vemurafenib (Zelboraf®)
EOCCO POLICY

Policy Type: PA/SP/NF Pharmacy Coverage Policy: EOCCO070

Description
Vemurafenib (Zelboraf) is an orally administered BRAF kinase inhibitor used for the treatment of unresectable or metastatic melanoma, or Erdheim-Chester Disease in patients with a BRAFV600E mutation.

Length of Authorization
- Initial: Three months
- Renewal: 12 months

Quantity limits

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<tr>
<th>Product Name</th>
<th>Dosage Form</th>
<th>Indication</th>
<th>Quantity Limit</th>
<th>DDID</th>
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<td>vemurafenib (Zelboraf)</td>
<td>240 mg tablets</td>
<td>Unresectable or metastatic melanoma; Erdheim-Chester Disease</td>
<td>240 tablets/30 days</td>
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Initial Evaluation

I. Vemurafenib (Zelboraf) may be considered medically necessary when the following criteria below are met:
   A. Prescribed by or in consultation with an oncologist; **AND**
   B. A diagnosis of one of the following:
      1. **Unresectable or metastatic melanoma; AND**
         i. Documented BRAF V600E mutation by an FDA-approved test; **AND**
         ii. To be used in combination with cobimetinib (Cotellic); **OR**
      2. **Erdheim-Chester Disease; AND**
         i. Documented BRAF V600E mutation by an FDA-approved test

II. Vemurafenib (Zelboraf) is considered **investigational** when used for all other conditions, including but not limited to:
   A. Thyroid cancer (e.g. anaplastic thyroid carcinoma, advanced papillary thyroid cancers with BRAF v600 mutation)
   B. Non-small cell lung cancer (NSCLC) with BRAF V600E mutation
   C. Hairy cell leukemia
Renewal Evaluation

I. Member has previously received treatment with vemurafenib (Zelboraf); AND
II. Continues to meet criteria identified in section I of the Initial Evaluation; AND
III. Absence of disease progression; AND
IV. Absence of unacceptable toxicity from the medication

Supporting Evidence

I. FDA-approved companion diagnostic for BRAF V600E mutation includes FoundationOne CDx and Cobas® 4800 V600 Mutation Test
II. A Cochrane Review meta-analysis concluded that vemurafenib (Zelboraf) used in combination with cobimetinib (Cotellic) is superior over monotherapy vemurafenib (Zelboraf) in the setting of unresectable or metastatic melanoma.
III. There is limited treatment option for Erdheim-Chester Disease (ECD). The use of vemurafenib (Zelboraf) in ECD was studied in a single-arm, open-label, and multiple cohort basket trial. Given the study design, and the inability to distinguish between the effect of vemurafenib (Zelboraf) and the natural history of ECD, the evidence is considered low quality.

Investigational or Not Medically Necessary Uses

I. Thyroid cancers (e.g. anaplastic thyroid carcinoma, advanced papillary thyroid cancers with BRAF v600 mutation)
   A. Evidence for the use of vemurafenib (Zelboraf) in the setting of thyroid cancers are limited to phase I trials
II. Non-small cell lung cancer (NSCLC) with BRAF V600E mutation
   A. Evidence for the use of vemurafenib (Zelboraf) in the setting of NSCLC is limited to case studies.
III. Hairy cell leukemia
   A. Evidence for the use of vemurafenib (Zelboraf) in the setting of hairy cell leukemia are limited to phase II trials

References


Policy Implementation/Update:

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<th>Date Created</th>
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<td>Date Effective</td>
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<tr>
<td>Last Updated</td>
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<td>Last Reviewed</td>
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Action and Summary of Changes

- After review of evidence regarding safety, the removal of split fill management is clinically appropriate.
- Updated renewal duration from 3 months to 12 months to align with usual oncolytic renewal approval duration.
- Convert criteria format into policy format

Clarified use of concomitant medication 09/2017