pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
June 25, 2015	July 20, 2015	*See below

SUBJECT

Prior Authorization of Platelet Aggregation Inhibitors - Pharmacy Service

BY

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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 Platelet Aggregation Inhibitors, 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 Services' (Department) Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and make recommendations relating to 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, and classes of drugs to be added to or deleted from the PDL. The P&T Committee also recommends new guidelines or modifications to existing guidelines to evaluate requests for prior authorization of prescriptions for medical necessity.

*01-15-20	09-15-20	27-15-17	
02-15-17	11-15-17	30-15-17	
03-15-17	14-15-17	31-15-20	
08-15-20	24-15-18	32-15-17	33-15-19

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.state.pa.us/provider/healthcaremedicalassistance/index.htm

DISCUSSION:

During the May 20, 2015, meeting, the P&T Committee recommended revisions to the guidelines to determine medical necessity of Platelet Aggregation Inhibitors to include the new Food and Drug Administration (FDA) approved agent, Zontivity (vorapaxar), and to address appropriate selection of patients for the use of this agent given its serious safety concerns. The revised guidelines to determine medical necessity of Platelet Aggregation Inhibitors were subject to public review and comment, and subsequently approved for implementation by the Department. The revised clinical review guidelines to determine the medical necessity of Platelet Aggregation Inhibitors are included in the attached updated provider handbook pages.

PROCEDURE:

The procedures for prescribers to request prior authorization of Platelet Aggregation Inhibitors 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 Platelet Aggregation Inhibitors) 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
Platelet Aggregation Inhibitors

I. Requirements for Prior Authorization of Platelet Aggregation Inhibitors

A. Prescriptions That Require Prior Authorization

Prescriptions for Platelet Aggregations Inhibitors which meet any of the following conditions must be prior authorized:

1. A prescription for a non-preferred Platelet Aggregation Inhibitor. See Preferred Drug List (PDL) for the list of preferred Platelet Aggregation Inhibitors at: www.providersynergies.com/services/documents/PAM_PDL.pdf

2. A prescription for a preferred or non-preferred Platelet Aggregation Inhibitor with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at: http://www.dhs.state.pa.us/provider/doingbusinesswithdhs/pharmacyservices/quantitylimitslist/index.htm

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Platelet Aggregation Inhibitor, the determination of whether the requested prescription is medically necessary will be subject to physician review and will take into account the following:

1. For a non-preferred Platelet Aggregation Inhibitor, whether the recipient:

   a. Has a documented history of therapeutic failure, intolerance, or contraindication to the preferred Platelet Aggregation Inhibitors.

OR

2. For Zontivity (vorapaxar), whether the recipient:

   a. Is being treated for a condition that is U.S. Food and Drug Administration (FDA) approved or a medically accepted indication

AND

b. Will be taking Zontivity in addition to aspirin and/or clopidogrel

AND

c. Is being prescribed Zontivity by, or in consultation with, a cardiologist or other vascular specialist

AND

d. Does not have any contraindications to Zontivity

AND

e. Will not be concomitantly taking any of the following:

i. Anticoagulants
ii. Chronic NSAIDs
iii. SSRIs
iv. SNRIs

AND

f. Had any potential drug interactions addressed by the prescriber

AND

g. Does not have severe hepatic impairment

AND

3. In addition, if a prescription for either a preferred or non-preferred Platelet Aggregation Inhibitor 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.

OR

4. The recipient 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.

C . Clinical Review Process

Prior authorization personnel will refer the request to a physician reviewer to assess the medical necessity of the Platelet Aggregation Inhibitor. If the guidelines in Section B are met, the physician reviewer will prior authorize the prescription. If the guidelines are not met, the physician reviewer will approve the request when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. References:

1. Zontivity (vorapaxar) [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; April 2015.
2. Merck & Co., Inc. FDA approves Zontivity (vorapaxar), first-in-class PAR-1 antagonist, for the reduction of thrombotic cardiovascular events in patients with a history of heart attack or with peripheral arterial disease. Merck Newsroom. http://www.mercknewsroom.com/news-release/corporate-news/fda-approves-zontivity-vorapaxar-first-class-par-1-antagonist-reduction- Published May 12, 2014. Accessed April 28, 2015.
3. National Institute for Health and Care Excellence. Vorapaxar for the secondary prevention of atherothrombotic events after myocardial infarction - draft scope. London, United Kingdom. http://www.nice.org.uk/guidance/gid-tag493/documents/atherothrombotic-events-vorapaxar-id616-draft-scope-for-consultation-prereferral-november-2013-2. Published November 2013. Accessed April 30, 2015.
4. Hennekens CH, Kaski JC. Secondary prevention of cardiovascular disease. In: UpToDate [Internet Database]. Saperia GM ed. Waltham, MA: UpToDate. Updated April 13, 2015. Accessed April 30, 2015.
5. Alfredsson J, Roe MT. Balancing the risks and benefits of long-term antiplatelet therapies for cardiovascular disease: clinical, research, and regulatory implications. *J Am Heart Assoc*. 2015;4:e001897.