Commercial/Healthcare Exchange PA Criteria

Effective: August 2016

Prior Authorization: Zelboraf

Products Affected: Zelboraf (vemurafenib) oral tablets

Medication Description:
Zelboraf is a kinase inhibitor indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E mutation as detected by a Food and Drug Administration (FDA)-approved test. Zelboraf is not recommended in patients with wild-type BRAF melanoma. Zelboraf inhibits some mutated forms of BRAF serine-threonine kinase, including BRAF V600E. Some mutations in the BRAF gene, including V600E, result in constitutively activated BRAF proteins, which can cause cell proliferation in the absence of growth factors that would normally be required for proliferations. Zelboraf has displayed antitumor effects in cellular and animal models of melanomas with mutated BRAF V600E.

Covered Uses:
1. Treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.
2. Treatment of patients with Erdheim-Chester Disease (ECD) with BRAF V600 mutation.

Exclusion Criteria:
1. Unresectable or Metastatic Melanoma: Patients with wild-type BRAF melanoma

Required Medical Information:
1. Diagnosis
2. BRAF mutation status as detected by an FDA-approved test

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, an oncologist.

Coverage Duration: 3 years

Other Criteria:

Malignant Melanoma
A. Patient has a diagnosis of metastatic or unresectable melanoma; **AND**
B. Patient has the BRAF V600E mutation as detected by an FDA-approved test

Erdheim-Chester Disease
A. Patient has a diagnosis of Erdheim-Chester Disease (ECD); AND
B. Patient has the BRAF V600E mutation.

References:

1. Zelboraf [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; June 2016.
2. The NCCN Melanoma Clinical Practice Guidelines in Oncology (Version 2.2016). National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on June 7, 2016.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	6/7/2016
2	Update	Removed from CCI Oncology policy and adopted EmblemHealth (parent company) Zelboraf PA Policy Added Erdheim-Chester Disease (ECD) indication/criteria to match FDA label Added age restriction Added diagnosis in required medical information Removed dose and frequency & Prior therapies tried and failed from Required medical information Updated exclusion criteria to:Unresectable or Metastatic Melanoma: Patients with wild-type BRAF melanoma	All	8/4/2020