UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Tafinlar

Program	Prior Authorization/Notification
Medication	Tafinlar® (dabrafenib)
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	3/2018
Effective Date	5/2018

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.[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 and in patients with metastatic non-small cell lung cancer (NSCLC) with BRAFV600E mutation as detected by an FDA-approved test.[1]

The National Comprehensive Cancer Network (NCCN) also recommends use of Tafinlar in combination with Mekinist for the adjuvant treatment of stage III melanoma with BRAF V600 mutations; and as monotherapy in the treatment of central nervous system (CNS) cancer where Tafinlar is active against the primary tumor.[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 stage III melanoma

-AND-

ii. Used in combination with Mekinist (trametinib)

-AND-

(2) Cancer is BRAF V600 mutant type (MT)

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 [off-label]

1. Initial Authorization

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

(1) Metastatic brain lesions that are recurrent

-AND-

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

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 **both** the following:

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

-AND-

(2) Cancer is positive for BRAF V600E 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.

D. 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. Reauthorization

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; June 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed January 12, 2018.

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.