

**Generic Name:** Vemurafenib**Therapeutic Class or Brand Name:** Zelboraf**Applicable Drugs (if Therapeutic Class):** N/A**Preferred:** N/A**Non-preferred:** N/A**Date of Origin:** 2/1/2013**Date Last Reviewed / Revised:** 1/15/2024

## PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

- I. Documented diagnosis of one of the following conditions A through B and must meet criteria listed under applicable diagnosis:
  - A. Unresectable or metastatic melanoma and criterion 1 is met:
    1. Must provide documentation of a BRAF V600E mutation.
  - B. Erdheim-Chester Disease and criterion 1 is met:
    1. Must provide documentation of a BRAF V600 mutation.
- II. Minimum age requirement: 18 years old.
- III. Prescriber is an oncologist or hematologist.
- IV. Medication is prescribed in accordance with FDA labeling or current clinical practice guidelines
- V. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

## EXCLUSION CRITERIA

- Patients with wild-type BRAF melanoma.

## OTHER CRITERIA

- Use of Zelboraf with strong CYP3A4 inhibitors or inducers should be avoided. Exceptions may be made for higher doses (up to 300 tablets per 30 days) when concomitant use with CYP3A4 inducers (medications that decrease Zelboraf serum concentrations) cannot be avoided (i.e. phenytoin, carbamazepine, rifampin, etc.).

## QUANTITY / DAYS SUPPLY RESTRICTIONS

- 240 tablets per 30 days [see under Other Criteria for possible exceptions for higher doses (up to 300 tablets per 30 days)].

## APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

## APPENDIX

N/A

## REFERENCES

1. Swetter S, Johnson D, et, al., . Cutaneous Melanoma. Version 3.2023. Updated October 27, 2023.. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/cutaneous\\_melanoma.pdf](https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf).
2. Diamond EL, et. al., Consensus guidelines for the diagnosis and clinical management of Erdheim-Chester disease. Blood. 2014 Jul 24;124(4):483-92. doi: 10.1182/blood-2014-03-561381. Epub 2014 May 21. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/24850756>.
3. Zelboraf. Prescribing Information. Genentech; May 2020. Available at: [http://www.gene.com/download/pdf/zelboraf\\_prescribing.pdf](http://www.gene.com/download/pdf/zelboraf_prescribing.pdf).

**DISCLAIMER:** Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.