

Pharmacy

PRIOR AUTHORIZATION FORM

For Prior Authorization, please fax to: (877) 974-4411 toll free, or (616) 942-8206

This form applies to: Commercial Plan Medicaid Plan Medicare Plan

Zelboraf[®] (vemurafenib)

URGENT (life threatening)

Non-Urgent (standard review)

A claim involving "urgent care" applies when then standard review time will seriously jeopardize the life or health of the member, or subject the member to severe pain that cannot be managed without the care or treatment requested in the subject of this request. **Priority Health averages between 1 and 3 business days for our standard review response time.**

Member Information

Member Name:	Member No.:
DOB:	Gender:
Member's PCP:	

Provider Information

Provider Name:	
Office Contact Name:	Provider Phone:
Provider NPI:	Provider Fax:
Provider Address:	

Provider Signature

Date

PRODUCT INFORMATION

Zelboraf 240 mg tablets

Dose: 960 mg (4 tablets) twice daily

Start Date: _____

Note: Management of symptomatic adverse drug reactions may require dose reduction, treatment interruption, or treatment discontinuation of Zelboraf. Dose reductions resulting in a dose below 480 mg twice daily are not recommended. See Table 1 for dose medication information.

PRIORITY HEALTH PRECERTIFICATION DOCUMENTATION

Authorization for Zelboraf (vemurafenib) requires the following information to certify:

Authorization for Zelboraf[®] requires:

1. Diagnosis of unresectable or metastatic BRAF^{V600E} mutation-positive melanoma (confirmation of mutation detected using an FDA-approved test, such as the cobas[®] 4800 BRAF V600 Mutation Test).
2. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.
3. Baseline ECG, electrolytes (including potassium, magnesium, and calcium), liver enzymes (transaminases and alkaline phosphatase), and bilirubin baseline values are within clinically acceptable limits and will continued to be monitored throughout treatment.
4. Prescriber must communicate directly, face-to-face, with patient to provide both verbal and printed materials regarding the safety risks associated with the use of Zelboraf[®].

PRIORITY HEALTH PRECERTIFICATION DOCUMENTATION

Authorization for Zelboraf (vemurafenib) requires the following information to certify:

A. What is the patient's diagnosis?

- a. Unresectable or metastatic melanoma **ICD Code:** _____
- i. BRAF^{V600E} mutation-positive melanoma, *confirmed* by laboratory testing
- ii. wild-type disease (authorization will not be given)
- b. *Other:* _____
- Rationale for use:* _____

Note: Authorization for indications not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the drug's use for the identified indication.

B. What is the patient's ECOG performance status?

- 0: Fully active, able to carry on all pre-disease performance without restriction
- 1: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature (e.g. light house work, office work)
- 2: Ambulatory and capable of all self care but unable to carry out any work activities. Up and about more than 50% of waking hours.
- 3: Capable of only limited self care, confined to bed or chair more than 50% of waking hours
- 4: Completely disabled. Cannot carry on any self care. Totally confined to bed or chair.

C. Which of the following tests and laboratory results have been completed (or will be completed prior to start of therapy) and are within acceptable limits?

- a. Baseline **ECG and electrolytes**, including potassium, magnesium, and calcium
- i. Prescriber agrees to monitor patients ECG and electrolytes on day 15 after treatment initiation, monthly for the first 3 months following treatment initiation, followed by every 3 months thereafter, or more often if clinically necessary.
- ii. Zelboraf will be discontinued in patients with QTc > 500 ms.
- b. Baseline **liver enzymes** (transaminases and alkaline phosphatase) and **bilirubin**
- i. Prescriber agrees to monitor liver enzymes and bilirubin monthly following treatment initiation, or more often if clinically necessary.

D. Prescriber is familiar with the FDA labeling dose modification information for Zelboraf based on potential adverse events experienced by the patient during treatment (see Table 1)?

- a. Yes
- b. No (authorization will not be given)

E. Prescriber has communicated verbally with the patient through direct, face-to-face communication and has provided printed materials regarding the safety risks associated with the use of Zelboraf[®].

- a. Yes
- b. No (authorization will not be given)

FOR MEDICARE ONLY

If none of the above precertification criteria is applicable to this member, please check off which, if any, of the following apply:

1. All covered Part D drugs on any tier of a plan's formulary would not be as effective for the enrollee as the non-formulary drug, and/or would have adverse effects
2. The number of doses available under a dose restriction for the prescription drug:
 - a. Has been ineffective in the treatment of the enrollee's disease or medical condition, or
 - b. Based on sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.
3. The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements:
 - a. Has been ineffective in the treatment of the enrollee's disease or medical condition, or
 - b. Based on sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.
 - c. Has caused or, based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee.
4. None of the above apply

****If you selected 1, 2, or 3 above, supporting evidence/documentation is required for review. If no supporting evidence/documentation is provided, this request will not be approved.**

***** All fields must be complete and legible for Prior Authorization Review***
 Please fax this request to: (877)974-4411 toll free or (616)942-8206
 YOUR OFFICE WILL RECEIVE A RESPONSE VIA FAX**

Table 1. Dose Modification Information

Grade (CTC-AE) [†]	Recommended Zelboraf Dose Modification
Grade 1 or Grade 2 (tolerable)	Maintain Zelboraf at a dose of 960 mg daily.
Grade 2 (intolerable) or Grade 3	
1 st Appearance	Interrupt treatment until grade 0-1. Resume dosing at 720 mg twice daily.
2 nd Appearance	Interrupt treatment until grade 0-1. Resume dosing at 480 mg twice daily.
3 rd Appearance	Discontinue permanently
Grade 4	
1 st Appearance	Discontinue permanently or interrupt Zelboraf treatment until grade 0-1. Resume dosing at 480 mg twice daily.
2 nd Appearance	Discontinue permanently

[†] The intensity of clinical adverse events graded by the Common Terminology Criteria for Adverse Events v4.0 (CTC-AE)