PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – BRAF Inhibitor) – Tafinlar Prior Authorization Policy
- Tafinlar® (dabrafenib capsules and tablets for oral suspension – Novartis)

REVIEW DATE: 04/09/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Tafinlar, a BRAF inhibitor, is indicated for the following uses:[1]

- **Low-grade glioma,** in combination with Mekinist® (trametinib tablets and oral solution), for the treatment of pediatric patients ≥ 1 year of age with a *BRAF V600E* mutation who require systemic therapy.
- **Melanoma**, in the following situations:
  - As a single agent for unresectable or metastatic disease with *BRAF V600E* mutation as detected by an FDA-approved test.
  - In combination with Mekinist, for unresectable or metastatic disease with a *BRAF V600E* or *V600K* mutation as detected by an FDA-approved test.
  - In combination with Mekinist, as adjuvant treatment of *BRAF V600E* or *V600K* mutation-positive disease as detected by an FDA-approved test, with involvement of the lymph node(s), following complete resection.

- **Non-small cell lung cancer**, in combination with Mekinist, for metastatic disease that has the *BRAF V600E* mutation as detected by an FDA-approved test.
- **Solid tumors**, unresectable or metastatic, in combination with Mekinist, for *BRAF V600E* mutation-positive disease in patients ≥ 1 year of age who have progressed following prior treatment and have no satisfactory alternative treatment options.
- **Thyroid cancer**, in combination with Mekinist, for locally advanced or metastatic anaplastic disease with *BRAF V600E* mutation as detected by an FDA-approved test and with no satisfactory locoregional treatment options.

Limitations of Use**:** Tafinlar is not indicated for treatment of patients with colorectal cancer because of the known intrinsic resistance to BRAF inhibition. Tafinlar is not indicated for treatment of patients with wild-type BRAF solid tumors.[1]

The indication of solid tumors is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) Compendium recommends use of Tafinlar for the indications listed in the FDA-Approved Indications and Other Uses with Supportive Evidence sections of this Policy.[2]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Tafinlar. All approvals are provided for the duration noted below.

- **Tafinlar® (dabrafenib capsules and tablets for oral suspension (Novartis)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Low Grade Glioma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 1 year of age; AND
   B) Patient has *BRAF V600* mutation-positive disease; AND
   C) The medication will be taken in combination with Mekinist (trametinib tablets or oral solution).

2. **Melanoma.** Approve for 1 year 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 and no evidence of disease post-surgery.
B) Patient has *BRAF V600* mutation-positive disease.

3. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient has recurrent, advanced, or metastatic disease; AND
   B) Patient has *BRAF V600* mutation-positive disease.

4. **Solid Tumors.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   Note: Examples of solid tumors include: biliary tract cancer, brain metastases due to melanoma, high-grade gliomas, ovarian/fallopian tube/primary peritoneal cancer, gastrointestinal stromal tumors, gastric cancer, esophageal and esophagogastric junction cancers, salivary gland tumors, occult primary, pancreatic adenocarcinoma, neuroendocrine tumors, and ampullary adenocarcinoma.
   A) Patient is ≥ 1 year of age; AND
   B) Patient has *BRAF V600* mutation-positive disease; AND
   C) The medication will be taken in combination with Mekinist (trametinib tablets or oral solution).

5. **Thyroid Carcinoma, Anaplastic.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient has locally advanced or metastatic anaplastic disease; AND
   B) Patient has *BRAF V600* mutation-positive disease; AND
   C) The medication will be taken in combination with Mekinist (trametinib tablets or oral solution).

Other Uses with Supportive Evidence

6. **Hairy Cell Leukemia.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient has not been previously treated with a BRAF inhibitor therapy; AND
   B) The medication will be used for relapsed/refractory disease; AND
   C) The medication will be taken in combination with Mekinist (trametinib tablets and oral solution).

7. **Histiocytic Neoplasm.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient meets ONE of the following (i or ii):
      i. Patient has Langerhans cell histiocytosis; OR
      ii. Patient has Erdheim-Chester disease; AND
   B) Patient has *BRAF V600*-mutation positive disease.

8. **Small Bowel Adenocarcinoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient meets BOTH of the following (i and ii):

i. Patient has *BRAF V600E* mutation-positive advanced or metastatic disease; AND

ii. The medication will be taken in combination with Mekinist (trametinib tablets and oral solution); AND

B) Patient meets ONE of the following (i or ii):

i. Patient meets BOTH of the following (a and b):

a) The medication will be used as initial therapy; AND

b) Patient has received previous FOLFOX/CAPEOX therapy in the adjuvant setting within the past 12 months or has a contraindication; OR

ii. The medication will be used as second-line and subsequent therapy.

