

<b>ISSUE DATE</b>  July 31, 2019	<b>EFFECTIVE DATE</b>  January 1, 2020	<b>NUMBER</b>  *See below
<b>SUBJECT</b>  Prior Authorization of Antianginal Agents – Pharmacy Services		<b>BY</b>   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:  
[http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S\\_001994](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 Antianginal Agents 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 Antianginal Agents to the appropriate managed care organization.

**BACKGROUND:**

The Department of Human Services’ (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed clinical literature and makes recommendations relating to the following:

*01-19-39	09-19-37	27-19-35	33-19-37
02-19-34	11-19-33	30-19-33	
03-19-33	14-19-33	31-19-39	
08-19-42	24-19-35	32-19-33	

<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.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm">http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm</a></p>
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- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate requests for prior authorization of prescriptions for medical necessity.

### **DISCUSSION:**

During the May 15, 2019, meeting, the P&T Committee recommended the Department add Ranexa (ranolazine) to the Vasodilators, Coronary class of drugs on the PDL. Ranexa (ranolazine) was previously not included on the PDL. The Department is changing the title of the Vasodilators, Coronary class of drugs to Antianginal Agents to more accurately reflect the drugs included in this class.

Guidelines to determine medical necessity of Ranexa (ranolazine) were previously recommended by the Department's Drug Utilization Review Board. These guidelines were subject to public review and comment, approved by the Department, and implemented on December 9, 2014. The Department is including the previously-approved medical necessity guidelines for Ranexa (ranolazine) in the Antianginal Agents handbook chapter. There are no clinical changes to the guidelines to determine medical necessity.

The revisions to the guidelines to determine medical necessity of Antianginal Agents 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 Antianginal Agents 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 Antianginal Agents) 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

<http://www.dhs.pa.gov/provider/pharmacyservices/pharmacypriorauthorizationgeneralrequirements/index.htm>

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

<http://www.dhs.pa.gov/provider/pharmacyservices/drugsrequiringclinicalpriorauthorization/index.htm>

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**I. Requirements for Prior Authorization of Antianginal Agents**

A. Prescriptions That Require Prior Authorization

Prescriptions for Antianginal Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Antianginal Agent. See the Preferred Drug List (PDL) for the list of preferred Antianginal Agents at: <https://papdl.com/preferred-drug-list>.
2. An Antianginal Agent with a prescribed quantity that exceeds the quantity limit. 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>.
3. A prescription for Ranexa (ranolazine).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antianginal Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antianginal Agent, has a documented history of therapeutic failure, contraindication, or intolerance of the preferred Antianginal Agents; **AND**
2. For Ranexa (ranolazine), **all** of the following:
  - a. Is prescribed Ranexa (ranolazine) for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,
  - b. Does not have a history of a contraindication to Ranexa (ranolazine),
  - c. Has documentation of baseline EKG results,
  - d. **One** of the following:
    - i. Has a documented history of therapeutic failure of **one** of the following:
      - a) Beta blocker,
      - b) Calcium channel blocker,
      - c) Long-acting nitrate,
    - ii. Has a documented history of intolerance or contraindication to **all** of the following:

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- a) Beta blocker,
- b) Calcium channel blocker,
- c) Long-acting nitrate;

**AND**

- 3. If a prescription for an Antianginal Agent 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.

FOR RENEWALS OF PRESCRIPTIONS FOR RANEXA (ranolazine): The determination of medical necessity of a request for renewal of a prior authorization for Ranexa (ranolazine) that was previously approved will take into account whether the beneficiary:

- 1. Has a documented improvement of chronic angina symptoms; **AND**
- 2. Does not have a contraindication to Ranexa (ranolazine); **AND**
- 3. Has documented EKG monitoring; **AND**
- 4. If a prescription for Ranexa (ranolazine) 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 an Antianginal Agent. 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.