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

BIONCOLOGY® | 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† 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.

*Required field. Genentech BioOncology Access Solutions cannot process your SMN unless these fields are completed.
†Genentech® Access to Care Foundation. ‡National Provider Identifier. §Provider Transaction Access Number.

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‡: _____

PTAN§: _____

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: _____

Print patient's name here

Patient last name*: _____ First name*: _____ Birth date*: _____

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.

Sign and date here

Prescriber's Signature*: _____ Date*: _____

(This form cannot be processed without an original signature.)

*Required field.

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 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, Genentech-Access.com/Tarceva or 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.

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