UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1103-10
Program	Prior Authorization/Notification
Medication	Tafinlar® (dabrafenib)
P&T Approval Date	7/2013, 2/2014, 5/2014, 5/2015, 5/2016, 3/2017, 3/2018, 3/2019, 3/2020, 3/2021
Effective Date	6/1/2021; Oxford only: 6/1/2021

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; and as monotherapy for the treatment of follicular, Hürthle cell, and papillary thyroid carcinomas with a BRAF mutation; in combination with Mekinist for the treatment for recurrent, advanced, or metastatic NSCLC in patients with BRAF V600E mutation, or as 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]

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other

Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria:

A. Patients less than 19 years of age

1. Tafinlar will be approved based on the following criterion:

a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. 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.

C. Central Nervous System (CNS) Cancers

1. Initial Authorization

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

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

(a) **Both** of the following:

i. Patient has metastatic brain lesions

-AND-

ii. Tafinlar is active against primary tumor (melanoma)

-OR-

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

i. Patient has **one** of the following:
- Pilocytic astrocytoma
- Pleomorphic xanthoastrocytoma (PXA)
- Ganglioglioma

-AND-

ii. Incomplete resection, biopsy, or surgically inaccessible location

-AND-

(2) Cancer is positive for BRAF V600E mutation

-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.

D. Non-Small Cell Lung Cancer (NSCLC)

1. Initial Authorization

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

(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) In combination with Mekinist (trametinib)

(b) As 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.

E. 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 diagnosis:

            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.

F. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Tafinlar [package insert]. Research Triangle Park, NC: GlaxoSmithKline; April 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed January 25, 2021.

Program	Prior Authorization/Notification - Tafinlar (dabrafenib)
Change Control	
7/2013	New criteria for Tafinlar which was approved 5/29/2013.
2/2014	Updated approval for combination therapy with Mekinist.
5/2014	Auto-update to get on cycle.
5/2015	Annual review. Updated coverage criteria and background with NCCN melanoma recommendation. Added criteria for CNS cancer and NSCLC. Updated references. Increased authorization from 5 months to 12 months.
5/2016	Annual review with no change to clinical criteria. Updated background and references.
3/2017	Annual review, changed member to patient, with no changes to coverage criteria. Updated reference.
3/2018	Annual review. 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. Updated references.
3/2019	Annual review. 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. Added general NCCN recommendations for use criteria. Updated references.
3/2021	Annual review. Updated coverage criteria for CNS cancer based on NCCN recommendations. Updated references.