VENTURA COUNTY
HEALTH CARE PLAN

# PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Tafinlar Prior Authorization Policy
- Tafinlar® (dabrafenib capsules – GlaxoSmithKline)

**REVIEW DATE:** 08/04/2021

---

## OVERVIEW

Tafinlar, a BRAF inhibitor, is indicated for the following uses:[1]

- **Melanoma**, in the following situations:[1]
  - As a single agent for the treatment of patients with unresectable or metastatic disease with *BRAF V600E* mutation as detected by an FDA-approved test; AND
  - In combination with Mekinist® (trametinib tablets), for the treatment of patients with unresectable or metastatic disease with *BRAF V600E* or *V600K* mutations as detected by an FDA-approved test; AND
  - As adjuvant treatment of *BRAF V600E* or *V600K* mutation-positive disease as detected by an FDA-approved test, and involvement of the lymph node(s), following complete resection.
- **Non-small cell lung cancer**, in combination with Mekinist for treatment of disease that has the *BRAF V600E* mutation as detected by an FDA-approved test.
- **Thyroid cancer**, in combination with Mekinist, for treatment of patients with locally advanced or metastatic anaplastic disease with *BRAF V600E* mutation and with no satisfactory locoregional treatment options.

Tafinlar is not indicated for the treatment of patients with wild-type BRAF disease.

## Guidelines

National Comprehensive Cancer Network (NCCN) guidelines support use in multiple cancers.

- **Central Nervous System Cancers** (version 1.2021 – June 4, 2021): Guidelines recommend a BRAF/MEK inhibitor combination (i.e., Tafinlar/Mekinist or Zelboraf® [vemurafenib tablets]/Cotellic® [cobimetinib tablets]) for treatment of *BRAF V600E* activation mutation in the following situations: adjuvant treatment of pilocytic astrocytoma, pleomorphic xanthoastrocytoma, or ganglioglioma; for recurrent or progressive disease low-grade glioma; recurrent anaplastic glioma; and recurrent glioblastoma. BRAF/MEK combination therapy is also recommended for melanoma with brain metastases.[6]
- **Hepatobiliary Cancers** (version 3.2021 – June 15, 2021): Guidelines recommend Tafinlar + Mekinist for subsequent therapy for biliary tract cancers, if the patient has a *BRAF V600E* mutation.[7]
- **Melanoma,** Cutaneous (version 2.2021 – February 19, 2021): Guidelines for cutaneous disease recommend BRAF/MEK inhibitor combinations among the preferred therapies for first-line and subsequent treatment of metastatic or unresectable melanoma with a *V600*-activating mutation.[2] While combination BRAF/MEK inhibition is preferred, if a combination is contraindicated, monotherapy with a BRAF inhibitor is a recommended option. Tafinlar + Mekinist is also recommended in guidelines as adjuvant therapy (including for nodal recurrence) in some patients with Stage III disease, including use post-surgery or use after complete lymph node dissection. If unacceptable toxicity to Tafinlar/Mekinist, other BRAF/MEK combinations can be considered.
- **Histiocytic Neoplasms** (version 1.2021 – March 1, 2021): NCCN recommends Zelboraf (preferred) or Tafinlar (other recommended regimen) for *BRAF V600E*-mutated Erdheim-Chester

disease and for multisystem, pulmonary, or central nervous system (CNS) Langerhans cell histocytosis.[5]

- **Non-Small Cell Lung Cancer** (version 5.2021 – June 15, 2021): Guidelines list Tafinlar + Mekinist among the first-line therapy and subsequent therapy options for tumors with a *BRAF* mutation.[3] NCCN also notes that monotherapy with a BRAF inhibitor (Tafinlar or Zelboraf) is a treatment option when combination therapy is not tolerated.
- **Thyroid Cancer** (version 1.2021 – April 9, 2021): Guidelines list Tafinlar + Mekinist as a treatment option for metastatic anaplastic thyroid cancer with a *BRAF* mutation.[4] Tafinlar and Zelboraf are also treatment options if not amenable to radioiodine treatment for differentiated thyroid cancer (follicular, Hürthle cell, and papillary cancer subtypes) with a *BRAF V600* mutation.

## POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Tafinlar. All approvals are provided for the duration noted below.

**Automation:** None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tafinlar is recommended in those who meet the following criteria:

### FDA-Approved Indications

1. **Melanoma.** Approve for 3 years if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has unresectable, advanced (including Stage III or Stage IV disease), or metastatic melanoma; AND
     Note: This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery.
   - **C)** Patient has *BRAF V600* mutation-positive disease.

2. **Non-Small Cell Lung Cancer.** Approve for 3 years if the patient meets the following (A and B)
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has *BRAF V600E* mutation-positive disease.

3. **Thyroid Carcinoma, Anaplastic.** Approve for 3 years if the patient meets the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has locally advanced or metastatic anaplastic disease; AND
   - **C)** Patient has *BRAF V600* mutation-positive disease; AND
   - **D)** The medication will be taken in combination with Mekinist (trametinib tablets), unless intolerant.

**Other Uses with Supportive Evidence**

4. **Biliary Tract Cancer.** Approve for 3 years if the patient meets following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has tried at least one systemic chemotherapy regimen; AND
   - **C)** Patient has *BRAF V600* mutation-positive disease; AND
   - **D)** The medication will be taken in combination with Mekinist (trametinib tablets).

5. **Central Nervous System Cancer.** Approve for 3 years if the patient meets the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication is being used in one of the following situations (i, ii, or iii):
     - **i.** Adjuvant treatment of one of the following conditions (a, b, or c):
       - **a)** Pilocytic astrocytoma; OR
       - **b)** Pleomorphic xanthoastrocytoma; OR
       - **c)** Ganglioglioma; OR
     - **ii.** Recurrent disease for one of the following conditions (a, b, or c):
       - **a)** Low-grade glioma; OR
       - **b)** Anaplastic glioma; OR
       - **c)** Glioblastoma; OR
     - **iii.** Brain metastases from melanoma; AND
   - **C)** Patient has *BRAF V600* mutation-positive disease; AND
   - **D)** The medication will be taken in combination with Mekinist (trametinib tablets).

6. **Histiocytic Neoplasm.** Approve for 3 years if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets one of the following (i or ii):
     - **i.** Patient has Langerhans cell histiocytosis AND one of the following (a, b, or c):
       - **a)** Multisystem disease; OR
       - **b)** Pulmonary disease; OR
       - **c)** Central nervous system lesions; OR
     - **ii.** Patient has Erdheim-Chester disease; AND
   - **C)** Patient has *BRAF V600*-mutation positive disease.

7. **Thyroid Carcinoma, Differentiated.** Approve for 3 years if the patient meets the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has differentiated thyroid carcinoma; AND
     Note: Examples of differentiated thyroid carcinoma include papillary, follicular, or Hürthle cell thyroid cancers.
   - **C)** Patient has disease that is refractory to radioactive iodine therapy; AND
   - **D)** Patient has *BRAF* mutation-positive disease.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tafinlar is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Tafinlar® capsules [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; April 2020.
2. The NCCN Melanoma Clinical Practice Guidelines in Oncology (Version 2.2021 – February 19, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed on July 27, 2021.
3. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 5.2021 – June 15, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed on July 16, 2021.
4. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (Version 1.2021 – April 9, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed on July 16, 2021.
5. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (Version 1.2021 – March 1, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed on July 25, 2021.
6. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (Version 1.2021 – June 4, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed on July 25, 2021.
7. The NCCN Hepatobiliary Cancers Clinical Practice Guidelines in Oncology (Version 3.2021 – June 15, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org/. Accessed on July 31, 2021.