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 (including brain metastases), BRAF V600 activating mutation-positive
2. NSCLC, BRAF V600E, single agent

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. Non-Small Cell Lung Cancer (NSCLC)
Authorization of 12 months may be granted for treatment of BRAF V600E mutation-positive NSCLC.

C. Anaplastic Thyroid Cancer (ATC)
Authorization of 12 months may be granted for treatment of BRAF V600E mutation-positive ATC.

III. CONTINUATION OF THERAPY

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

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IV. REFERENCES

1. Tafinlar [package insert]. East Hanover, NJ: Novartis Pharmaceutical Corporation; May 2018.
2. The NCCN Drugs & Biologics Compendium® ©2017 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 4, 2017.
3. The NCCN Clinical Practice Guidelines in Oncology™ Melanoma (Version 1.2018). ©2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed December 4, 2017.
4. The NCCN Clinical Practice Guidelines in Oncology™ Central Nervous System Cancers (Version 1.2017). ©2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed December 4, 2017.
5. The NCCN Clinical Practice Guidelines in Oncology™ Non-Small Cell Lung Cancer (Version 1.2018). ©2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed December 4, 2017.