Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

TAFLINAR® (dabrafenib)

GPI CODING:

215320251001**

DESCRIPTION:

Tafinlar (dabrafenib) is indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF melanoma.

APPROVAL DURATION:

Initial approvals and renewals: 12 months

CRITERIA FOR TAFLINAR

I. Patient has a diagnosis of unresectable or metastatic melanoma **AND**
I. Patient has positive BRAF-V600E mutation documented by an FDA-approved test (THxID-BRAF Kit) or Clinical Laboratory Improvement Amendments (CLIA)-approved facility **AND**
II. Tafinlar is being used as monotherapy

OR

III. Off label uses for oncology drugs if considered medically acceptable in one or more of the following compendia (i.e., Micromedex DrugDex, AHFS, Clinical Pharmacology, and NCCN.) *A use is identified by a compendium as medically accepted if the:*
   A. Indication is a Category 1 or 2A in NCCN,
   B. Indication is a Class I, Class IIa or Class IIb in DrugDex,
   C. Narrative text in AHFS or Clinical Pharmacology is supportive; or
   D. The use is supported by clinical research in 2 or more peer-reviewed medical journals

Authorization for continued use shall be reviewed at least every 12 months to confirm that the patient has experienced an objective response to therapy.