

Tafinlar (dabrafenib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Tafinlar (dabrafenib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Tafinlar (dabrafenib) may be approved if the following criteria are met:

Individual has a diagnosis of one of the following:

- I. Unresectable or metastatic Hepatobiliary Cancer (NCCN 2A); **AND**
 - A. Individual is using in combination with trametinib; **AND**
 - B. Individual has confirmed disease progression after systemic treatment; **AND**
 - C. Individual has BRAF V600E mutation;

OR

- II. Individual has a diagnosis of unresectable or metastatic Gastrointestinal Stromal Tumor (NCCN 2A); **AND**
 - A. Individual is using in combination with trametinib; **AND**
 - B. Individual has BRAF V600E;

OR

- III. Individual has a diagnosis of symptomatic and/or relapsed/refractory Histiocytic Neoplasm, including Erdheim-Chester Disease or Langerhans Cell Histiocytosis (NCCN 2A); **AND**
 - A. Individual is using as monotherapy; **AND**
 - B. Individual has mitogen-activated protein (MAP) kinase pathway mutation, or no detectable mutation, or testing not available;

OR

- IV. Unresectable or metastatic cutaneous melanoma (Label, NCCN 1, 2A):
 - A. Individual is using in combination with trametinib for disease with BRAF V600E or V600K mutation; **OR**
 - B. Individual is using in combination with trametinib *and* has BRAF V600 activating mutation with test results confirmed; **AND**
 1. Using as first line subsequent therapy for disease progression (NCCN 1, 2A); **OR**
 2. Using in re-induction therapy with disease control, but experiences disease progression/relapse > 3 months after treatment discontinuation (NCCN 2A);

OR

C. Individual is using as monotherapy for disease with BRAF V600E mutation;

OR

V. Cutaneous Melanoma (Label, NCCN 1, 2A):

- A. Individual is using as adjuvant treatment; **AND**
- B. Individual is using in combination with trametinib; **AND**
- C. Individual has BRAF V600E or V600K mutations; **AND**
- D. Individual has disease involvement of lymph node(s), following complete resection or wide excision;

OR

VI. Locally advanced or metastatic anaplastic thyroid cancer (ATC):

- A. Individual is using in combination with trametinib; **AND**
- B. Individual has BRAF V600E mutation; **AND**
- C. Individual has no satisfactory locoregional treatment options;

OR

V. Recurrent or metastatic Thyroid Carcinoma (Follicular, Papillary, or Hurthle Cell) (NCCN 2A); **AND**

- A. Individual has progressive and/or symptomatic disease that is not amenable to radioactive iodine (RAI) therapy; **AND**
- B. Individual has BRAF-positive disease;

OR

VI. Metastatic Non-Small Cell Lung Cancer (NSCLC) (NCCN 2A):

- A. Individual is using in combination with trametinib for disease with BRAF V600E mutation; **OR**
- B. Individual is using for disease with BRAF V600E mutation, as a single agent if the combination of dabrafenib plus trametinib is not tolerated (NCCN 2A);

OR

VII. Central Nervous System (CNS) cancers (NCCN 2A):

- A. Individual is using in combination with trametinib for one of the following:
 - 1. Individual has a primary diagnosis of melanoma, and disease has metastasized to the brain; **OR**
 - 2. Individual is using for Adult Circumscribed Glioma; **OR**
 - 3. Individual is using for recurrent or progressive Adult Glioma Glioblastoma; **OR**
 - 4. Individual is using for primary CNS cancer; **OR**
 - 5. Individual has relapsed or refractory pediatric diffuse high-grade gliomas;

AND

- B. Individual has BRAF V600E mutation;

OR

VIII. Unresectable or metastatic solid tumors (Label, NCCN 2A); **AND**

- A. Individual is 1 years of age and older; **AND**
- B. Individual is using in combination with trametinib; **AND**

- C. Individual has progressed following prior treatment and has no satisfactory alternative treatment options; **AND**
- D. Individual has BRAF V600E mutation;

OR

- IX. Low-grade glioma (LGG) (Label):
 - A. Individual is 1 years of age and older; **AND**
 - B. Individual is using in combination with trametinib; **AND**
 - C. Individual requires systemic therapy; **AND**
 - D. Individual has BRAF V600E mutation.

Tafinlar (dabrafenib) may not be approved for the following:

- I. Individual with wild-type BRAF melanoma, wild-type BRAF NSCLC, wild-type BRAF ATC, or any other wild-type BRAF solid tumor; **OR**
- II. Individual with colorectal cancer.

Key References:

1. Brown NF, Carter T, Kitchen N, Mulholland P. Dabrafenib and trametinib in BRAFV600E mutated glioma. *CNS Oncol.* 2017;6(4):291-296. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6004887/pdf/cns-06-291.pdf>
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 19, 2021.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 1, 2021.
 - a. Ampullary Adenocarcinoma. V1.2023. Revised April 27, 2023.
 - b. Biliary Tract Cancers. V2.2023. Revised May 10, 2023.
 - c. Central Nervous System Cancers. V1.2023. Revised March 24, 2023.
 - d. Cutaneous Melanoma. V2.2023. Revised March 10, 2023.
 - e. Esophageal and Esophagogastric Junction Cancers. V2.2023. Revised March 10, 2023.
 - f. Gastric Cancer. V1.2023. Revised March 10, 2023.
 - g. Gastrointestinal Stromal Tumors. V1.2023. Revised March 13, 2023.

- h. Hepatobiliary Cancers. V1.2022. Revised March 29, 2022.
- i. Head and Neck Cancers. V2. 2023. Revised May 15, 2023.
- j. Histiocytic Neoplasms. V1.2022. Revised May 20, 2022.
- k. Neuroendocrine and Adrenal Tumors. V2. 2022. Revised December 21, 2022.
- l. Non-Small Cell Lung Cancer. V3.2023. Revised April 13, 2023.
- m. Ovarian Cancer. V2.2023. Revised June 2, 2023.
- n. Pancreatic Adenocarcinoma. V2.2023. Revised June 19, 2023.
- o. Pediatric Central Nervous System Cancers. V2.2023. Revised October 31, 2022.
- p. Thyroid Carcinoma. V2.2023. Revised May 18, 2023
- q. Uveal Melanoma. V2.2022. Revised April 5, 2022.
- r. Marks AM, Bindra RS, DiLuna ML, et al. Response to the BRAF/MEK inhibitors dabrafenib/trametinib in an adolescent with a BRAF V600E mutated anaplastic ganglioglioma intolerant to vemurafenib. *Pediatr Blood Cancer*. 2018;65(5):e26969.

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