pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
December 27, 2017	January 8, 2018	*See Below

SUBJECT

Prior Authorization of Xermelo (telotristat ethyl) - Pharmacy Services

BY

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Office of Medical Assistance Programs

New 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:

1. Inform providers that the Department of Human Services (DHS) will require prior authorization of prescriptions for Xermelo (telotristat ethyl)
2. Issue handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Xermelo (telotristat ethyl) for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance Program and providing services in the fee-for-service delivery system, including pharmacy services to residents of long-term care facilities.

BACKGROUND:

The DHS 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 DHS Prospective Drug Use Review and Retrospective Drug Use Review programs.

*01-17-44	09-17-43	27-17-41	
02-17-39	11-17-39	30-17-40	
03-17-39	14-17-40	31-17-45	
08-17-46	24-17-40	32-17-39	33-17-44

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 20, 2017 DUR Board meeting, the DUR Board recommended that DHS require prior authorization of Xermelo (telotristat ethyl) to ensure safe and appropriate utilization of Xermelo (telotristat ethyl). The DUR Board recommended guidelines to determine medical necessity of Xermelo (telotristat ethyl) which were subject to public review and comment, and subsequently approved for implementation by DHS.

PROCEDURE:

The procedures for prescribers to request prior authorization of Xermelo (telotristat ethyl) are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. DHS 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 Xermelo (telotristat ethyl)) 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
Xermelo (telotristat ethyl)

Requirements for Prior Authorization of Xermelo (telotristat ethyl)

A. Prescriptions That Require Prior Authorization

All prescriptions for Xermelo (telotristat ethyl) require prior authorization

1. See Quantity Limits for the list of drugs with quantity limits at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Xermelo (telotristat ethyl), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is 18 years of age or older

AND

2. Is being prescribed Xermelo (telotristat ethyl) by or in consultation with an oncologist, endocrinologist, or gastroenterologist

AND

3. Has medical record documentation of a diagnosis that is indicated in the FDA-approved package insert OR listed in nationally recognized compendia for the determination of medically-accepted indications for off-label uses of Xermelo (telotristat ethyl)

AND

4. Has medical record documentation of inadequately controlled diarrhea despite the use of somatostatin analog therapy at a maximum recommended or tolerated dose

AND

5. Will be using Xermelo (telotristat ethyl) in combination with somatostatin analog therapy

OR

6. Does not meet the clinical review guidelines above, but in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary

7. In addition, if a prescription for Xermelo (telotristat ethyl) 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.

FOR RENEWALS OF PRESCRIPTIONS FOR XERMELO (TELOTRISTAT ETHYL) - The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Xermelo (telotristat ethyl), that were previously approved, will take into account whether the beneficiary:

1. Is being prescribed Xermelo (telotristat ethyl) by or in consultation with an oncologist, endocrinologist, or gastroenterologist

AND

2. Will continue to use Xermelo (telotristat ethyl) in combination with somatostatin analog therapy

AND

3. Has documentation of symptom improvement since starting Xermelo (telotristat ethyl)

AND

4. Has no signs of severe constipation and/or severe persistent or worsening abdominal pain

OR

5. Does not meet the clinical review guidelines above, but in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary

6. In addition, if a prescription for Xermelo (telotristat ethyl) 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 at. http://www.dhs.pa.gov/publications/bulletinsearch/bulletinselected/index.htm?bn=01-14-18&o=N&po=OMAP&id=04/25/2014

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 the request for a prescription for Xermelo (telotristat ethyl). 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.

References

1. Clinical features of the carcinoid syndrome. Up To Date. Accessed August 11, 2017.
2. Kulke MH, Hörsch D, Caplin ME, et al. Telotristat Ethyl, a Tryptophan Hydroxylase Inhibitor for the Treatment of Carcinoid Syndrome. Journal of Clinical Oncology 2017; 35:14-23
3. NCCN Guideline Version 3.2017 Neuroendocrine Tumors. www.nccn.org Accessed August 11, 2017
4. Treatment of the carcinoid syndrome. Up To Date. Accessed August 17, 2017.
5. Xermelo Package Insert. The Woodlands, TX: Lexicon Pharmaceuticals, Inc.; February 2017.