Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Zontivity (vorapaxar)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***July 2014 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Zontivity (vorapaxar).

Zontivity (vorapaxar) is indicated for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral artery disease (PAD). Vorapaxar (Zontivity) has been shown to reduce the rate of a combined endpoint of cardiovascular death, MI, stroke, and urgent coronary revascularization (UCR).

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy &

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Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Zontivity (vorapaxar), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by a cardiologist
- Must be age 18 years or older
- Must have a history of MI within the past 2 weeks to 12 months or have PAD
- Must provide clinical rationale for the use of vorapaxar (Zontivity) and an assessment of the member's underlying risk of bleeding to show that the benefits of vorapaxar (Zontivity) would be expected to outweigh the increased risk of bleeding
- Must be on concomitant therapy with another antiplatelet agent such as aspirin, clopidogrel (Plavix®)
- Must not have any of the following:
    - History of stroke
    - History of transient ischemic attack
    - History of intracranial hemorrhage
    - Current active pathological bleeding
    - High potential risk of bleeding

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to duration of member's membership with plan
Reauthorization	N/A
Quantity Level Limit	
Zontivity	30 tablets per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

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REFERENCES

1. Zontivity [prescribing information]. Whitehouse Station, NJ: Merck & Co. Inc.; May 2014.
2. Morrow D, Scirica B, Fox K, et. al. Evaluation of a novel antiplatelet agent for secondary prevention in patients with a history of atherosclerotic disease: Design and rationale for the Thrombin-Receptor Antagonist in Secondary Prevention fo Atherothrombotic Ischemic Events (TRA 2°P)-TIMI trial. *American Heart Journal* 2009;158:335-341.e.3.
3. Morrow D, Braunwald E, Bonaca M, et. al. Vorapaxar in the Secondary Prevention of Atherothrombotic Events. *New England Journal of Medicine* 2012;366:1404-13.
4. Smith S, Benjamin E, Bonow R, et. al. AHA/ACCF Secondary Prevention and Risk Reduction Therapy for Patients with Coronary and Other Atherosclerotic Vascular Disease: 2011 Update: A Guidline From The American Heart Association and American College of Cardiology Foundation. *Circulation* 2011;124:2458-2473.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*

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