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
5. Glioma, BRAF V600 activating mutation-positive
6. Meningioma, BRAF V600 activating mutation-positive
7. Astrocytoma, BRAF V600 activating 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)
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

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

F. Central Nervous System Cancer
Authorization of 12 months may be granted for treatment of BRAF V600 mutation-positive gliomas, meningiomas, or astrocytomas

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

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