Drug Therapy Guidelines	Applicable	Zelboraf™ (vemurafenib)
Medical Benefit		**Effective:** 1/1/18
Pharmacy- Formulary 1	x	**Next Review:** 12/18
Pharmacy- Formulary 2	x	**Date of Origin:** 6/15/12
Pharmacy- Formulary 3/Exclusive	x	**Review Dates:** 12/11, 12/12, 12/13, 12/14, 12/15, 12/16, 12/17
Pharmacy- Formulary 4/AON	x	

I. Medication Description

Vemurafenib is a low molecular weight, orally available inhibitor of some mutated forms of BRAF serinethreonine kinase, including BRAF V600E. Vemurafenib also inhibits other kinases in vitro such as CRAF, ARAF, wild-type BRAF, SRMS, ACK1, MAP4K5, and FGR at similar concentrations. Some mutations in the BRAF gene including V600E result in constitutively activated BRAF proteins, which can cause cell proliferation in the absence of growth factors that would normally be required for proliferation.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Zelboraf is available when the following criteria have been met:

- Member is at least 18 years of age **AND**
- The medication is prescribed by a hematologist/oncologist **AND**
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Coverage is available for up to 240 tablets per month (equates to 8 tablets per day to accommodate FDA-approved dosing).

V. Coverage Duration

Coverage is provided for 6 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression **AND**
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

- Available as Zelboraf 240mg tablets

VIII. Summary of Policy Changes

- 6/15/2012: new policy
- 3/15/13: addition of coverage for recurrent disease
- 3/15/14: no policy changes
- 3/15/15: policy updated to include criteria for coverage in treating brain metastases and NSCLC
- 4/30/15: addition of coverage for the treatment of Hairy Cell Leukemia per NCCN treatment guideline updates
- 7/1/15: formulary distinctions made
- 3/15/16: no policy changes
- 1/1/17: no policy changes
- 1/1/18: coverage criteria updated to allow use as supported by current NCCN guidelines

IX. References

1. Clinical Pharmacology Online: "Zelboraf". Accessed 10/2017.
2. Prescribing Information – Zelboraf. Genentech USA, Inc. A member of the Roche Group, 1 DNA Way, South San Fransisco, CA 94080-4990. Revised 9/2017.
3. Chapman PB, Hauschild A, Robert C, et al. Improved survival with vemurafenib in melanoma with BRAF V600E mutation. *NEJM* 2011;364:2507-16.
4. Fauci AS, Braunwald E, Kasper DL, et al. Cancer of the Skin. In: Kasper DL, Fauci AS, Longo DL, Braunwald E, Hauser SL, Jameson JL, eds. *Harrison's Principles of Internal Medicine.* 17th ed. Available from URL: http://www.accesspharmacy.com/Content.aspx?searchStr=melanoma&aid=9115235. Accessed 9/19/11.
5. Melanoma. American Academy of Dermatology. Available from URL: http://www.aad.org/skin-conditions/dermatology-a-to-z/melanoma. Accessed 9/20/11.
6. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Melanoma. Version 1.2018. Accessed 10/2017.
7. National Comprehensive Cancer Network Drugs & Biologics Compendium- "Vemurafenib". Accessed 10/2017.
8. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer. Version 9.2017. Accessed 10/2017.
9. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Central Nervous System Cancers. Version 1.2017. Accessed 10/2017.
10. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma. Version 2.2017. Accessed 10/2017.
11. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia. Version 2.2018. Accessed 10/2017.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.