

## Vemurafenib (ZELBORAF) Criteria for Use March 2020

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at [www.pbm.va.gov](http://www.pbm.va.gov) or <http://vawww.pbm.va.gov> for further information.

### Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive vemurafenib.

- Uncorrectable electrolyte abnormalities, QTc  $\geq$ 500msec, or long QT syndrome
- Use of concomitant medications known to prolong QT interval
- Severe baseline hepatic impairment (Child-Pugh Class C) or severe renal impairment (creatinine clearance < 30 mL/min)
- Active or symptomatic brain metastases
- Pregnancy (i.e. known pregnancy or positive pregnancy test)
- Breastfeeding

### Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria.

- Care is provided by a VA/VA purchased care oncology provider
- Eastern Cooperative Oncology Group (ECOG) performance status 0-2
- Goals of care and role of Palliative Care consult have been discussed and documented
- Female patients of child-bearing potential: counseling provided on contraception during treatment and for 2 weeks after completing treatment and risks vs. benefits of treatment.

### Additional Inclusion Criteria

The answer to ONE of the following must be fulfilled in order to meet criteria:

- Unresectable or metastatic melanoma with BRAF V600E mutation
- In combination with cobimetinib for unresectable or metastatic melanoma with BRAF V600E mutation if patient cannot tolerate dabrafenib plus trametinib\*
- Erdheim-Chester Disease (ECD) with BRAF V600 mutation.

\*dabrafenib plus trametinib is the preferred BRAF + MEK inhibitor combination

Prepared: May 2013; Updated March 2020. Contact: Mark C. Geraci, Pharm.D., BCOP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services 10P4P

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