

Generic Name: Dabrafenib**Preferred:** N/A**Therapeutic Class or Brand Name:** Tafinlar**Non-preferred:** N/A**Applicable Drugs (if Therapeutic Class):** N/A**Date of Origin:** 5/18/2018**Date Last Reviewed / Revised:** 1/26/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

- I. Documented diagnosis of one of the following conditions A through F and must meet criteria listed under each applicable diagnosis.
 - A. Unresectable or metastatic melanoma
 1. Documentation of BRAF V600E mutation
 - a) Tafinlar will be used as a single agent.
 2. Documentation of BRAF V600E or V600K mutations
 - a) Tafinlar will be used in combination with Mekinist (trametinib).
 3. Minimum age requirement: 18 years old.
 - B. Adjuvant treatment of melanoma with lymph node involvement following complete resection
 1. Documentation of BRAF V600E or V600K mutations
 2. Tafinlar will be used in combination with Mekinist (trametinib).
 3. Minimum age requirement: 18 years old.
 - C. Metastatic non-small cell lung cancer (NSCLC)
 1. Documentation of BRAF V600E mutation
 2. Tafinlar will be used in combination with Mekinist (trametinib).
 3. Minimum age requirement: 18 years old.
 - D. Locally advanced or metastatic anaplastic thyroid cancer (ATC)
 1. Documentation of BRAF V600E mutation
 2. Documentation that there are no satisfactory locoregional treatment options.
 3. Tafinlar will be used in combination with Mekinist (trametinib).
 4. Minimum age requirement: 18 years old.
 - E. Unresectable or metastatic solid tumors
 1. Documentation of BRAF V600E mutation

2. Documentation of disease progression after prior treatment and no satisfactory alternative treatment options.
 3. Minimum age requirement: 1 year old.
- F. Pediatric low-grade glioma
1. Documentation of BRAF V600E mutation
 2. Documentation that the patient requires systemic therapy.
 3. Minimum age requirement: 1 year old
- II. Treatment must be prescribed by or in consultation with an oncologist.
- III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Treatment of wild-type BRAF tumors.
- Treatment of colorectal cancer.

OTHER CRITERIA

- Off-label uses per National Comprehensive Cancer Network (NCCN) guidelines:
 - Brain metastases from melanoma
 - Central Nervous system cancers (eg, glioma, meningioma, astrocytoma, etc)
 - Follicular cancer
 - Hepatobiliary cancers (ie, gallbladder or cholangiocarcinoma)
 - Hürthle cell cancer
 - Low-grade serous ovarian cancer, fallopian tube cancer, primary peritoneal cancer
 - Papillary cancer

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Adults: 120 capsules per 30 days
- Pediatric patients
 - > 26 kg 120 capsules per 30 days
 - < 26 kg up to 12 tablets/day for oral suspension (360 tablets per 30 days)

APPROVAL LENGTH

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and the medication is effective. Please note: for adjuvant treatment of melanoma Tafinlar is only indicated to be given up to 1 year.

APPENDIX

- N/A.

REFERENCES

1. Tafinlar. Prescribing information. Novartis; 2023. Accessed January 26, 2024. <https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/tafinlar.pdf>.
2. NCCN Clinical Practice Guidelines in Oncology. Melanoma: cutaneous. V.3.2023. Updated October 27, 2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed January 26, 2024.
3. NCCN Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer. V.1.2024. Updated December 21, 2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed January 26, 2024.
4. NCCN Clinical Practice Guidelines in Oncology. Thyroid Carcinoma. V.4.2023. Updated August 16, 2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed January 26, 2024.
5. NCCN Clinical Practice Guidelines in Oncology

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.