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| ISSUE DATE December 15, 2020 | EFFECTIVE DATE January 5, 2021 | NUMBER *See below |
| SUBJECT Prior Authorization of Corlanor (ivabradine) – Pharmacy Services | | BY  Sally A. Kozak, Deputy Secretary 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: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx>.

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 Corlanor (ivabradine) 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 in the MA managed care delivery system should address any questions related to Corlanor (ivabradine) to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (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 and pharmacists

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| *01-20-52 | 09-20-51 | 27-20-47 | 33-20-48 |
| 02-20-45 | 11-20-45 | 30-20-44 | |
| 03-20-45 | 14-20-46 | 31-20-52 | |
| 08-20-55 | 24-20-46 | 32-20-44 | |

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| <p>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</p> <p>The appropriate toll-free number for your provider type.</p> <p>Visit the Office of Medical Assistance Programs Web site at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.</p> |
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through the Department's Prospective Drug Use Review and Retrospective Drug Use Review programs.

DISCUSSION:

During the October 21, 2020, meeting, the DUR Board recommended the following revisions to the guidelines to determine medical necessity of prescriptions for Corlanor (ivabradine):

- Addition of a guideline that the beneficiary is prescribed Corlanor (ivabradine) for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication;
- Revision to the guideline related to the prescribed dose to add nationally recognized compendia and peer-reviewed medical literature as sources for appropriate doses;
- Removal of guidelines related to adult patients with heart failure as Corlanor (ivabradine) now has an indication for pediatric patients;
- Removal of mineralocorticoid receptor blockers and diuretics from the guideline related to therapeutic failure, intolerance, or contraindication to the standard medications used for heart failure;
- Addition of beta blockers to the guideline related to therapeutic failure, intolerance, or contraindication to the standard medications used for heart failure;
- Addition of a guideline to the requests for renewal of the prior authorization section that the beneficiary continues to experience clinical benefit from and tolerability of Corlanor (ivabradine) based on the prescriber's assessment; and
- Addition of a guideline to the requests for renewal of the prior authorization section that the beneficiary is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

The revisions to the guidelines to determine medical necessity of prescriptions for Corlanor (ivabradine), as recommended by the DUR Board, were subject to public review and comment and subsequently approved for implementation by the Department.

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 chapter 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

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Corlanor (ivabradine)

A. Prescriptions That Require Prior Authorization

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

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Corlanor (ivabradine), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed Corlanor (ivabradine) for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed Corlanor (ivabradine) by or in consultation with a cardiologist; **AND**
4. Does not have a history of a contraindication to the prescribed medication; **AND**
5. **One** of the following:
 - a. Has a documented history of therapeutic failure of optimally tolerated doses of **both** the following:
 - i. **One** of the following:
 - a) ACE inhibitor,
 - b) Angiotensin receptor blocker,
 - c) Angiotensin receptor blocker and neprilysin inhibitor
 - ii. Beta blocker
 - b. Has a documented history of intolerance or contraindication to optimally titrated doses of **all** of the following:
 - i. ACE inhibitor,
 - ii. Angiotensin receptor blocker,
 - iii. Angiotensin receptor blocker and neprilysin inhibitor,
 - iv. Beta blocker;

AND

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6. If a prescription for Corlanor (ivabradine) is for 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. See Quantity Limits List: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

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 PRIOR AUTHORIZATION FOR CORLANOR (IVABRADINE): The determination of medical necessity of a request for renewal of a prior authorization for Corlanor (ivabradine) that was previously approved will take into account whether the beneficiary:

1. Continues to experience clinical benefit from and tolerability of Corlanor (ivabradine) based on the prescriber's assessment; **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed Corlanor (ivabradine) by or in consultation with a cardiologist; **AND**
4. Does not have a history of a contraindication to the prescribed medication; **AND**
5. If a prescription for Corlanor (ivabradine) is for 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. See Quantity Limits List: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

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 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 beneficiary.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

D. References

1. Colucci W.S. et al. Use of beta blockers and ivabradine in heart failure with reduced ejection fraction. Up To Date, accessed August 18, 2015.
2. Corlanor [prescribing information]. Amgen, Inc. April 2019.
3. New Drug: Corlanor (Ivabradine), The Pharmacist's Letter/Prescriber's Letter, June 2015.
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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.
6. Price JF. Congestive heart failure in children. Pediatr Rev. 2019; 40(2):60-70.