

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

\*FHK- Florida Healthy Kids

## 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:

- I. Individual has a diagnosis of one of the following:
  - A. Unresectable or metastatic melanoma;
 

**AND**

    1. Individual is using in combination with trametinib for disease with BRAF V600E or V600K mutation and results are confirmed; **OR**
    2. Individual is using in combination with trametinib AND has BRAF V600 activating mutation and results are confirmed; **AND**
      - a. Using in subsequent therapy for disease progression (NCCN 2A); **OR**
      - b. Using in re-induction therapy with disease control, but experiences disease progression/relapse > 3 months after treatment discontinuation (NCCN2A); **OR**
    3. Individual is using as monotherapy for disease with BRAF V600E mutation and results are confirmed;
  - B. Melanoma;
 

**AND**

    1. Individual is using as adjuvant treatment; **AND**
    2. Individual is using in combination with trametinib; **AND**
    3. Individual has BRAF V600E or V600K mutations and results are confirmed; **AND**
    4. Individual has disease involvement of lymph node(s), following complete resection;

**OR**

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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C. Locally advanced or metastatic anaplastic thyroid cancer (ATC);

**AND**

1. Individual has BRAF V600E mutation and results are confirmed; **AND**
2. Individual has no satisfactory locoregional treatment options; **AND**
3. Individual is using in combination with trametinib;

**OR**

D. Metastatic Non-Small Cell Lung Cancer (NSCLC);

**AND**

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

**OR**

E. Central Nervous System (CNS) cancers;

**AND**

1. Individual is using for recurrent disease for brain metastases if active against primary tumor (melanoma) (NCCN 2A).

**Note:** Tafinlar is not indicated for treatment of patients with wild-type BRAF melanoma, wild-type BRAF NSCLC, or wild-type BRAF ATC.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

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DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

The NCCN Drugs & Biologics Compendium (NCCN Compendium™) © 2018 National Comprehensive Cancer Network, Inc. Available at: [NCCN.org](http://NCCN.org). Updated periodically.

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