Pharmacy Prior Authorization Form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: ☒ **Commercial (Traditional)** ☒ **Commercial (Individual/Optimized)** ☐ **Medicaid**

This request is: ☐ **Urgent** (life threatening) ☐ **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Zelboraf® (vemurafenib)

Member

Last Name: _____ First Name: _____

ID #: _____ DOB: _____ Gender: _____

Primary Care Physician: _____

Requesting Provider: _____ Prov. Phone: _____ Prov. Fax: _____

Provider Address: _____

Provider NPI: _____ Contact Name: _____

Provider Signature: _____ Date: _____

Product Information

☐ New request ☐ Continuation request

Drug product: ☐ Zelboraf 240 mg tablet

Start date (or date of next dose): _____

Date of last dose (if applicable): _____

Dosing frequency: _____

Oral oncology partial fill program

Each fill of Zelboraf is limited to a 14 day supply at any network pharmacy. Patients are responsible for applicable deductible and copayments.

Drug cost information

The wholesale acquisition cost for each Zelboraf tablet is $45.21. The annual cost of treatment with this drug is more than $65,100 each year.

Precertification Requirements

Patient must meet one of the following criteria:

1. Diagnosis of unresectable or metastatic BRAFV600E mutation-positive melanoma (Confirmation of mutation detected using an FDA-approved test, such as cobas® 4800 BRAFv600 Mutation Test), WITH
    a. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, AND
    b. Baseline ECG, electrolytes (i.e. potassium, magnesium, calcium), liver enzymes (i.e. transaminases and alkaline phosphatase), and bilirubin within clinically acceptable limits, AND
    c. Continued monitoring throughout treatment
2. Diagnosis of Erdheim-Chester Disease (ECD) with BRAF V600 mutation, WITH
    a. Symptomatic disease, OR
    b. Central nervous system (CNS) involvement, OR
    c. Evidence of organ dysfunction or impending organ dysfunction

All fields must be complete and legible for review. Your office will receive a response via fax.

Updated 12/2017
Last reviewed 03/2019

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

Priority Health Precertification Documentation

A. What condition is this drug being requested for?

- ☐ unresectable or metastatic melanoma
  - i. ☐ $BRAF^{V600E}$ mutation-positive melanoma confirmed by laboratory testing
  - ii. ☐ wild-type disease
- ☐ Erdheim-Chester Disease (ECD)
  - i. ☐ $BRAF^{V600}$ mutation-positive confirmed by laboratory testing
- ☐ *Other – the patient's condition is:* _____

Rationale for use: _____

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) and are within acceptable limits prior to starting Zelboraf?

- ☐ **Baseline ECG and electrolytes** (including potassium, magnesium, and calcium)
  (ECG and electrolytes should be checked on day 15 of Zelboraf treatment, monthly for the first 3 months following treatment initiation, and then every 3 months (or more often if clinically necessary)
- ☐ **Baseline liver enzymes and bilirubin**
  Liver enzymes and bilirubin should be checked monthly after Zelboraf is started (or more often if clinically necessary)

D. For patients with ECD, which of the following apply?

- ☐ Symptomatic disease
- ☐ Central nervous system (CNS) involvement
- ☐ Evidence of organ dysfunction or impending organ dysfunction

Additional information

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.

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	
1st Appearance	Interrupt treatment until grade 0-1. Resume dosing at 720 mg twice daily.
2nd Appearance	Interrupt treatment until grade 0-1. Resume dosing at 480 mg twice daily.
3rd Appearance	Discontinue permanently
Grade 4	
1st Appearance	Discontinue permanently or interrupt Zelboraf treatment until grade 0-1. Resume dosing at 480 mg twice daily.
2nd Appearance	Discontinue permanently

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

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