

# STATEMENT OF MEDICAL NECESSITY (SMN) for Genentech BioOncology® Access Solutions

Phone: (888) 249-4918 Fax: (877) 313-2659 Genentech-Access.com/BioOncology

Please note: ALL fields denoted with an asterisk (\*) are required fields.

## ORAL PRODUCTS

### SERVICES REQUESTED\* (check only those that apply)

- Benefits Investigation/Prior Authorization
- GATCF<sup>†</sup> Patient Assistance
- Appeals Support
- Co-pay Assistance

### PATIENT INFORMATION

Last name\*: \_\_\_\_\_ First name\*: \_\_\_\_\_  
Birth date\*: \_\_\_\_\_ Gender:  Male  Female  
Street: \_\_\_\_\_  
City: \_\_\_\_\_ State\*: \_\_\_\_\_ ZIP: \_\_\_\_\_  
Home phone: \_\_\_\_\_  
Work/cell phone: \_\_\_\_\_ Email: \_\_\_\_\_  
OK to contact patient?  Yes  No  
Pt. preferred language (if other than English): \_\_\_\_\_  
Alternate contact last name: \_\_\_\_\_  
First name: \_\_\_\_\_  
Relationship to patient: \_\_\_\_\_  
Alternate contact phone: \_\_\_\_\_

### INSURANCE INFORMATION

No insurance  
Is the patient pending Medicaid determination?  Yes  No  
Please attach a copy of the patient's insurance card.  
**Primary insurance (PI) name:** \_\_\_\_\_  
PI phone: \_\_\_\_\_  
PI subscriber name: \_\_\_\_\_  
PI subscriber ID #: \_\_\_\_\_  
Policy/group #: \_\_\_\_\_  
**Secondary insurance (SI) name:** \_\_\_\_\_  
SI phone: \_\_\_\_\_  
SI subscriber name: \_\_\_\_\_  
SI subscriber ID #: \_\_\_\_\_  
Policy/group #: \_\_\_\_\_

### PHARMACY PREFERENCE (Optional)

Specialty  Retail  Onsite dispensing pharmacy  
Pharmacy name: \_\_\_\_\_  
Phone: \_\_\_\_\_  
Contact person: \_\_\_\_\_

For Erivedge, Tarceva and ZELBORAF, unless the patient requests otherwise, the prescription will be directed to the authorized specialty pharmacy providing the lowest cost-sharing for the patient. If more than one specialty pharmacy is found, a specialty pharmacy will be selected for the patient based on uniformly applied selection criteria.

### PATIENT MEDICAL INFORMATION

Indicate patient's therapy (check all that apply)\*:

- Erivedge® (vismodegib)  Tarceva® (erlotinib)
- ZELBORAF® (vemurafenib)

Has treatment started?  Yes  No Date: \_\_\_\_\_  
Primary diagnosis code\*: \_\_\_\_\_

(required to the highest level of specificity)

Secondary diagnosis code: \_\_\_\_\_  
(required to the highest level of specificity)

Clinical TNM stage:

- 0  I  IIA  IIB  IIIA  IIIB  IIIC  IV

Line of therapy\*:

- First  Second  Other

Previous treatment:

- None  Hormone therapy  Radiation  
 Surgery  Other: \_\_\_\_\_

Chemotherapy (please specify): \_\_\_\_\_

### PRESCRIBER INFORMATION

Facility/practice name: \_\_\_\_\_  
Prescriber's last name\*: \_\_\_\_\_  
First name\*: \_\_\_\_\_  
Specialty:  Oncologist  Other (specify): \_\_\_\_\_  
Prescriber license #: \_\_\_\_\_  
Street\*: \_\_\_\_\_  
City\*: \_\_\_\_\_ State\*: \_\_\_\_\_ ZIP\*: \_\_\_\_\_  
Clinical/medical contact: \_\_\_\_\_  
Phone: \_\_\_\_\_ Fax: \_\_\_\_\_  
Reimbursement contact: \_\_\_\_\_  
Phone: \_\_\_\_\_ Fax: \_\_\_\_\_  
GATCF contact: \_\_\_\_\_  
Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

