Generic Name: Dabrafenib

Therapeutic Class or Brand Name: Tafinlar®

Applicable Drugs (if Therapeutic Class)**:** Kinase Inhibitor

Date of Origin: 5/18/2018 **Date Last Reviewed/Revised:** _____

GPI Code: 21532025100130

Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met)

I. Documented diagnosis of one of the following conditions A through D and must meet criteria listed under each applicable diagnosis

A. Unresectable or metastatic melanoma and criterion 1 and 2 are met:

1. Documentation of BRAF V600E mutation as detected by an FDA approved test.
2. Tafinlar® will be used as a single agent

B. Unresectable or metastatic melanoma and criterion 1 and 2 are met:

1. Documentation of BRAF V600E or V600K mutations as detected by an FDA approved test.
2. Tafinlar® will be used in combination with Mekinist® (trametinib)

C. Melanoma with lymph node involvement following complete resection and criterion 1 and 2 are met:

1. Documentation of BRAF V600E or V600K mutations as detected by an FDA approved test
2. Tafinlar® will be used in combination with trametinib

D. Non-small cell lung cancer (NSCLC) and criterion 1 and 2 are met:

1. Documentation of BRAF V600E mutation as detected by an FDA approved test
2. Tafinlar® will be used in combination with trametinib

E. Locally advanced or metastatic anaplastic thyroid cancer (ATC) and criterion 1 and 2 are met:

1. Documentation of BRAF V600E mutation as detected by and FDA approved test
2. Documentation that there are no satisfactory locoregional treatment options
3. Tafinlar® will be used in combination with trametinib

II. Minimum age requirement: 18 years old

III. Prescribing physician is an oncologist

Exclusion Criteria:

- Not indicated for treatment of wild-type BRAF melanoma, wild-type BRAF NSCLC or wild type BRAF ATC

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- Unresectable or metastatic melanoma -150 mg twice per day (60 caps/30 days)
- Adjuvant treatment of melanoma- 150 mg twice per day (60 caps/30 days)for up to 1 year
- NSCLC and ATC- 150 mg twice per day (60 caps/30 days)

Approval Length:

- **Authorization:** 6 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and the medication is effective. *Please note:* for adjuvant treatment of melanoma Tafinlar® is only indicated to be given up to 1 year.

Appendix:

N/A

References:

1. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/tafinlar.pdf.
2. Medi-span
3. https://www.premera.com/medicalpolicies/5.01.534.pdf
4. https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summaries/dru308reg.pdf.