Clinical Policy: Dabrafenib (Tafinlar)

Reference Number: PA.CP.PHAR.239
Effective Date: 01/18
Last Review Date: 04/19
Line of Business: Medicaid

Coding Implications
Revision Log

Description
Dabrafenib (Tafinlar®) is kinase inhibitor.

FDA approved indication
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
- 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
  - 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
  - For the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test
  - For the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options

Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF melanoma, wild-type BRAF NSCLC, or wild-type BRAF ATC.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® that Tafinlar is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Melanoma (must meet all)**:**

1. Diagnosis of melanoma with BRAF V600E or V600K mutation;
2. Disease meets one of the following (a or b):
   a. Unresectable or metastatic;
   b. Presence of lymph node(s) involvement following complete resection;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years; Prescribed as one of the following (a or b):
   a. In combination with Mekinist®; for unresectable or metastatic disease or following complete lymph node resection;

   b. As a single agent for unresectable or metastatic disease with BRAF V600E mutation;
5. Dose does not exceed 300mg/day (4 capsules/day).

Approval duration: 6 months

B. Non-small Cell Lung Cancer (must meet all)**:**
1. Diagnosis of metastatic or recurrent non-small cell lung (NSCLC);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Presence of a BRAF V600E mutation as detected by an FDA approved test;
5. Prescribed in combination with Mekinist;
6. Dose does not exceed 300mg/day (4 capsules/day).

Approval duration: 6 months

C. Anaplastic Thyroid Cancer (ATC) (must meet all)**:**
1. Diagnosis of ATC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is positive for BRAF V600E mutation;
5. Prescribed in combination with Mekinist;
6. Dose does not exceed 300 mg/day (4 capsules/day).

Approval duration: 6 months

D. Other diagnoses/indications
1. Refer to PA.CP.PMN.53

II. Continued Therapy

A. All Indications (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed 300mg/day (4 capsules/day).

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**
1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
ATC: anaplastic thyroid cancer
BRAF: B-Raf proto-oncogene, serine/ threonine kinase
FDA: Food and Drug Administration
NSCLC: non-small cell lung cancer

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information

- Nearly half of patients with melanoma have a BRAF mutation gene. The most common forms of the BRAF mutation are V600E (80-90%) and V600K (10-20%).
- Tafinlar can potentiate the activity of the mitogen-activated protein kinases (MAPK) pathway in cells with wild-type BRAF and could accelerate the growth of some tumors with wild-type BRAF.
- Tafinlar is not FDA-approved to treat patients with V600K mutations. Studies with less than 20 patients showed a partial response rate ranging from 13 to 25 percent. Mekinist is FDA-approved to treat V600K mutations.
- According to NCCN, Tafinlar has category 2A recommendation for BRAF 600E mutation non-small lung cancer as a single agent or in combination with trametinib.
- According to NCCN, Tafinlar has category 2A recommendation for combination treatment with Mekinist for brain metastases if active against primary tumor (melanoma) for recurrent disease.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Melanoma, NSCLC, ATC	150 mg PO BID	300 mg/day

VI. Product Availability

Capsules: 50 mg, 75 mg

VII. References

1. Tafinlar Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2018. Available at: www.pharma.us.novartis.com/product/pi/pdf/tafinlar.pdf. Accessed February 26, 2019.
2. Dabrafenib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed February 26, 2019.

3. National Comprehensive Cancer Network. Cutaneous Melanoma Version 1.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed February 26, 2019.
4. National Comprehensive Cancer Network Guidelines. Central Nervous System Cancers Version 2.2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed February 26, 2019.
5. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer Version 3.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed February 26, 2019.
6. National Comprehensive Cancer Network Guidelines. Thyroid Carcinoma Version 3.2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed February 26, 2019.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: added age; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care and continuity of care statement; references reviewed and updated.	2.6.18	
2Q 2019 annual review: Updated criteria with new indications for anaplastic thyroid cancer and the adjuvant treatment of melanoma following complete lymph node(s) resection; references reviewed and updated.	04/19	