I. Medication Description

Tafinlar is a kinase inhibitor that has activity against some mutated forms of BRAF kinases including BRAF V600E, BRAF V600K, and BRAF V600D in melanoma cells.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for all requests.

III. Policy

Coverage of Tafinlar is available when the following criteria have been met:

- Member is at least 18 years of age AND
- The medication is prescribed by a hematologist/oncologist AND
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Coverage is provided for up to 120 capsules per each 30 days of either the 50mg or 75mg capsules.

V. Coverage Duration

Coverage is granted for 6 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression AND
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

- Available as 50mg and 75mg oral capsules

VIII. Summary of Policy Changes

- 9/15/13: New policy
• 4/15/14: Policy updated to include combination therapy with trametinib, CNS cancers and NSCLC
• 9/15/14: updated criteria for brain metastases
• 7/1/15: formulary distinctions made
• 12/15/15: no policy changes
• 9/15/16: no policy changes
• 10/16/17: coverage criteria updated to allow use as supported by current NCCN guidelines
• 11/1/18: no policy changes
• 11/15/19: no policy changes

IX. References

6. Cebon, et al. Comparison of BRAF inhibitor (BRAFi)-induced cutaneous squamous cell carcinoma (pts) (cuSCC) and secondary malignancies in BRAF mutation-positive metastatic melanoma (MM) in Patients treated with dabrafenib (D) as monotherapy or in combination with MEK 1/2 inhibitor (MEKi) trametinib (T). J Clin Oncol 31, 2013 (suppl; abstr 9016).

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.