pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
January 21, 2019	January 22, 2019	*See below

SUBJECT

Prior Authorization of Symdeko (tezacaftor/ivacaftor) – 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: 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 Symdeko (tezacaftor/ivacaftor).

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 Symdeko (tezacaftor/ivacaftor) 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 under the MA managed care delivery system should address any questions related to Symdeko (tezacaftor/ivacaftor) to the appropriate managed care organization.

*01-19-02	09-19-02	27-19-01	33-19-02
02-19-01	11-19-01	30-19-01	
03-19-01	14-19-01	31-19-02	
08-19-03	24-19-01	32-19-01	

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

BACKGROUND:

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.

DISCUSSION:

During the September 25, 2018, DUR Board meeting, the DUR Board recommended that DHS require prior authorization of Symdeko (tezacaftor/ivacaftor) to ensure appropriate patient selection and drug utilization of Symdeko (tezacaftor/ivacaftor). The DUR Board recommended guidelines to determine the medical necessity of Symdeko (tezacaftor/ivacaftor) that were subject to public review and comment and subsequently approved for implementation by DHS.

PROCEDURE:

The procedures for prescribers to request prior authorization of Symdeko (tezacaftor/ivacaftor), 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 Symdeko (tezacaftor/ivacaftor)) 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
Symdeko (tezacaftor/ivacaftor)

I. Requirements for Prior Authorization of Symdeko (tezacaftor/ivacaftor)

A. Prescriptions That Require Prior Authorization

All prescriptions for Symdeko (tezacaftor/ivacaftor) must be prior authorized.

B. Clinical Review Guidelines and Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Symdeko (tezacaftor/ivacaftor), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a diagnosis of cystic fibrosis,

AND

2. Has a documented cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation consistent with the package labeling.

AND

3. Is prescribed Symdeko (tezacaftor/ivacaftor) by, or in consultation with, a pulmonologist or cystic fibrosis specialist.

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. Is prescribed a dose consistent with package labeling or nationally recognized compendia.

AND

6. Has a baseline FEV1,

AND

7. Has a baseline ALT and AST,

AND

8. Will have repeat ALT and AST every 3 months during the first year of therapy then annually thereafter.

AND

9. Does not have a contraindication to Symdeko (tezacaftor/ivacaftor).

AND

10. If a prescription for Symdeko (tezacaftor/ivacaftor) 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.

    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 PRESCRIPTIONS FOR SYMDEKO (tezacaftor/ivacaftor): Requests for prior authorization of renewals of prescriptions for Symdeko (tezacaftor/ivacaftor) that were previously approved will take into account whether the beneficiary:

1. Is prescribed Symdeko (tezacaftor/ivacaftor) by, or in consultation with, a pulmonologist or cystic fibrosis specialist.

AND

2. 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

3. Is prescribed a dose consistent with package labeling or nationally recognized compendia.

AND

4. Based on the prescriber's assessment, continues to benefit from Symdeko (tezacaftor/ivacaftor).

AND

5. Had a repeat ALT and AST that is not greater than 5 times the upper limit of normal, or a repeat ALT and AST that is not greater than 3 times the upper limit of normal with bilirubin that is not greater than 2 times the upper limit of normal.

AND

6. Does not have a contraindication to Symdeko (tezacaftor/ivacaftor).

AND

7. If a prescription for Symdeko (tezacaftor/ivacaftor) 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.

   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 Symdeko (tezacaftor/ivacaftor). 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 Symdeko (tezacaftor/ivacaftor) will be approved as follows:

1. Initial approvals of requests for prior authorization of Symdeko (tezacaftor/ivacaftor) and subsequent requests during the first year of therapy will be approved for up to 3 months of therapy.

2. Renewals of requests for prior authorization of Symdeko (tezacaftor/ivacaftor) after the first year of therapy that were previously approved will be approved for up to 12 months.

E. References

1. Institute for Clinical and Economic Review. Modulator Treatments for Cystic Fibrosis: Effectiveness and Value. Published June 7, 2018.
2. Katkin JP. Cystic fibrosis: Genetics and pathogenesis. UpToDate. Waltham, MA: UpToDate Inc**.** https://www.uptodate.com/contents/cystic-fibrosis-genetics-and-pathogenesis?topicRef=6367&source=see_link#H12 (Accessed August 21, 2018).
3. Symdeko (package insert). Vertex Pharmaceuticals Incorporated, Boston, MA; February 2018.