

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X

Zelboraf (vemurafenib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Zelboraf (vemurafenib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Zelboraf (vemurafenib) may be approved if the following criteria are met:

Individual has a diagnosis of one of the following:

- I. Individual has unresectable or metastatic Melanoma (Label, NCCN 1, 2A); **AND**
 - A. Individual is using in combination with cobimetinib for disease with BRAF V600E or V600K mutation with test result confirmed;

OR

 - B. Individual is using in combination with cobimetinib *and* has a BRAF V600 activating mutation with test result confirmed; **AND**
 1. Using as first line, or subsequent therapy for disease progression; **OR**
 2. Using in re-induction therapy with disease control, but experiences disease progression/relapse > 3 months after treatment discontinuation;

OR

 - C. Individual is using as monotherapy for disease with BRAF V600E mutation with test result confirmed;

- OR**
- II. Recurrent, advanced, or metastatic Non-Small Cell Lung Cancer (NCCN 2A); **AND**
 - A. Individual is using as first-line therapy or as subsequent therapy (following progression on first-line therapy with a non-BRAF-targeted regimen); **AND**
 - B. Individual has a BRAF V600E mutation with test result confirmed; **AND**
 - C. Individual cannot tolerate the combination of dabrafenib plus trametinib;

- OR**
- III. Erdheim-Chester Disease; **AND**
 - A. Individual has BRAF V600 mutation with test result confirmed;

OR

- IV. Relapsed or refractory Hairy cell leukemia (NCCN 2A); **AND**

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- A. Individual is using as monotherapy; **OR**
- B. Individual is using in combination with rituximab (or rituximab biosimilars);

OR

- V. Recurrent or metastatic Thyroid Carcinoma (Follicular, Papillary, or Hurthle Cell) (NCCN 2A); **AND**
 - A. Individual has progressive and/or symptomatic disease that is not amenable to radioactive iodine (RAI) therapy; **AND**
 - B. Individual has BRAF-positive disease with test result confirmed;

OR

- VI. Central Nervous System Cancer (NCCN 2A); **AND**
 - A. Individual is using in combination with cobimetinib; **AND**
 - B. Individual is using as adjuvant therapy for primary CNS cancer; **AND**
 - C. Individual has BRAF V600E mutation with test result confirmed.

Zelboraf (vemurafenib) may **not** be used for the following:

- I. Individual is using for the treatment of wild-type BRAF melanoma.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 8, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Hyman DM, Puzanov I, Subbiah V, et al. Vemurafenib in Multiple Nonmelanoma Cancers with BRAF V600 Mutations [published correction appears in N Engl J Med. 2018 Oct 18;379(16):1585]. *N Engl J Med*. 2015;373(8):726-736. Available at <https://www.nejm.org/doi/pdf/10.1056/NEJMoa1502309?articleTools=true>
5. Kaley T, Touat M, Subbiah V, et al. BRAF Inhibition in BRAFV600-Mutant Gliomas: Results from the VE-BASKET Study. *J Clin Oncol*. 2018;36(35):3477-3484. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6286161/pdf/JCO.2018.78.9990.pdf>
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on February 26, 2020.
 - a. Central Nervous System Cancers. V2.2020. Revised April 30, 2020.
 - b. Cutaneous Melanoma. V3.2020. Revised May 18, 2020.
 - c. Hairy Cell Leukemia. V1.2020. Revised August 23, 2019.
 - d. Non-Small Cell Lung Cancer. V6.2020. Revised June 15, 2020.
 - e. Thyroid Carcinoma. V1.2020. Revised June 12, 2020.

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Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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