PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 07/15/2020

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 of Tafinlar in multiple cancers.

- **Melanoma:** Guidelines (version 3.2020 – May 18, 2020) recommend BRAF/MEK inhibitor combinations for first-line (preferred if clinically needed for early response) 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 (Tafinlar or Zelboraf® [vemurafenib tablets]) is a recommended option, particularly if the patient is not a candidate for checkpoint immunotherapy. Following resection of limited metastatic disease with a *BRAF V600*-activating mutation, BRAF/MEK combination therapy is among the treatment options for patients with no evidence of disease. 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.
- **Non-Small Cell Lung Cancer:** Guidelines (version 6.2020 – June 25, 2020) 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:** Guidelines (version 1.2020 – June 12, 2020) list Tafinlar + Mekinist as a treatment option for metastatic anaplastic thyroid cancer with a *BRAF* mutation.[4] Tafinlar and Zelboraf are also treatment options for the treatment of iodine-refractory 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 BOTH of the following (A and B):
   - **A)** 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.
   - **B)** Patient has *BRAF V600* mutation-positive disease.

2. **Non-Small Cell Lung Cancer.** Approve for 3 years if the patient has *BRAF V600E* mutation-positive disease.

3. **Thyroid Cancer, Anaplastic.** Approve for 3 years if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient has locally advanced or metastatic anaplastic disease; AND
   - **B)** Tafinlar will be taken in combination with Mekinist, unless intolerant; AND
   - **C)** Patient has *BRAF V600* mutation-positive disease.

Other Uses with Supportive Evidence

4. **Thyroid Cancer, Differentiated.** Approve for 3 years if the patient meets ALL of the following conditions (A, B, and C):
   - **A)** Patient has differentiated thyroid carcinoma; AND
     Note: Examples of differentiated thyroid carcinoma include papillary, follicular, or Hürthle cell thyroid cancers.
   - **B)** Patient has disease that is refractory to radioactive iodine therapy; AND
   - **C)** 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 3.2020 – May 18, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 2, 2020.

3. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 6.2020 – June 15, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 2, 2020.
4. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (Version 1.2020 – June 12, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 2, 2020.