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 Indication
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, Hűrthle cell thyroid carcinoma
8. Colorectal cancer, BRAF V600E activating mutation-positive

All other indications are considered experimental/investigational and are not a covered benefit.

II. DOCUMENTATION

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

III. CRITERIA FOR INITIAL APPROVAL

A. Melanoma
1. Authorization of 12 months may be granted for treatment of unresectable or metastatic cutaneous melanoma with a BRAF V600 activating mutation as a single agent or in combination with trametinib (Mekinist).

2. Authorization of 12 months may be granted for treatment of brain metastases from melanoma with a BRAF V600 activating mutation in combination with trametinib (Mekinist).
3. Authorization of 12 months may be granted for adjuvant treatment of cutaneous melanoma with a BRAF V600 activating mutation in combination with trametinib (Mekinist) following complete lymph node dissection/resection or recurrence.

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 as a single agent or in combination with trametinib (Mekinist).

C. Anaplastic Thyroid Cancer (ATC)
Authorization of 12 months may be granted for treatment of metastatic BRAF V600E mutation-positive ATC in combination with trametinib (Mekinist).

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

E. Thyroid carcinoma
Authorization of 12 months may be granted for treatment of progressive and/or symptomatic radioiodine-refractory BRAF-activating mutation positive follicular, Hurthle cell, or papillary thyroid carcinoma.

F. Colorectal Cancer
Authorization of 12 months may be granted for treatment of unresectable advanced or metastatic colorectal cancer when the following criteria are met:
1. Tafinlar is used in combination with trametinib (Mekinist) and either cetuximab or panitumumab
2. Tumor is positive for BRAF V600E mutation.
3. Will be used as subsequent therapy

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; October 2019.
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9. 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.
10. 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.