

## SPECIALTY GUIDELINE MANAGEMENT

### ZELBORAF (vemurafenib)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

Zelboraf is indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.

Limitation of use: Zelboraf is not indicated for treatment of patients with wild-type BRAF melanoma.

B. Compendial Uses

- A. Melanoma (including brain metastases), BRAF V600 activating mutation-positive
- B. Non-small cell lung cancer, BRAF V600E mutation-positive
- C. Hairy cell leukemia
- D. Erdheim-Chester disease

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. CRITERIA FOR INITIAL APPROVAL

A. **Melanoma**

Authorization of 12 months may be granted for treatment of melanoma (including brain metastases from melanoma) with a BRAF V600 activating mutation (e.g., BRAF V600E or BRAF V600K mutation).

B. **Non-small cell lung cancer (NSCLC)**

Authorization of 12 months may be granted for treatment of BRAF V600E mutation-positive NSCLC.

C. **Hairy cell leukemia**

Authorization of 12 months may be granted for treatment of hairy cell leukemia.

D. **Erdheim-Chester disease (ECD)**

Authorization of 12 months may be granted for treatment of ECD.

##### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

##### IV. REFERENCES

1. Zelboraf [package insert]. South San Francisco, CA: Genentech USA, Inc.; August 2016.

2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed March 17, 2017.
3. The NCCN Clinical Practice Guidelines in Oncology™ Melanoma (Version 1.2017). ©2016 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 17, 2017.
4. The NCCN Clinical Practice Guidelines in Oncology™ Central Nervous System Cancers (Version 1.2016). ©2016 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 18, 2017.
5. The NCCN Clinical Practice Guidelines in Oncology™ Non-Small Cell Lung Cancer (Version 4.2017). ©2017 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 17, 2017.
6. The NCCN Clinical Practice Guidelines in Oncology® Hairy Cell Leukemia (Version 2.2017). ©2017 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 18, 2017.
7. Diamond EL, Dagna L, Hyman DM, et al. Consensus guidelines for the diagnosis and clinical management of Erdheim-Chester disease. *Blood*. 2014;124(4):483-492.
8. Haroche J, Cohen-Aubart F, Emile JF, et al. Reproducible and sustained efficacy of targeted therapy with vemurafenib in patients with BRAF V600E-mutated Erdheim-Chester disease. *J Clin Oncol*. 2015;33:411-418.
9. Hyman DM, Puzanov I, Subbiah V, et al. Vemurafenib in multiple nonmelanoma cancers with BRAF V600 mutations. *N Engl J Med*. 2015;373(8):726-736.