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 Corlanor (ivabradine).
2. Issue handbook pages that include instructions on how to request prior authorization of Corlanor (ivabradine), 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 practices for efficacy, safety, and quality and to recommend interventions for prescribers


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
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 Corlanor (ivabradine) and proposed guidelines to determine medical necessity to ensure appropriate patient selection and drug utilization of Corlanor (ivabradine). 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 Corlanor (ivabradine) are included in the attached updated provider handbook pages.

**PROCEDURE:**

The procedures for prescribers to request prior authorization of Corlanor (ivabradine) 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 Corlanor [ivabradine]) 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
Corlanor (ivabradine)
I. Requirements for Prior Authorization of Corlanor (ivabradine)

A. Prescriptions That Require Prior Authorization

All prescriptions for Corlanor (ivabradine) must be prior authorized.

See the Quantity Limits for Corlanor (ivabradine) 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 an initial prior authorization of a prescription for Corlanor (ivabradine), the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

1. Has stable, symptomatic heart failure with a left ventricular ejection fraction ≤35%

AND

2. Is prescribed the medication by or in consultation with a cardiologist

AND

3. Has a sinus rhythm with a resting heart rate of ≥70 beats per minute

AND

4. Is currently receiving a beta blocker at the maximum tolerated dose for heart failure (carvedilol, metoprolol succinate sustained release, bisoprolol) unless prior use of a beta blocker resulted in significant side effects or the recipient has a contraindication to beta blockers

AND

5. Was hospitalized for heart failure within the past year

AND

6. Does not have a contraindication to Corlanor (ivabradine)
7. Is currently receiving optimally tolerated doses of all of the following:
   a. ACE inhibitor or angiotensin receptor blocker
   b. Mineralocorticoid receptor blocker
   c. Diuretic

OR

8. Has a contraindication or intolerance to optimally titrated doses of all of the following:
   a. ACE inhibitor or angiotensin receptor blocker
   b. Mineralocorticoid receptor blocker
   c. Diuretic

AND

9. Is prescribed a dose consistent with package labeling

OR

10. 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

In addition, if a prescription for Corlanor (ivabradine) 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 CORLANOR (ivabradine) - The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Corlanor (ivabradine), that were previously approved, will take into account whether the recipient:

1. Is prescribed the medication by or in consultation with a cardiologist

AND

2. Does not have a contraindication to Corlanor (ivabradine)

OR

3. 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

December 1, 2015
4. In addition, if the renewal of a prescription for Corlanor (ivabradine) 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 assess the medical necessity of the request for a prescription for Corlanor (ivabradine). 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.

REFERENCES

5. McMurray JJ, Adamopoulos S, Anker SD, et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012: The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC. Eur Heart J. 2012;33:1787-1847.