

## SPECIALTY GUIDELINE MANAGEMENT

### BRAFTOVI (encorafenib)

#### 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

Braftovi is indicated, in combination with binimetinib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.

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

###### B. Compendial Uses

1. Glioma, BRAF V600 activating mutation-positive
2. Meningioma, BRAF V600 activating mutation-positive
3. 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 unresectable or metastatic melanoma when all of the following criteria are met:

1. Braftovi is used in combination with binimetinib
2. Tumor is positive for BRAF V600E or V600K mutation

###### B. **Central Nervous System Cancer**

Authorization of 12 months may be granted for treatment of BRAF V600E or V600K 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

1. Braftovi [package insert]. Boulder, CO: Array BioPharma, Inc.; June 2018.
2. Usabalieva A, Pierson CR, Kavran CA, et al. Primary Meningeal Pleomorphic Xanthoastrocytoma With Anaplastic Features: A Report of 2 Cases, One With *BRAFV600E* Mutation and Clinical Response to

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- the *BRAF* Inhibitor Dabrafenib. *Journal of neuropathology and experimental neurology*. 2015;74(10):960-969. doi:10.1097/NEN.0000000000000240.
3. Mordechai O, Postovsky S, Vlodavsky E, et al. Metastatic Rhabdoid Meningioma with *BRAF* V600E Mutation and Good Response to Personalized Therapy: Case Report and Review of the Literature. *Pediatric Hematology and Oncology*. 2015; 32:3, 207-211, DOI: [10.3109/08880018.2014.936058](https://doi.org/10.3109/08880018.2014.936058)
  4. Lassaletta, A, Guerreiro Stucklin, A, Ramaswamy, V, et al. Profound clinical and radiological response to BRAF inhibition in a 2-month-old diencephalic child with hypothalamic/chiasmatic glioma. *Pediatric Blood and Cancer*. 2016; 63: 2038-2041. doi:[10.1002/pbc.26086](https://doi.org/10.1002/pbc.26086).
  5. Meletah SK, Pavlick D, Brennan T, et al. Personalized Treatment for a Patient with a BRAF V600E Mutation using Dabrafenib and a Tumor Treatment Fields Device in a High-Grade Glioma Arising from Ganglioglioma. *Journal of the National Comprehensive Cancer Network*. 2016; 14(11): 1345-1350.