UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Zelboraf

Program	Prior Authorization
Medication	Zelboraf (vemurafenib)
Issue Date	8/2012
Pharmacy and Therapeutics Approval Date	3/2018
Effective Date	5/2018

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] It is also indicated for the treatment of patients with Erdheim-Chester Disease with BRAF V600 mutation.

The National Cancer Comprehensive Network (NCCN) guidelines recommends use of Zelboraf in central nervous system (CNS) cancer, hairy cell leukemia, non-small cell lung cancer (NSCLC), colon, rectal, and thyroid cancer when cancer is positive BRAF V600 mutation.[2] 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.

E. Erdheim-Chester Disease

1. Initial Authorization

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

(1) Diagnosis of Erdheim-Chester Disease

-AND-

(2) Cancer is positive for BRAF V600 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.

F. Colon Cancer [off-label]

1. Initial Authorization

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

(1) Diagnosis of colon cancer

-AND-

(2) Cancer is positive for BRAF V600E mutation

-AND-

(3) **One** of the following:

(a) Unresectable or advanced disease
(b) Metastatic disease

-AND-

(4) **Both** of the following:

(a) Used in combination with irinotecan

-AND-

(b) Used in combination with **one** of the following:

i. Erbitux (cetuximab)
ii. Vectibux (panitumumab)

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.

G. Rectal Cancer [off-label]

1. Initial Authorization

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

(1) Diagnosis of rectal cancer

-AND-

(2) Cancer is positive for BRAF V600E mutation

-AND-

(3) **One** of the following:

(a) Unresectable or advanced disease
(b) Metastatic disease

-AND-

(4) **Both** of the following:

(a) Used in combination with irinotecan

-AND-

(b) Used in combination with **one** of the following:

i. Erbitux (cetuximab)
ii. Vectibux (panitumumab)

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.

H. Thyroid Cancer [off-label]

1. Initial Authorization

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

(1) Diagnosis of **one** of the following:

(a) Follicular carcinoma
(b) Hürthle cell carcinoma
(c) Papillary carcinoma

-AND-

(2) **One** of the following:

(a) Unresectable or locally recurrent disease
(b) Metastatic disease
(c) Persistent locoregional disease

-AND-

(3) **One** of the following:

(a) Patient has symptomatic disease
(b) Patient has progressive disease

-AND-

(4) Disease is refractory to radioactive iodine

-AND-

(5) Cancer is positive for BRAF V600 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.

I. NCCN Recommended Regimens

1. Initial Authorization

a. **Zelboraf** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Zelboraf therapy

Authorization will be issued for 12 months.

3. References:

1. Zelboraf [package insert]. South San Francisco, CA: Genentech, Inc.; November 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed January 30, 2018.

Program	Prior Authorization –Zelboraf
Change Control	
Date	Change
5/2014	Annual review with no change to coverage.
5/2015	Annual review. Added criteria for CNS cancer and NSCLC. Updated background and references. Increased authorization to 12

	months.
5/2016	Annual review. Removed incompletely resected or recurrent from melanoma. Updated background and references.
5/2016	New program –align with Employer and Individual
3/2017	Annual review. Updated references and policy template.
3/2018	Updated background and criteria to include new indication for Erdheim-Chester Disease and NCCN recommended off-label use in BRAF mutation positive colon, rectal, and thyroid cancer. Added NCCN recommended regimens review criteria. Updated references.