MEDICATION POLICY:

Tafinlar®

Generic Name: Dabrafenib

Therapeutic Class or Brand Name: Tafinlar

Applicable Drugs (if Therapeutic Class): Kinase Inhibitor

GPI Code: 21532025100130

Preferred: N/A

Non-preferred: N/A

Date of Origin: 5/18/2018

Date Last Reviewed / Revised: 11/8/2020

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 E 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.nccn.org/