# 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

1. 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.

Zelboraf is indicated for the treatment of patients with Erdheim-Chester Disease with BRAF V600 mutation.

# B. Compendial Uses

- 1. Melanoma (including brain metastases), BRAF V600 activating mutation-positive
- 2. Non-small cell lung cancer, BRAF V600E mutation-positive
- 3. Hairy cell leukemia
- 4. Thyroid carcinoma papillary carcinoma, follicular carcinoma, Hurthle cell carcinoma, BRAF mutation-positive

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. Erdheim-Chester disease (ECD)<sup>1</sup>

Authorization of 12 months may be granted for treatment of ECD with BRAF V600 mutation.

## C. Non-small cell lung cancer (NSCLC)

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

### D. Hairy cell leukemia

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

### E. Thyroid carcinoma

Authorization of 12 months may be granted for treatment of BRAF mutation-positive papillary carcinoma, follicular carcinoma, or Hurthle carcinoma.

Zelboraf SGM P2018

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#### **III. CONTINUATION OF THERAPY**

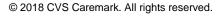
All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

## **IV. REFERENCES**

- 1. Zelboraf [package insert]. South San Francisco, CA: Genentech USA, Inc.; November 2017.
- 2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 4, 2017.
- 3. 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.
- 4. 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.
- 5. 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.
- 6. Clinical Consult. CVS Caremark Clinical Programs Review. Focus on Oncology Agents Clinical Programs. June 10, 2016.



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