HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

VORAPAXAR SULFATE (ZONTIVITY)

Generic	Brand	HICL	GCN	Exception/Other
VORAPAXAR SULFATE	ZONTIVITY	41137		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Was Zontivity prescribed by, or in consultation with, a cardiologist?

   If yes, continue to #2.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Zontivity (vorapaxar sulfate) guideline, this medication is only covered when prescribed by, or in consultation with, a cardiologist. Your provider did not indicate that he or she specializes in this area or has consulted with a specialist and therefore your request was not approved.

2. Does the patient have a diagnosis of peripheral artery disease (PAD) or history of myocardial infarction (MI)?

   If yes, continue to #3.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Zontivity (vorapaxar sulfate) guideline, this medication is only covered for members with peripheral artery disease or history of myocardial infarction. Your provider did not indicate that you have one of these conditions and therefore your request was not approved.

3. Has the patient tried and failed therapy with clopidogrel and aspirin dual-therapy **OR** is there clinical rationale (e.g., increased risk of thrombotic cardiovascular events) for not using clopidogrel and aspirin dual-therapy?

   If yes, continue to #4.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Zontivity (vorapaxar sulfate) guideline, this medication is only covered after a trial with clopidogrel and aspirin dual-therapy **OR** if there is clinical rationale for not using clopidogrel and aspirin dual-therapy. Your provider did not indicate that you have tried or cannot use clopidogrel and aspirin dual-therapy and therefore your request was not approved.

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VORAPAXAR SULFATE (ZONTIVITY)

INITIAL CRITERIA (CONTINUED)

4. Will Zontivity be used in combination with aspirin and/or clopidogrel?

   If yes, **approve for 24 months by HICL**. Please use status code #057 and the approval text provided.
   APPROVAL TEXT: Your request for Zontivity has been approved for a 24 month period.

   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Zontivity (vorapaxar sulfate) guideline, this medication is only covered when used in combination with aspirin and/or clopidogrel. Your provider did not indicate that you will be using Zontivity in combination with one of these medications and therefore your request was not approved.

RENEWAL CRITERIA

1. Was Zontivity prescribed by, or in consultation with, a cardiologist?

   If yes, continue to #2.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Zontivity (vorapaxar sulfate) guideline, this medication is only covered when prescribed by, or in consultation with, a cardiologist. Your provider did not indicate that he or she specializes in this area or has consulted with a specialist and therefore your request was not approved.

2. Does the patient have a diagnosis of peripheral artery disease (PAD) or history of myocardial infarction (MI)?

   If yes, continue to #3.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Zontivity (vorapaxar sulfate) guideline, this medication is only covered for members with peripheral artery disease or history of myocardial infarction. Your provider did not indicate that you have one of these conditions and therefore your request was not approved.

3. Is the patient stable or shown improvement on Zontivity therapy?

   If yes, **approve for 24 months by HICL**. Please use status code #057 and the approval text provided.
   APPROVAL TEXT: Your request for Zontivity has been approved for a 24 month period.

   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Zontivity (vorapaxar sulfate) guideline, authorization for renewal requires documentation that you are stable or have shown improvement while on Zontivity therapy. Your provider did not indicate that you are stable or have shown improvement and therefore your request was not approved.

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RATIONALE
To ensure appropriate use of Zontivity as second line to dual-therapy and based on FDA-approved indication.

FDA APPROVED INDICATIONS
Zontivity is a protease-activated receptor-1 (PAR-1) antagonist indicated for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction or with peripheral arterial disease.

REFERENCES
- Merck & Co., Inc. Zontivity package insert. Whitehouse Station, NJ 08889. April 2015.

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