9. Thyroid Carcinoma, Differentiated. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient has differentiated thyroid carcinoma; AND
Note: Examples of differentiated thyroid carcinoma include papillary, follicular, and oncocytic thyroid carcinoma.

B) Patient has recurrent or metastatic disease; AND

C) Patient has *BRAF V600* mutation-positive disease.

CONDITIONS NOT COVERED

- **Tafinlar® (dabrafenib capsules and tablets for oral suspension (Novartis)**

is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. Colon or Rectal Cancer. Tafinlar is not indicated for the treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition.[1]

REFERENCES

1. Tafinlar® capsules and tablets for oral suspension [prescribing information]. East Hanover, NJ: Novartis; March 2025.
2. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.ncc.org. Accessed on April 1, 2025. Search term: dabrafenib.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	Added new oral solution formulation to the policy. For all indications, removed weight ≥ 26 kg criterion due to the approval of an oral suspension formulation for ≥ 8 kg. **Solid Tumors – Unresectable or Metastatic:** Modified indication to match FDA label. Previously listed as "Metastatic or solid tumors". Included "Note" below indication heading with a long list of examples of solid tumors that are supported by National Comprehensive Cancer Network (NCCN) guidelines/compendium.	04/05/2023

	For criterion D, added phrase "According to the prescriber" in reference to unavailability of satisfactory alternative treatment options. **Non-Small Cell Lung Cancer:** Similar to other criteria, deleted "E" from *BRAF V600* mutation reference. This is due to the possibility of occurrence of other point mutations than V600E. **Low Grade Glioma:** Added new condition and criteria based on FDA-approval **Other Uses with Supportive Evidence:** Deleted Biliary Tract Cancer, Central Nervous System Cancer, Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, and Thyroid Cancer, Differentiated conditions since they are now listed as examples under FDA-approved use "Solid Tumors – Unresectable or Metastatic". Histiocytic Neoplasm was not deleted because combination use with Mekinist is not required for this condition (Solid Tumor indication requires use with Mekinist).	
Selected Revision	**Solid Tumors – Unresectable or Metastatic:** Age indication expanded for use in patients 1 year and older. The required age was changed from ≥ 6 years of age to be ≥ 1 years of age.	09/13/2023
Annual Revision	**Melanoma:** Deleted age criterion ≥ 6 years of age. **Non-Small Cell Lung Cancer:** Deleted age criterion ≥ 6 years of age. **Thyroid Carcinoma, Anaplastic:** Deleted age criterion ≥ 6 years of age. **Histiocytic Neoplasm:** Deleted age criterion ≥ 6 years of age. **Solid Tumors – Unresectable or Metastatic:** Added "occult primary" to the list of examples of solid tumors in the Note. **Hairy Cell Leukemia:** Added new indication and criteria based on Compendium recommendations. **Small Bowel Adenocarcinoma:** Added new indication and criteria based on Compendium recommendations.	04/24/2024
Annual Revision	**Low Grade Glioma:** The requirement which states that patient requires systemic therapy was removed. **Non-Small Cell Lung Cancer:** The following requirement was added, "patient has recurrent, advanced, or metastatic disease." **Solid Tumors:** The following verbiage from the condition of approval "unresectable or metastatic" was removed. Differentiated thyroid cancer was removed from the note of examples of solid tumors. The requirement that according to the prescriber, the patient has no satisfactory alternative treatment options was removed. **Thyroid Carcinoma, Anaplastic:** The requirement that "the medication will be taken in combination with Mekinist (trametinib tablets or oral solution) unless intolerant" was reworded to, "the medication will be taken in combination with Mekinist (trametinib tablets or oral solution)." **Histiocytic Neoplasm:** For a patient that has Langerhans cell histiocytosis, the requirements that the patient has multisystem disease, pulmonary disease, or central nervous system lesions were removed. **Thyroid Carcinoma, Differentiated:** New condition of approval and criteria were added under Other Uses with Supportive Evidence.	04/09/2025
Update	04/11/2025: The policy name was changed from "Oncology – Tafinlar PA Policy" to "Oncology (Oral – BRAF Inhibitor) – Tafinlar PA Policy."	N/A