## Prior Authorization Approval Criteria

### Zontivity (vorapaxar)

<table>
<thead>
<tr>
<th>Generic name:</th>
<th>Vorapaxar</th>
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</thead>
<tbody>
<tr>
<td>Brand name:</td>
<td>Zontivity</td>
</tr>
<tr>
<td>Medication class:</td>
<td>Platelet aggregation inhibitor</td>
</tr>
<tr>
<td>FDA-approved uses:</td>
<td>Reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction or with peripheral arterial disease</td>
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<tr>
<td>Available dosage forms:</td>
<td>2.08mg tablet</td>
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<tr>
<td>Usual dose:</td>
<td>2.08mg orally once daily</td>
</tr>
<tr>
<td>Approximate monthly cost:</td>
<td>$320</td>
</tr>
<tr>
<td>(based on AWP)</td>
<td></td>
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<tr>
<td>Duration of therapy:</td>
<td>Indefinite</td>
</tr>
</tbody>
</table>

**Criteria for use (bullet points below are all inclusive unless otherwise noted):**

- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records
- History of myocardial infarction or peripheral arterial disease
- Must be used with aspirin and/or clopidogrel or have a contraindication to the use of either medication
- Must be prescribed by a cardiologist

**Criteria for continuation of therapy:**

- Same criteria as initial approval

**Caution:**

- Risk of clinically significant bleeding (15.5% vs 10.9%)
- No known treatment to reverse the antiplatelet effect
- Significant inhibition of platelet aggregation remains 4 weeks after discontinuation (≥ 80% versus 50%)

**Contraindication:**

- History of stroke
- History of transient ischemic attack
- History of intracranial hemorrhage
- Active pathologic bleeding

**Not approved if:**

- Does not meet above criteria
- Has any contraindications to treatment
- Therapy with vorapaxar is being initiated within the setting of acute coronary syndrome

The criteria listed above applies to Fallon Health Plan and its subsidiaries.
(within 2 weeks of a myocardial infarction)

- Being used without aspirin or clopidogrel
- Being used with any other antiplatelet drug besides aspirin and/or clopidogrel

**Special considerations:**

- Increases the risk of clinically significant bleeding (15.5% vs. 10.9%)
- Effectiveness is supported by a multicenter, randomized, double-blind, placebo-controlled study conducted in patients who had evidence or a history of atherosclerosis involving the coronary, cerebral, or peripheral vascular systems. Patients were randomized to receive daily treatment with ZONTIVITY (n=13,225) or placebo (n=13,224) in addition to standard of care. The study’s primary endpoint was the composite of cardiovascular death, MI, stroke, and urgent coronary revascularization (UCR). The findings in all randomized patients for the primary efficacy composite endpoint show a 3-year K-M event rate of 11.2% in the ZONTIVITY group compared to 12.4% in the placebo group.

**Approval Duration:**

- Initial 1 year
- Renewal 1 year

Fallon Health Pharmacy and Therapeutics Committee approval: ____________________________

Adopted: 09/17/2014
Effective: 11/17/14
Revised: