Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

ZELBORAF™ (vemurafenib)

GPI CODING:

215320800003**

DESCRIPTION:

Zelboraf™ (vemurafenib) exerts its effects by inhibiting the BRAF serine-threonine kinase protein. The BRAF protein plays a role in various cellular signaling pathways which affect cell proliferation, differentiation and secretion. Certain mutations in the BRAF gene, one of which is known as BRAF V600E, result in continuously active BRAF proteins which can cause cell proliferation in the absence of growth factors and can lead to tumor formation. Vemurafenib is Food and Drug Administration (FDA)-approved for the treatment of patients with unresectable or metastatic melanoma with BRAF-V600E mutation as detected by an FDA-approved test. The current test is known as the cobas® 4800 BRAF V600 Mutation Test. It is intended to be used as an aid in selecting melanoma patients who could potentially be candidates for vemurafenib.

APPROVAL DURATION:

Quantity limit: 240 tablets per 30 days
Initial approvals and renewals: 12 months

CRITERIA FOR ZELBORAF

I. Patient is ≥18 years of age **AND**
II. Patient has a diagnosis of unresectable or metastatic melanoma **AND**
III. Patient has positive BRAF-V600E mutation documented by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility **AND**
IV. Zelboraf will be used as monotherapy **AND**
V. Patient has tried and is intolerant to treatment with Tafinlar®

OR

VI. 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.