Billing information for:  Group  Individual

Tax ID #: \_\_\_\_\_  
NPI<sup>‡</sup>: \_\_\_\_\_  
PTAN<sup>§</sup>: \_\_\_\_\_  
State license #\*: \_\_\_\_\_  
DEA #: \_\_\_\_\_

### SHIPPING FOR GATCF

Shipping location:  Patient  Facility  Practice  
Shipping address same as address listed above?  Yes  No

If no, please complete the remainder of this section.

Facility/practice or patient name: \_\_\_\_\_  
DEA #: \_\_\_\_\_ License #: \_\_\_\_\_  
Street (street address required, no PO boxes): \_\_\_\_\_  
City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP: \_\_\_\_\_

Contact name: \_\_\_\_\_  
Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

\*Required field. Genentech BioOncology Access Solutions cannot process your SMN unless these fields are completed.

<sup>†</sup>Genentech® Access to Care Foundation. <sup>‡</sup>National Provider Identifier. <sup>§</sup>Provider Transaction Access Number.

**For Erivedge® (vismodegib) patients:**

Metastatic basal cell carcinoma?\*  Yes  No  
 Locally advanced basal cell carcinoma recurred following surgery or not candidate for surgery?\*  Yes  No  
 Locally advanced basal cell carcinoma not candidate for radiation?\*  Yes  No

**Erivedge prescription**

150 mg daily  Other: \_\_\_\_\_  
 Dispense: \_\_\_\_\_ -month supply Refill \_\_\_\_\_ times

**Erivedge Sure Start™ free starter supply**

150 mg daily  
 Dispense: 14-day supply Refill \_\_\_\_\_ times

**For Tarceva® (erlotinib) patients:**

First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test?  Yes  No  
 Maintenance treatment of patients with locally advanced or metastatic NSCLC whose disease has not progressed after 4 cycles of platinum-based first-line chemotherapy?  Yes  No  
 Treatment of patients with locally advanced or metastatic NSCLC after failure of at least 1 prior chemotherapy regimen?  Yes  No  
 First-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine?  Yes  No

**Tarceva prescription**

150 mg daily  100 mg daily  Other: \_\_\_\_\_ mg daily  
 Dispense: \_\_\_\_\_ -day supply Refill \_\_\_\_\_ times

**Tarceva Sure Start free starter supply**

150 mg daily  100 mg daily  
 Dispense: 15-day supply Refill \_\_\_\_\_ times

**For ZELBORAF® (vemurafenib) patients:**

Clinical TNM stage\*:  Metastatic melanoma/unresectable  Other  
 Confirmed positive for BRAF V600E?\*  Yes  No

**ZELBORAF prescription**

960 mg twice a day  Other: \_\_\_\_\_  
 Dispense: \_\_\_\_\_ -month supply Refill \_\_\_\_\_ times

**ZELBORAF Sure Start free starter supply**

960 mg twice a day  
 Dispense: 14-day supply Refill \_\_\_\_\_ times

**UNAPPROVED USE WARNING:** Please read the FDA-approved label for Genentech BioOncology® products before prescribing. If the indication for which you are prescribing Genentech BioOncology products is not listed in the label, you are prescribing the medication for an “unapproved” use. The fact that the use for which you are prescribing this medication is not listed in the FDA-approved label indicates that the FDA has not approved the efficacy, dosage amount or safety of this medication when used for such a use. Nevertheless, the Genentech® Access to Care Foundation (GATCF) will consider providing the medication for your patient with this admonition, based upon your medical order, within program requirements.

