of prescriptions for a GI Motility, Chronic Agent that were previously approved will take into account whether the recipient:

1. Does not have a contraindication to the prescribed GI Motility, Chronic Agent

AND

2. Had all potential drug interactions addressed by the prescriber

AND

3. For Lotronex (alosetron hydrochloride):

   a. Is prescribed Lotronex (alosetron hydrochloride) by a prescriber enrolled in the Prescribing Program for Lotronex/alosetron

   AND

   b. Has adequate control of IBS symptoms after 4 weeks of treatment with 1 mg twice a day

   AND

   c. Does not have constipation or signs of ischemic colitis (rectal bleeding, bloody diarrhea, or new or worsening abdominal pain) since initiation of treatment

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guideline in Section B. above to assess the medical necessity of the request for 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 recipient.

D. Dose and Duration of Therapy

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

1. Initial approvals of requests for prior authorization of Lotronex (alosetron hydrochloride) will be limited to 4 weeks of therapy

2. Renewals of requests for prior authorization of Lotronex (alosetron hydrochloride) that were previously approved will be approved for up to 3 months

References

1. Amitiza prescribing information, April 2013.
2. Linzess prescribing information, July 2014.
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