

Applicable Drugs: Tafinlar (dabrafenib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 5/18/2018

Date Last Reviewed / Revised: 6/19/2025

PRIOR AUTHORIZATION CRITERIA

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

- I. Documentation of one of the following diagnoses A through F AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

- A. Unresectable or metastatic melanoma
 - i. BRAF V600E mutation as detected by an FDA-approved test.
 - 1. Tafinlar will be used as a single agent.
 - ii. BRAF V600E or V600K mutations as detected by an FDA-approved test.
 - 1. Tafinlar will be used in combination with Mekinist (trametinib).
 - iii. Minimum age requirement: 18 years old.
- B. Adjuvant treatment of melanoma with lymph node involvement following complete resection
 - i. BRAF V600E or V600K mutations as detected by an FDA-approved test.
 - ii. Tafinlar will be used in combination with Mekinist (trametinib).
 - iii. Minimum age requirement: 18 years old.
- C. Metastatic non-small cell lung cancer (NSCLC)
 - i. BRAF V600E mutation as detected by an FDA-approved test.
 - ii. Tafinlar will be used in combination with Mekinist (trametinib).
 - iii. Minimum age requirement: 18 years old.
- D. Locally advanced or metastatic anaplastic thyroid cancer (ATC)
 - i. BRAF V600E mutation as detected by an FDA-approved test.
 - ii. Documentation that there are no satisfactory locoregional treatment options.
 - iii. Tafinlar will be used in combination with Mekinist (trametinib).
 - iv. Minimum age requirement: 18 years old.
- E. Unresectable or metastatic solid tumors

- i. BRAF V600E mutation.
 - ii. Documentation of disease progression following prior treatment and no satisfactory alternative treatment options.
 - iii. Minimum age requirement: 1 year old.
- F. Pediatric low-grade glioma (LGG)
 - i. BRAF V600E mutation.
 - ii. Documentation that the patient requires systemic therapy.
 - iii. 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.)
 - Esophageal, esophagogastric junction, and gastric cancer
 - Follicular cancer
 - Hairy Cell Leukemia
 - Head and neck cancers
 - 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. Tafinlar is indicated for use until disease progression or unacceptable toxicity occurs.
 - Adjuvant treatment of melanoma: 6 months (treatment not exceeding 1 year)

APPENDIX

N/A

REFERENCES

1. Tafinlar. Prescribing information. Novartis; 2025. Accessed June 19, 2025.
https://www.novartis.com/us-en/sites/novartis_us/files/tafinlar.pdf
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Melanoma: Cutaneous. Version 2.2025. Updated January 28, 2025. Accessed June 19, 2025.
https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer. Version 4.2025. Updated May 23, 2025. Accessed June 19, 2025.
https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Thyroid Carcinoma. Version 1.2025. Updated March 27, 2025. Accessed June 19, 2025.
https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Ampullary Adenocarcinoma. Version 2.2025. Updated January 10, 2025. Accessed June 19, 2025.
https://www.nccn.org/professionals/physician_gls/pdf/ampullary.pdf
6. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Biliary Tract Cancers. Version 1.2025. Updated March 20, 2025. Accessed June 19, 2025.
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7. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Central Nervous System Cancers. Version 1.2025. Updated June 3, 2025. Accessed June 19, 2025.
https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf
8. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Esophageal and Esophagogastric Junction Cancers. Version 3.2025. Updated April 22, 2025. Accessed June 19, 2025.
https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf
9. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Gastric. Version 2.2025. Updated April 4, 2025. Accessed June 19, 2025.
https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf
10. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Gastrointestinal Stromal Tumors. Version 1.2025. Updated April 17, 2025. Accessed June 19, 2025.
https://www.nccn.org/professionals/physician_gls/pdf/gist.pdf
11. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Hairy Cell Leukemia. Version 1.2025. Updated September 26, 2024. Accessed June 19, 2025.
https://www.nccn.org/professionals/physician_gls/pdf/hairy_cell.pdf
12. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Head and Neck Cancers. Version 3.2025. Updated June 11, 2025. Accessed June 19, 2025.
https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf
13. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Ovarian Cancer. Version 2.2025. Updated May 23, 2025. Accessed June 19, 2025.
https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf

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.