

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 mutation;

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 BRAF V600E mutation;

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; **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 (Label, NCCN 2A) (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 Oncocytic 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 primary CNS cancer; **OR**

3. 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.
7. 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.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.