



Prior Authorization Approval Criteria

Zelboraf (vemurafenib)

Generic name:	Vemurafenib
Brand name:	Zelboraf
Medication class:	Antineoplastic; kinase inhibitor
FDA-approved uses:	Unresectable or metastatic melanoma with BRAFV600E mutation as detected with an FDA-approved test
Available dosage forms:	240mg film-coated tablet
Usual dose:	960mg twice daily
Approximate monthly cost: (based on AWP 2011)	\$5,600 per month
Duration of therapy:	Until disease progression or unacceptable toxicity occurs

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records
- Clinically diagnosed with unresectable or metastatic melanoma with BRAF mutation
- Patient received dermatologic evaluation before initiation
- Electrolytes and liver enzymes are assessed before treatment initiation
- 18 years of age or older
- Eastern Cooperative Oncology Group performance status of 0 or 1
- Approval will be for 3 months at a time

Criteria for continuation of therapy:

- Disease has not progressed
- Patient is able to tolerate therapy
- Electrolytes and liver enzymes are being assessed at least every 3 months

Caution:

- Cutaneous squamous cell carcinomas
- Liver laboratory abnormalities
- Photosensitivity
- QT prolongation
- Ophthalmologic reactions

Monitoring:

- Dermatological examinations every two months
- ECG and electrolytes at least every 3 months
- Liver enzymes and bilirubin monthly

Contraindication:

- Wild-type BRAF melanoma

Not approved if:

- Patient does not meet the above stated criteria
- Patient does not have BRAFV600E mutation

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 12/14/11