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 Orkambi (lumacaftor/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 requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Orkambi (lumacaftor/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 Orkambi (lumacaftor/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

*01-18-35	09-18-36	27-18-35	33-18-35
02-18-30	11-18-30	30-18-30	
03-18-31	14-18-31	31-18-36	
08-18-38	24-18-32	32-18-30	

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

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 update the guidelines to determine medical necessity of Orkambi (lumacaftor/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 Kalydeco (ivacaftor), and ensure consistency. The revisions include: clarifying the 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, adding a renewal guideline to verify that based on the prescriber's assessment the beneficiary continues to benefit from the medication, and updating the ALT and AST monitoring guideline based on package labeling.

PROCEDURE:

The procedures for prescribers to request prior authorization of Orkambi (lumacaftor/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 Orkambi (lumacaftor/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
Orkambi (lumacaftor/ivacaftor)

I. Requirements for Prior Authorization of Orkambi (lumacaftor/ivacaftor)

A. Prescriptions That Require Prior Authorization

All prescriptions for Orkambi (lumacaftor/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 Orkambi (lumacaftor/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 being prescribed Orkambi (lumacaftor/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 Orkambi (lumacaftor/ivacaftor)

AND

10. If a prescription for Orkambi (lumacaftor/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 a 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 ORKAMBI (lumacaftor/ivacaftor) - The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Orkambi (lumacaftor/ivacaftor) that were previously approved will take into account whether the beneficiary:

1. Is prescribed Orkambi (lumacaftor/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 Orkambi (lumacaftor/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 Orkambi (lumacaftor/ivacaftor)

AND

7. If a prescription for Orkambi (lumacaftor/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 Orkambi (lumacaftor/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 Orkambi (lumacaftor/ivacaftor) will be approved as follows:

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

E. References

1. Katkin, J.P. Cystic fibrosis: Clinical manifestations and diagnosis. Up To Date. Accessed August 14, 2015.
2. Katkin, J.P. Cystic fibrosis: Genetics and pathogenesis. Up To Date. Accessed August 14, 2015.
3. Orkambi prescribing information. Vertex Pharmaceuticals Incorporated, Cambridge, MA; August 2018.
4. Simon, R.H. Cystic fibrosis: Overview of the treatment of lung disease. Up To Date. Accessed August 14, 2015.