Prior Authorization Approval Criteria

Tafinlar (dabrafenib)

Generic name: dabrafenib
Brand name: Tafinlar
Medication class: kinase inhibitor

FDA-approved uses: As a single agent: treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA approved test; In combination with trametinib: treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutation as detected by an FDA approved test

Available dosage forms: Capsules: 50mg, 75mg
Usual dose: 150mg orally twice daily.
Approximate monthly cost: $9,120.00/month (based on AWP 2013)

Criteria for use (bullet points below are all inclusive unless otherwise noted):
- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Must be prescribed by an oncologist.
- Must be clinically diagnosed with unresectable or metastatic melanoma.
- The presence of BRAF V600E or V600K mutation in tumor specimens must be confirmed by an FDA approved test.
- If patient has V600K mutation, must be used in combination with trametinib

Criteria for continuation of therapy:
- Patient is tolerating and responding to medication and there continues to be a medical need for the medication

Contraindication:
- none

Not approved if:
- patient has wild-type BRAF melanoma

Authorization Approval Duration:
- 6 months

Fallon Health Pharmacy and Therapeutics Committee approval: ________________________________

The criteria listed above applies to Fallon Health Plan and its subsidiaries.
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