

<b>ISSUE DATE</b> April 25, 2014	<b>EFFECTIVE DATE</b> May 12, 2014	<b>NUMBER</b> *See Below	
<b>SUBJECT</b>  Prior Authorization of Kalydeco (ivacaftor) – Pharmacy Services		<b>BY</b>   Vincent D. Gordon, Deputy Secretary Office of Medical Assistance Programs	

**PURPOSE:**

The purpose of this bulletin is to issue updated handbook pages that include instructions on how to request prior authorization of prescriptions for Kalydeco (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 for residents of long term care facilities.

**BACKGROUND:**

On December 21, 2012, the Department of Public Welfare (Department) issued MA Bulletin Number 01-12-60, et al, announcing the requirement for prior authorization of Kalydeco (ivacaftor) and issuing the clinical review guidelines to determine medical necessity.

**DISCUSSION:**

Kalydeco (ivacaftor) was first approved by the U.S. Food and Drug Administration (FDA) in January 2012 for people with cystic fibrosis, ages 6 and older, who have a G551D mutation. Since then, the FDA approved Kalydeco (ivacaftor) for use in eight additional mutations that cause cystic fibrosis. The Department is amending the clinical review guidelines to recognize all genetic mutations as noted in the package labeling.

*01-14-17	09-14-12	27-14-10	33-14-11
02-14-10	11-14-10	30-14-10	
03-14-13	14-14-10	31-14-15	
08-14-13	24-14-10	32-14-10	

<p><b>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</b></p> <p>The appropriate toll free number for your provider type</p> <p>Visit the Office of Medical Assistance Programs Web site at  <a href="http://www.dpw.state.pa.us/provider/healthcaremedicalassistance/index.htm">http://www.dpw.state.pa.us/provider/healthcaremedicalassistance/index.htm</a></p>
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**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. 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 chapter related to Kalydeco [ivacaftor]) in 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