MEDICATION POLICY

Generic Name: Vemurafenib

Therapeutic Class or Brand Name: Zelboraf®

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 12/13/17

GPI Code: 2153208000

Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met):

I. Documented diagnosis of one of the following conditions A through B and must meet criteria listed under applicable diagnosis:
   A. Unresectable or metastatic melanoma and criterion 1 is met:
      1. Must provide documentation of a BRAF V600E mutation.
   B. Erdheim-Chester Disease and criterion 1 is met:
      1. Must provide documentation of a BRAF V600 mutation.

II. Minimum age requirement: 18 years old.

III. Prescriber is an oncologist or hematologist.

Exclusion Criteria:

- Patients with wild-type BRAF melanoma.

Other Criteria:

- Use of Zelboraf® with strong CYP3A4 inhibitors or inducers should be avoided. Exceptions may be made for higher doses (up to 300 tablets per 30 days) when concomitant use with CYP3A4 inducers (medications that decrease Zelboraf® serum concentrations) cannot be avoided (i.e. phenytoin, carbamazepine, rifampin, etc.).

Quantity/Days Supply Restrictions:

- 240 tablets per 30 days [see under Other Criteria for possible exceptions for higher doses (up to 300 tablets per 30 days)].

Approval Length:

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix:

N/A

References:

1. http://blue.regence.com/trgmedpol/drugs/dru266.pdf.
2. https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/zelboraf-commercial-direct.
3. Medi-Span.
4. http://www.gene.com/download/pdf/zelboraf_prescribing.pdf.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
12/13/2017	1. **Changed** "I. Documented diagnosis of unresectable or metastatic melanoma; II. Must provide documentation of a BRAF V600E mutation as detected from an FDA-approved test; III. Minimum age requirement: 18 years old; IV. Prescriber is an oncologist" **to** "I. Documented diagnosis of one of the following conditions A through B and must meet criteria listed under applicable diagnosis: A. Unresectable or metastatic melanoma and criterion 1 is met: 1. Must provide documentation of a BRAF V600E mutation; B. Erdheim-Chester Disease and criterion 1 is met: 1. Must provide documentation of a BRAF V600 mutation; II. Minimum age requirement: 18 years old; III. Prescriber is an oncologist or hematologist" **under Prior Authorization Criteria**. 2. **Changed** "N/A" **to** "Use of Zelboraf® with strong CYP3A4 inhibitors or inducers should be avoided. Exceptions may be made for higher doses (up to 300 tablets per 30 days) when concomitant use with CYP3A4 inducers (medications that decrease Zelboraf® serum concentrations) cannot be avoided (i.e. phenytoin, carbamazepine, rifampin, etc.)" **under Other Criteria**. 3. **Changed** "240 tablets per 30 days" **to** "240 tablets per 30 days [see under Other Criteria for possible exceptions for higher doses (up to 300 tablets per 30 days)]." **under Quantity/Days Supply Restrictions**.
10/6/2016	1. **Updated** "http://www.tuftshealthplan.com/providers/pdf/pharmacy_criteria/zelboraf.pdf" **to** "https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/zelboraf-commercial-direct" **under References**.
4/21/2015	1. Policy reviewed: no changes made.
12/3/2013	1. **Adapted policy to new format.** 2. **Added GPI Code**. 3. **Changed** "Must provide documentation of a BRAFV600 mutation; Copy of BRAFV600 mutation test results obtained from an FDA-approved test" **to** "Must provide documentation of a BRAF V600E mutation as detected from an FDA-approved test" **under Prior Authorization Criteria**. 4. **Added** "Patients with wild-type BRAF melanoma" **to Exclusion Criteria**. 5. **Updated references** to include Medi-Span.