Clinical Policy: Dabrafenib (Tafinlar)

Reference Number: CP.PHAR.239
Effective Date: 07/16
Last Review Date: 07/17
Line of Business: Medicaid

Coding Implications
Revision Log

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

Description
Dabrafenib (Tafinlar®) is kinase inhibitor indicated.

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
  - metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test

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

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 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 unresectable or metastatic melanoma;
2. Presence of a BRAF V600E or V600K mutation as detected by an FDA approved test;
3. The BRAF mutation is not considered a wild-type;
4. Tafinlar will be used in one of the following ways:
   a. As a single agent (limited to the BRAF V600E mutation);
   b. In combination with trametinib (BRAF V600E or V600K mutation);
5. Dose does not exceed 300mg/day (4 capsules/day).

Approval duration: 3 months

B. Non-small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of metastatic or recurrent non-small cell lung (NSCLC);
2. Presence of a BRAF V600E mutation as detected by an FDA approved test;

3. Tafinlar will be used in one of the following ways:
   a. FDA approved use: in combination with trametinib;
   b. Off-label NCCN recommended use: As a single agent if the combination of dabrafenib plus trametinib is not tolerated;
4. Dose does not exceed 300mg/day (4 capsules/day).

Approval duration: 3 months

C. Other diagnoses/indications

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
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: 6 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BRAF: B-Raf proto-oncogene, serine/ threonine kinase
FDA: Food and Drug Administration
LVEF: left ventricular ejection fraction
LLN: lower limits of normal
NSCLC: non-small cell lung cancer

V. Dosage and Administration

Indication	Dosing Regimen	Max Dose
Single agent for treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation	150 mg orally twice daily	300 mg/day
In combination with trametinib, for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations	150 mg orally twice daily	300 mg/day

NSCLC	150 mg orally twice daily	300 mg/day

VI. Product Availability

Capsules: 50 mg, 75 mg

VII. References

1. Tafinlar Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2017. Available at www.pharma.us.novartis.com/product/pi/pdf/tafinlar.pdf. Accessed June 30, 2017.
2. Dabrafenib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed June 30, 2017.
3. Melanoma (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed May 16, 2017.

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
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

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.