pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
December 13, 2018	December 17, 2018	*See below

SUBJECT

Prior Authorization of Kalydeco (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 issue updated handbook pages that include the type of information needed to evaluate the medical necessity of prescriptions for Kalydeco (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 Kalydeco (ivacaftor) to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (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.

*01-18-32	09-18-33	27-18-32	33-18-32
02-18-27	11-18-27	30-18-27	
03-18-28	14-18-28	31-18-33	
08-18-35	24-18-29	32-18-27	

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 25, 2018, DUR Board meeting, the DUR Board recommended that DHS update the guidelines to determine medical necessity of Kalydeco (ivacaftor). The revisions align the guidelines to determine medical necessity with the guidelines to determine medical necessity of other cystic fibrosis transmembrane conductance regulator potentiators, Symdeko (tezacaftor/ivacaftor) and Orkambi (lumacaftor/ivacaftor), and ensure consistency. The revisions include: adding a guideline for prescriber specialty, adding a guideline that all drug interactions have been addressed, confirming that the dosing of the medication is consistent with package labeling or nationally recognized compendia, and updating a renewal guideline to verify that based on the prescriber's assessment the beneficiary continues to benefit from the medication.

PROCEDURE:

The procedures for prescribers to request prior authorization of Kalydeco (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 Kalydeco (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
Kalydeco (ivacaftor)

I. Requirements for Prior Authorization of Kalydeco (ivacaftor)

A. Prescriptions That Require Prior Authorization

All prescriptions for Kalydeco (ivacaftor) must be prior authorized.

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.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Kalydeco (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 genetic mutation as noted in the package labeling

AND

3. Is prescribed Kalydeco (ivacaftor) by or in consultation with a pulmonologist or cystic fibrosis specialist

AND

4. Is not homozygous for the F508del mutation in the CFTR gene

AND

5. 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

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

AND

7. Has a baseline FEV1

AND

8. Has a baseline ALT and AST

AND

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

AND

10. Does not have a contraindication to Kalydeco (ivacaftor)

AND

11. If a prescription for Kalydeco (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 KALYDECO (ivacaftor): Requests for prior authorization of renewals of prescriptions for Kalydeco that were previously approved will take into account whether the beneficiary:

1. Is prescribed Kalydeco (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 Kalydeco (ivacaftor)

AND

5. Has had a repeat ALT and AST that is not greater than 5 times the upper limit of normal

AND

6. Does not have a contraindication to Kalydeco (ivacaftor)

AND

7. If a prescription for Kalydeco (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 Kalydeco (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 Kalydeco (ivacaftor) will be approved as follows:

1. Initial approvals of requests for prior authorization of Kalydeco (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 Kalydeco (ivacaftor) after the first year of therapy that were previously approved will be approved for up to 12 months.

E. References

1. Kalydeco (package insert). Vertex Pharmaceuticals Incorporated, Cambridge, MA; August 2018.