pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 8, 2021	January 3, 2022	*See below

SUBJECT

Prior Authorization of GI Motility, Chronic Agents – Pharmacy Services

BY

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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: https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx.

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. The guidelines to determine the medical necessity of GI Motility, Chronic Agents will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of GI Motility, Chronic Agents to the appropriate MCO.

BACKGROUND:

*01-21-46	09-21-45	27-21-37	33-21-45
02-21-33	11-21-35	30-21-40	
03-21-33	14-21-36	31-21-48	
08-21-48	24-21-43	32-21-33	

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 website at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- 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 September 15, 2021, meeting, the P&T Committee recommended revisions to the guidelines to determine medical necessity of GI Motility, Chronic Agents to reflect updated consensus treatment guidelines and to remove the guideline that the beneficiary 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).

The revisions to the guidelines to determine medical necessity of prescriptions for GI Motility, Chronic Agents submitted for prior authorization, 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
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx

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;

   AND

7. 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: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

   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; **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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

   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.

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.