Clinical Policy: Dabrafenib (Tafinlar)

Reference Number: CP.PHAR.239
Effective Date: 11.16.16
Last Review Date: 05.20
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. 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;

5. Prescribed as one of the following (a or b):
   a. In combination with Mekinist®;
   b. As a single agent for unresectable or metastatic disease with BRAF V600E mutation;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 300 mg (4 capsules) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

**Prescribed regimen must be FDA-approved or recommended by NCCN*

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

B. Non-Small Cell Lung Cancer (must meet all)**:**
1. Diagnosis of advanced, metastatic, or recurrent NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is positive for a BRAF V600E mutation;
5. Prescribed in combination with Mekinist;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 300 mg (4 capsules) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

**Prescribed regimen must be FDA-approved or recommended by NCCN*

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. Disease is positive for BRAF V600E mutation;
5. Prescribed in combination with Mekinist;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 300 mg (4 capsules) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

**Prescribed regimen must be FDA-approved or recommended by NCCN*

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

D. Colon Cancer, Rectal Cancer (off-label) (must meet all)**:**
1. Diagnosis of colon cancer or rectal cancer with BRAF V600E mutation;
2. Disease is unresectable, advanced, or metastatic;
3. Prescribed by or in consultation with an oncologist;

4. Age ≥ 18 years;
5. Prescribed in combination with Mekinist and either Erbitux® or Vectibix®;
6. One of the following (a or b):
   a. Member previously received adjuvant therapy (e.g., FOLFOX, CapeOX);
   b. Request is for subsequent therapy following previous treatment (e.g., oxaliplatin or irinotecan based therapy);
7. Request meets one of the following (a or b):*
   a. Dose does not exceed 300 mg (4 capsules) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

**Prescribed regimen must be FDA-approved or recommended by NCCN*

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

E. 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 a covered indication 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, request meets one of the following (a or b):*
   a. New dose does not exceed 300 mg (4 capsules) per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

**Prescribed regimen must be FDA-approved or recommended by NCCN*

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

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
FOLFOX (fluorouracil, leucovorin, and oxaliplatin); CapeOX (capecitabine and oxaliplatin); FOLFIRI (irinotecan, leucovorin, 5-FU); FOLFOXIRI (irinotecan, oxaliplatin, leucovorin, fluorouracil); IROX (oxaliplatin, irinotecan); oxaliplatin and irinotecan	Colorectal Cancer: Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

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.
- 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; October 2019. Available at: https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/tafinlar.pdf. Accessed February 10, 2020.
2. Dabrafenib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed February 10, 2020.
3. National Comprehensive Cancer Network. Cutaneous Melanoma Version 1.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed February 6, 2020.
4. National Comprehensive Cancer Network. Central Nervous System Cancers Version 3.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed February 6, 2020.
5. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer Version 2.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed February 6, 2020.
6. National Comprehensive Cancer Network Guidelines. Thyroid Carcinoma Version 2.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed February 6, 2020.
7. National Comprehensive Cancer Network. Colon Cancer Version 1.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed February 6, 2020.
8. National Comprehensive Cancer Network. Rectal Cancer Version 1.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Accessed February 6, 2020.

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
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.26.19	05.19
2Q 2020 annual review: added NCCN supported off-label uses in colon and rectal cancers; added NCCN supported off-label dosing verbiage; for NSCLC added advanced disease; references reviewed and updated.	02.10.20	05.20

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.