Clinical Policy: Dabrafenib (Tafinlar)

Reference Number: CP.PHAR.239
Effective Date: 11.16.16
Last Review Date: 08.18
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Dabrafenib (Tafinlar®) is a kinase inhibitor.

FDA Approved Indication(s)

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(s) 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 (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® 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. Member meets one of the following (a or b), disease is:
   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;

5. Meets 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;
6. Dose does not exceed 300 mg/day (4 capsules/day).

Approval duration:
Medicaid/HIM – 6 months
Commercial – Length of Benefit

B. Non-Small Cell Lung Cancer (must meet all)**:**
1. Diagnosis of metastatic or recurrent NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Positive for a BRAF V600E mutation;
5. Tafinlar will be used in combination with Mekinist;
6. Dose does not exceed 300 mg/day (4 capsules/day).

Approval duration:
Medicaid/HIM – 6 months
Commercial – Length of Benefit

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. Positive for a BRAF V600E mutation;
5. Tafinlar will be used in combination with Mekinist;
6. Dose does not exceed 300 mg/day (4 capsules/day).

Approval duration:
Medicaid/HIM – 6 months
Commercial – Length of Benefit

D. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Tafinlar for melanoma, ATC, or NSCLC and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 300 mg/day (4 capsules/day).

Approval duration:
Medicaid/HIM – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid 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
Not applicable

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.
- The current National Comprehensive Cancer Network (NCCN) guideline recommends that the preferred therapy for patients with metastatic melanoma is participation in a clinical trial, even though Zelboraf, Yervoy, and Tafinlar received a category 1 recommendation.
- 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 single-agent treatment 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 May 11, 2018.
2. Dabrafenib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed January 27, 2018.
3. Melanoma (Version 2.2018). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed January 27, 2018.
4. Central Nervous System Cancers (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed January 27, 2018.
5. Non-Small Cell Lung Cancer (Version 2.2018). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed January 27, 2018.
6. Thyroid Carcinoma (Version 2.2018). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed May 11, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PHAR.117.Mekinist and Tafinlar and converted to new template. Age requirement removed. Maximum dose added. NCCN compendial uses for melanoma are covered within the scope of the FDA approved uses; the remaining NCCN uses for NSCLC are added.	06.16	07.16
Safety criteria revised according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Added NSCLC criteria per new FDA approved indication.	06.17	07.17
2Q 2018 annual review: no significant changes; policies combined for Medicaid, Commercial, and HIM ; 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.	02.06.18	05.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Updated criteria with new indications for anaplastic thyroid cancer and the adjuvant treatment of melanoma following complete lymph node(s) resection.	05.29.18	08.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace (HIM) members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.