Reference number(s)
1685-A

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.

2. 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)[1]
Authorization of 12 months may be granted for treatment of ECD with BRAF V600 mutation.

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

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.