UnitedHealthcare Community Plan

Clinical Pharmacy Program Guideline for Zelboraf

Program	Prior Authorization
Medication	Zelboraf (vemurafenib)
Pharmacy & Therapeutics Approval Date	8/2012, 7/2013, 5/2014, 5/2015, 5/2016
Effective Date	11/1/2016

1. Background:

Zelboraf (vemurafenib) is a kinase inhibitor indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.[1] The National Cancer Comprehensive Network (NCCN) Melanoma guidelines recommends use of Zelboraf for treatment of melanoma in patients with BRAF V600 mutation.[2,3] NCCN also recommends use of Zelboraf in central nervous system (CNS) cancer, hairy cell leukemia, and non-small cell lung cancer (NSCLC).[2,3] Zelboraf is not recommended for use in patients with wild-type BRAF melanoma.[1]

Information on FDA-approved tests for the detection of BRAF V600 mutations in melanoma may be found at: http://www.fda.gov/CompanionDiagnostics.[1]

2. Coverage Criteria:

A. Melanoma

1. Initial Authorization

a. Zelboraf will be approved based on **both** of the following criteria:

(1) One of the following diagnoses:

(a) Unresectable melanoma

(b) Metastatic melanoma

-AND-

(2) Patient is positive for BRAFV600 mutation

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Zelboraf will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Zelboraf therapy

Authorization will be issued for 12 months.

B. Central Nervous System (CNS) Cancers [off-label]

1. **Initial Authorization**

a. Zelboraf will be approved based on the following diagnosis:

(1) Metastatic brain lesions that are recurrent

-AND-

(2) Zelboraf is active against primary tumor (melanoma)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Zelboraf will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Zelboraf therapy

Authorization will be issued for 12 months.

C. Non-Hodgkin Lymphoma (NHL) [off-label]

1. **Initial Authorization**

a. Zelboraf will be approved based on the following diagnosis:

(1) Diagnosis of hairy cell leukemia

Authorization will be issued for 12 months.

2. Reauthorization

a. Zelboraf will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Zelboraf therapy

Authorization will be issued for 12 months.

D. Non-Small Cell Lung Cancer (NSCLC) [off-label]

1. Initial Authorization

a. Zelboraf will be approved based on **both** the following:

(1) Diagnosis of non-small cell lung cancer (NSCLC)

-AND-

(2) Cancer is positive for BRAF V600E mutation

Authorization will be issued for 12 months.

2. Reauthorization

a. Zelboraf will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Zelboraf therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

Supply limits may be in place.

4. References:

1. Zelboraf [package insert]. South San Francisco, CA: Genentech, Inc.; August 2015.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed March 28, 2016.
3. The NCCN Drugs and Biologics Guidelines (NCCN Guidelines™). Available at www.nccn.org. Accessed. March 28, 2016.

Program	Prior Authorization –Zelboraf
Change Control	
Date	Change
9/2013	New guideline.
5/2016	Updated policy to new template. Updated clinical criteria to align with E&I notification except less than 19 criteria.