

Reference number(s)
1683-A

## SPECIALTY GUIDELINE MANAGEMENT

### TAFINLAR (dabrafenib)

#### 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. Tafinlar is indicated as a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.
2. Tafinlar is indicated, in combination with trametinib, for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.
3. Tafinlar is indicated, in combination with trametinib, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test.
4. Tafinlar is indicated, in combination with trametinib, for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection.
5. Tafinlar is indicated, in combination with trametinib, for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and no satisfactory locoregional treatment options.

##### B. Compendial Uses

1. Melanoma, BRAF V600 activating mutation-positive
2. Brain metastases from melanoma
3. NSCLC, BRAF V600E
4. Glioma, BRAF V600 activating mutation-positive
5. Meningioma, BRAF V600 activating mutation-positive
6. Astrocytoma, BRAF V600 activating mutation-positive
7. Papillary, follicular, Hürthle cell thyroid carcinoma

All other indications are considered experimental/investigational and not medically necessary.

#### II. DOCUMENTATION

Submission of BRAF mutation documentation is necessary to initiate prior authorization review.

#### III. CRITERIA FOR INITIAL APPROVAL

##### A. **Melanoma**

Authorization of 12 months may be granted for treatment of melanoma with a BRAF V600 activating mutation (e.g., V600E or V600K) in any of the following settings:

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1. Unresectable or metastatic cutaneous melanoma as a single agent or in combination with trametinib (Mekinist).
2. Brain metastases from melanoma in combination with trametinib (Mekinist).
3. Adjuvant treatment of stage III cutaneous melanoma in combination with trametinib (Mekinist) following complete resection or no evidence of disease.

**B. Non-Small Cell Lung Cancer (NSCLC)**

Authorization of 12 months may be granted for treatment of BRAF V600E mutation-positive recurrent, advanced, or metastatic NSCLC in combination with trametinib (Mekinist).

**C. Central Nervous System Cancer**

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

**D. Thyroid carcinoma**

Authorization of 12 months may be granted for treatment of thyroid carcinoma when any of the following criteria are met:

1. Member has progressive and/or symptomatic BRAF-positive follicular, Hürthle cell, or papillary thyroid carcinoma that is not amenable to radioactive iodine (RAI) therapy.
2. Member has BRAF V600E mutation positive metastatic anaplastic thyroid carcinoma and will be used in combination with trametinib (Mekinist).

**IV. CONTINUATION OF THERAPY**

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. For patients using Tafinlar for adjuvant treatment of cutaneous melanoma, only 12 months of therapy total will be approved.

**V. REFERENCES**

1. Tafinlar [package insert]. East Hanover, NJ: Novartis Pharmaceutical Corporation; April 2020.
2. The NCCN Drugs & Biologics Compendium 2020 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed December 8, 2020.
3. Usualieva 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 the *BRAF* Inhibitor Dabrafenib. *Journal of neuropathology and experimental neurology*. 2015;74(10):960-969. doi:10.1097/NEN.0000000000000240.
4. Mordechai O, Postovsky S, Vlodaysky E, et al. Metastatic Rhabdoid Meningioma with *BRAFV600E* 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
5. 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.
6. Meletath 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.