Commercial/Healthcare Exchange PA Criteria

Effective: November 2, 2016

Prior Authorization: Tafinlar

Products Affected: Tafinlar (dabrafenib) oral capsules

Medication Description:
Dabrafenib selectively inhibits some mutated forms of the protein kinase B-raf (BRAF). BRAF V600 mutations result in constitutive activation of the BRAF pathway; through BRAF inhibition, dabrafenib inhibits tumor cell growth. The combination of dabrafenib and trametinib allows for greater inhibition of the MAPK pathway, resulting in BRAF V600 melanoma cell death. Dabrafenib plus trametinib has been reported to synergistically inhibit cell growth in lung cancer cell lines which are BRAF V600E-mutant.

Covered Uses:

1. **Malignant melanoma, unresectable or metastatic with BRAF V600E mutation.**
2. **Malignant melanoma, unresectable or metastatic with BRAF V600E or V600K mutation, in combination with Mekinist.**
3. **Metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation.**
4. **Locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAFV600E mutation.**

Exclusion Criteria:

Tafinlar has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval in the following circumstances.

1. Resectable malignant melanoma
2. Wild-type BRAF melanoma
3. Wild-type BRAF NSCLC
4. Wild-type BRAF ATC
5. Malignant melanoma with BRAF mutations other than V600E or V600K

Required Medical Information:

1. Diagnosis
2. BRAF V600E or V600K mutation as detected by an FDA-approved test
3. Previous therapies tried
4. Dose and frequency

Age Restrictions: None

Prescriber Restrictions: None

Coverage Duration:
Initial: 12 months
Continuation: 3 years

Other Criteria:

1. Malignant melanoma, unresectable or metastatic. Approve if the patient meets the following critieria:
a. Patient has a diagnosis of melanoma; AND
b. Patient has disease that is unresectable or metastatic; AND
c. Patient has BRAF V600E mutation and receiving Tafinlar as monotherapy; OR
D.Patient has BRAF V600E or V600K mutation and receivng Tafinlar in combination with Mekinist.

2. Non-Small Cell Lung Cancer (NSCLC). Approve if the patient meets the following critieria:
a. Tafinlar (dabrafenib) is being used as a single agent or in combination with Mekinist(trametinib) as first line or subsequent therapy for recurrent or metastatic BRAF V600Emutation-positive NSCLC.

3. Thyroid Cancer. Approve if the patient meets the following critieria:
a. Patient has locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options.

References:

1. Tafinlar [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2016.
2. The NCCN Melanoma Clinical Practice Guidelines in Oncology (Version 3.2016). © 2015 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 19, 2016

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	9/13/2016

2	Update	Updates to match indications CCI Adopted EH Criteria, Removed Tafinlar from CCI "Oncology" Policy	ALL	3/7/19
3	Update	Added continuation coverage duration of 3 years	Coverage Duration	7/1/2019