By signing below, I certify that (a) the above therapy is medically necessary, (b) I have received the necessary authorization to release the above-referenced information and other protected health information (as defined by the Health Insurance Portability and Accountability Act of 1996 [HIPAA]) to Genentech, Inc., Genentech BioOncology Access Solutions and contracted dispensing pharmacy or other contractors for the purpose of requesting reimbursement, assisting in initiating or continuing therapy and/or the evaluation of the patient's eligibility for GATCF related to Genentech BioOncology products, as a break in treatment would negatively impact the patient's therapeutic outcome and (c) I will not attempt to seek reimbursement for free product provided directly to the patient. I request Genentech BioOncology Access Solutions convey to the pharmacy chosen by the above-named patient the prescription described herein.

I agree to comply with the program guidelines as established by Genentech, Inc. and understand that GATCF, at its sole and absolute discretion, reserves the right to modify or discontinue the program at any time and to verify the accuracy of the information submitted.

If applying for GATCF, I certify that this patient has no medical insurance coverage or otherwise meets the financial criteria for the pharmaceutical identified above and is not eligible for other public health insurance programs.

Special Note: Prescribers in all states must follow applicable law for a valid prescription. For prescribers in states with official prescription form requirements, such as New York, please submit prescriptions on an official state prescription blank along with this form.

## INSTRUCTIONS FOR USE

- Use this form to enroll all insured and uninsured patients needing Genentech BioOncology® Access Solutions assistance
- Complete this form online via My Patient Solutions™, our online patient management tool. Visit [Genentech-Access.com/BioOncology](http://Genentech-Access.com/BioOncology) to register for My Patient Solutions

## SERVICES REQUESTED

- Check the appropriate services requested on behalf of the patient. Genentech BioOncology Access Solutions and/or GATCF cannot perform services without your specific request:
  - Check GATCF Patient Assistance if patient has no insurance. Patient may receive assistance through GATCF

## INSURANCE INFORMATION

- Please check the appropriate boxes to reflect the patient's insurance status

## PATIENT MEDICAL INFORMATION

- Check all therapies the patient is prescribed
- Indicate the appropriate diagnosis code(s). For dates of service prior to October 1, 2015, ICD-9-CM codes must be used. For dates of service on or after October 1, 2015, only ICD-10-CM codes will be accepted

## PRESCRIPTIONS

- Complete the prescription sections for all appropriate products

### Sure Start™ Free Starter Supply

- To request a starter supply of Erivedge® (vismodegib), Tarceva® (erlotinib) or ZELBORAF, please complete the Sure Start prescription on page 2 of this form
- Payers may not be billed for a starter supply of Erivedge, Tarceva or ZELBORAF
- For eligibility criteria, please visit [Genentech-Access.com/Erivedge](http://Genentech-Access.com/Erivedge), [Genentech-Access.com/Tarceva](http://Genentech-Access.com/Tarceva) or [Genentech-Access.com/ZELBORAF](http://Genentech-Access.com/ZELBORAF) and/or speak to your Erivedge Access Solutions, Tarceva Access Solutions or ZELBORAF Access Solutions Specialist

## SHIPPING FOR GATCF

- Indicate where you would like the product to be shipped if the patient meets the required medical and income criteria for GATCF

## PLEASE ATTACH THE FOLLOWING:

- A signed and dated Patient Authorization and Notice of Release of Information (PAN) form
- A front and back copy (enlarged and legible) of the patient's insurance card. For Tarceva patients, please provide a front and back copy of the patient's drug card
- If your claim or prior authorization submission has been denied, include a completed GATCF Insurance Attestation form. No further documentation is necessary

**PROVIDING ADDITIONAL DOCUMENTS OR INFORMATION WITH THIS FORM, OTHER THAN WHAT IS REQUESTED, WILL DELAY PROCESSING.**

**Reminder:** Genentech BioOncology Access Solutions cannot work with the insurance plan on your patient's behalf without a physician's signature and date, as well as a completed PAN form.

Tarceva® is a registered trademark of OSI Pharmaceuticals, LLC, an affiliate of Astellas Pharma US, Inc. Erivedge®, Genentech BioOncology®, its logo, ZELBORAF® and the Access Solutions logo are registered trademarks of Genentech, Inc.

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