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

Phone: (888) 249-4918 **Fax:** (888) 249-4919 BioOncologyAccessSolutions.com

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

Genentech BIOONCOLOGY™ Access Solutions™ Treatment made possible.

Services Requested* (check all that apply)

☐ Benefits Investigation/Prior Authorization ☐ Appeals Support
☐ Co-pay Assistance ☐ GATCF† Patient Assistance
☐ GATCF Eligibility Screening

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
Alternate contact last name: ____
First name: ____
Relationship to patient: ____
Alternate contact phone: ____
Is patient deceased? ☐ Yes ☐ No

Insurance Information

☐ No insurance
Is the patient pending Medicaid determination? ☐ Yes ☐ No ☐ Pending
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 #: ____

Oral Oncologic Pharmacy Preference

☐ Specialty ☐ Retail ☐ Onsite pharmacy/Physician dispenser
Pharmacy name: ____
Phone: ____
Contact person: ____

Clinical Trial Patient

Clinical Trial Patient? ☐ Yes ☐ No
If Yes, study site: ____
Study #: ____
Clinical coordinator: ____
Phone: ____

*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.

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: ____

Billing information for: ☐ Group ☐ Individual
Tax ID #: ____
NPI‡ #: ____
PTAN§ #: ____
DEA #*: ____

Patient Medical Information

Indicate patient's therapy (check all that apply):
☐ AVASTIN® (bevacizumab) ☐ Herceptin® (trastuzumab)
☐ Rituxan® (rituximab) ☐ Tarceva® (erlotinib) ☐ XELODA® (capecitabine)
Has treatment started? ☐ Yes ☐ No Date: ____

Place of administration:
☐ Physician's office ☐ Hospital outpatient ☐ Hospital inpatient
Primary ICD-9-CM code*: ____ Description: ____
(required to the highest level of specificity)
Secondary ICD-9-CM code: ____ Description: ____
Date of diagnosis: ____

Clinical TNM stage:
☐ 0 ☐ I ☐ IIA ☐ IIB ☐ IIIA ☐ IIIB ☐ IIIC ☐ IV
Line of therapy **(required)**:
☐ First ☐ Second ☐ Other

Previous treatment:
☐ None ☐ Hormone therapy ☐ Radiation
☐ Surgery ☐ Other: ____
Chemotherapy (please specify): ____
Concurrent treatment prescribed with Genentech product (required): ____

If applicable, HER2 Positive? ☐ Yes ☐ No
Test results: FISH (ratio)____ IHC____ 1+ ____ 2+ ____ 3+ Other: ____
Adjuvant: ☐ Yes ☐ No

▶ For Rituxan Patients Only

Disease Characteristics:
☐ Indolent ☐ Aggressive ☐ CD20-positive

PATIENT

Last name*: ____________ First name*: ____________ Birth date*: ____________

PRESCRIPTION

▶ For Tarceva Patients Only

☐ 150-mg daily ☐ 100-mg daily ☐ Other: ____mg daily Dispense: 30-day supply Refill: ____ times

▶ For XELODA Patients Only

XELODA 500 mg:

Take _____ tablets _____ times per day for _____ days, then off for ____ days

SIG (Other): ____________

# of tablets per cycle: ____________ 500 mg

XELODA 150 mg:

Take ____ tablets ____ times per day for ____ days, then off for ____ days

SIG (Other): ____________

# of tablets per cycle: ____________ 150 mg

# of cycles per fill: ☐ 2 ☐ 3 Other: ___ **# of refills:** ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 Other: ___

Instructions for Use

- Use this form to enroll all insured and uninsured patients needing Genentech BioOncology Access Solutions assistance

Services Requested

- Check the appropriate services requested. Genentech BioOncology Access Solutions and/or GATCF cannot perform services without your specific authorization
  - Check GATCF Patient Assistance if patient has no insurance. Patient may receive assistance through GATCF
  - Check GATCF Eligibility Screening if you would like a pretreatment check against the GATCF medical and financial criteria for your *insured* patients
- Additional medical documents/information may be needed based on the services requested

Appeals

- The diagnosis, line of therapy and concurrent treatment prescribed with Genentech products is required to be completed

Insurance Information

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

Clinical Trial Patient

- Please complete if your patient is currently involved in a clinical trial

For Tarceva Patients Only

- Please complete the prescription information for Tarceva® (erlotinib)

For XELODA Patients Only

- Please complete the prescription information for XELODA® (capecitabine)

Shipping Instructions 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 copy of the denial letter

UNAPPROVED USE WARNING: Please read the FDA-approved label for Genentech BioOncology products before prescribing. If the indication for which you are prescribing a Genentech BioOncology product 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 the 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.**

Shipping Instructions for GATCF

Shipping location: ☐ Patient ☐ Facility

Shipping address same as address listed on page 1 of this form? ☐ 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: ____________

Certification Statements

- 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 seeking reimbursement, assisting in initiating or continuing therapy and/or the evaluation of the patient's eligibility for GATCF related to Genentech products as a break in treatment would negatively impact the patient's therapeutic outcome and (c) I appoint Genentech BioOncology Access Solutions solely to convey on my behalf to the pharmacy chosen by the above-named patient the prescription described herein
- I further certify that I will not attempt to seek reimbursement for free or replacement product provided directly to the patient or for the dates of service for which free or replacement product was provided
- 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. I further understand that Genentech will provide vial replacement in a configuration that will create the least amount of wastage.
- If applying for GATCF, I certify that this patient has no medical insurance coverage for the pharmaceutical identified above and is not eligible for other public health insurance programs

____________ ____________

Prescriber Signature* **Date***

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

*Required field.

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.

Genentech BIOONCOLOGY

Access Solutions™ Treatment made possible.

Rituxan® is a trademark of Biogen Idec, Inc. Tarceva® is a trademark of OSI Pharmaceuticals, Inc.
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