



ISSUE DATE November 30, 2015	EFFECTIVE DATE December 1, 2015	NUMBER *See below
SUBJECT Prior Authorization of Orkambi (lumacaftor/ivacaftor) - Pharmacy Service		BY  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers (including all associated service locations - 13 digits) who enrolled on or before **March 25, 2011** must revalidate their enrollment information no later than **March 24, 2016**. New enrollment application including all revalidation requirements may be found at http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994. Please send in your application(s) as soon as possible.

PURPOSE:

The purpose of this bulletin is to:

1. Inform providers about new requirements for prior authorization of Orkambi (lumacaftor/ivacaftor).
2. Issue handbook pages that include instructions on how to request prior authorization of Orkambi (lumacaftor/ivacaftor), including the type of medical information needed to evaluate requests for medical necessity.

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 (FFS) delivery system, including pharmacy services to residents of long term care facilities.

BACKGROUND:

The Department of Human Service's (Department) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing

*01-15-40	09-15-38	27-15-32	
02-15-32	11-15-31	30-15-31	
03-15-32	14-15-33	31-15-39	
08-15-38	24-15-33	32-15-32	33-15-37

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>

practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective Drug Use Review (ProDUR) and Retrospective Drug Use Review (RetroDUR) programs.

DISCUSSION:

During the September 10, 2015 meeting, the DUR Board recommended that the Department require prior authorization of Orkambi (lumacaftor/ivacaftor) and proposed guidelines to determine medical necessity to ensure appropriate patient selection and drug utilization of Orkambi (lumacaftor/ivacaftor). The requirement for prior authorization and guidelines to determine medical necessity, as recommended by the DUR Board, were subject to public review and comment, and subsequently approved for implementation by the Department. The requirements for prior authorization and clinical review guidelines to determine the medical necessity of Orkambi (lumacaftor/ivacaftor) are included in the attached updated provider handbook pages.

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. 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 chapters 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)

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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.

See the Quantity Limits for Orkambi (lumacaftor/ivacaftor) at:
http://www.dhs.pa.gov/cs/groups/webcontent/documents/document/s_002077.pdf

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 recipient:

1. Has a diagnosis of cystic fibrosis

AND

2. Is being prescribed Orkambi (lumacaftor/ivacaftor) by a cystic fibrosis specialist

AND

3. Has a documented genetic mutation as noted in the package labeling

AND

4. Is prescribed a dose consistent with package labeling

AND

5. Has a baseline FEV₁

AND

6. Has a baseline ALT and AST

AND

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

AND

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8. Does not have a contraindication to Orkambi (lumacaftor/ivacaftor)

OR

9. 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 recipient
10. In addition, 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.

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 recipient:

1. Is prescribed a dose consistent with package labeling

AND

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

AND

3. Does not have a contraindication to Orkambi (lumacaftor/ivacaftor)

OR

4. 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 recipient
5. In addition, if the renewal of 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.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to

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assess the medical necessity of the request for 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 recipient.

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 limited 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

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; July 2015.
4. Simon, R.H. Cystic fibrosis: Overview of the treatment of lung disease. Up To Date. Accessed August 14, 2015.