UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Tafinlar

Program	Prior Authorization/Notification
Medication	Tafinlar® (dabrafenib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania -CHIP, Rhode Island, South Carolina
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	3/2020
Effective Date	5/2020

1. Background:

Tafinlar® (dabrafenib) is a kinase inhibitor 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. Tafinlar is not indicated for treatment of patients with wild-type BRAF melanoma, wild-type BRAF non-small cell lung cancer (NSCLC), or wild-type BRAF anaplastic thyroid cancer (ATC).[1]

Tafinlar, in combination with Mekinist® (trametinib), is indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or BRAF V600K mutations as detected by an FDA-approved test and for the adjuvant treatment of melanoma with BRAF V600E or BRAF V600K mutations, as detected by an FDA-approved test, involving the lymph node(s), following complete resection. Tafinlar, in combination with Mekinist, is also indicated for the treatment of patients with metastatic NSCLC with BRAF V600E mutation as detected by an FDA-approved test and for the treatment of locally advanced or metastatic ATC with BRAF V600E mutation and with no satisfactory locoregional treatment options.[1]

The National Comprehensive Cancer Network (NCCN) also recommends use of Tafinlar in combination with Mekinist for the adjuvant treatment of ATC with BRAF V600E mutations following resection; as monotherapy for the treatment of follicular, Hürthle cell, and papillary thyroid carcinomas with a BRAF mutation; in combination with Mekinist for the treatment of recurrent, advanced, or metastatic NSCLC in patients with BRAF V600E mutation or as a single agent if the combination of Tafinlar and Mekinist is not tolerated; and in the treatment of central nervous system (CNS) cancer in patients with melanoma.[2]

Information on FDA-approved tests for the detection of BRAF V600 mutations in melanoma may be found at: http://www.fda.gov/CompanionDiagnostics.[1]

2. Coverage Criteria:

A. Melanoma

1. Initial Authorization

a. **Tafinlar** will be approved based on **both** of the following criteria:

(1) **One** of the following:

(a) Unresectable melanoma
(b) Metastatic melanoma
(c) **Both** of the following:

i. Prescribed as adjuvant therapy for melanoma involving the lymph node(s)

-AND-

ii. Used in combination with Mekinist (trametinib)

-AND-

(2) Cancer is positive for BRAF V600 mutation

Authorization will be issued for 12 months.

2. Reauthorization

a. **Tafinlar** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Tafinlar therapy

Authorization will be issued for 12 months.

B. Central Nervous System (CNS) Cancers

1. Initial Authorization

a. **Tafinlar** will be approved based on **all** of the following criteria:

(1) Patient has metastatic brain lesions

-AND-

(2) Tafinlar is active against primary tumor (melanoma)

-AND-

(3) Used in combination with Mekinist (trametinib)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Tafinlar** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Tafinlar therapy

Authorization will be issued for 12 months.

C. Non-Small Cell Lung Cancer (NSCLC)

1. Initial Authorization

a. **Tafinlar** will be approved based on **all** the following:

(1) Diagnosis of non-small cell lung cancer (NSCLC)

-AND-

(2) Disease is **one** of the following:

(a) Metastatic
(b) Advanced
(c) Recurrent

-AND-

(3) Cancer is positive for BRAF V600E mutation

-AND-

(4) **One** of the following:

(a) Used in combination with Mekinist (trametinib)
(b) Used as a single agent if the combination of Mekinist and Tafinlar is not tolerated

Authorization will be issued for 12 months.

2. Reauthorization

a. **Tafinlar** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Tafinlar therapy

Authorization will be issued for 12 months.

D. Thyroid Cancer

1. **Initial Authorization**

a. **Tafinlar** will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Diagnosis of anaplastic thyroid cancer (ATC)

-AND-

(b) Cancer is positive for BRAF V600E mutation

-AND-

(c) Used in combination with Mekinist (trametinib)

-AND-

(d) **One** of the following:

i. Disease is **one** of the following:

1. Metastatic
2. Locally advanced
3. Unresectable

-OR-

ii. Prescribed as adjuvant therapy following resection

-OR-

(2) **All** of the following:

(a) **One** of the following diagnoses:

i. Follicular carcinoma
ii. Hürthle cell carcinoma
iii. Papillary carcinoma

-AND-

(b) **One** of the following:

i. Unresectable locoregional recurrent disease
ii. Persistent disease
iii. Metastatic disease

-AND-

(c) **One** of the following:

i. Patient has symptomatic disease
ii. Patient has progressive disease

-AND-

(d) Disease is refractory to radioactive iodine treatment

-AND-

(e) Cancer is positive for BRAF V600 mutation

Authorization will be issued for 12 months.

2. Reauthorization

a. **Tafinlar** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Tafinlar therapy

Authorization will be issued for 12 months.

E. NCCN Recommended Regimens

1. Initial Authorization

a. **Tafinlar** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics

Compendium.

Authorization will be issued for 12 months.

2. <u>Reauthorization</u>

a. **Tafinlar** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Tafinlar therapy

Authorization will be issued for 12 months.

3. References:

1. Tafinlar [package insert]. Research Triangle Park, NC: GlaxoSmithKline; October 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed January 30, 2020.

Program	Prior Authorization - Tafinlar (dabrafenib)
Change Control	
Date	Change
5/2016	New program.
3/2017	Annual review. Updated reference and policy template.
3/2018	Updated background information to include new indication in NSCLC with BRAF V600E mutation. Updated criteria to include NCCN recommendation of adjuvant treatment in combination with Mekinist in stage III disease. Added NCCN recommended review criteria. Updated references.
3/2019	Updated background information to include new indications for the adjuvant treatment of melanoma with BRAF V600 mutation. Updated background and criteria to include new indication for ATC and NCCN recommendation for thyroid cancer. Updated references.
3/2020	Annual review. Updated references.