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.

Rituxan® is a trademark of Biogen Idec, Inc. Tarceva® is a trademark of OSI Pharmaceuticals, Inc.
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PATIENT AUTHORIZATION AND NOTICE OF RELEASE OF INFORMATION (PAN)

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

Genentech BioOncology Access Solutions is a free program for you from Genentech.

We work to help you pay for your Genentech product. We can help in many different ways. We assist people who have a health care plan as well as those who don't.

If you don't have a health care plan, or your plan won't pay for your Genentech products, we might be able to help. If you meet certain financial and medical standards, we can supply free medicine. This is done through the Genentech® Access to Care Foundation (GATCF).

For us to help, we need to look at, use and disclose your personal health information (PHI). Your doctor and health care plan may disclose your PHI to us only with your written consent. Once you sign this form and it is sent back to us, we can start to provide these services. We can provide you with a copy of this release. You need to ask us for this first before we can send the copy back to you.

You do not have to agree to this authorization. But we cannot provide our services without your consent. This means you might need to pay for certain medicines on your own.

PLEASE READ THROUGH THIS FORM CAREFULLY. IF YOU HAVE ANY QUESTIONS, TALK TO YOUR DOCTOR'S OFFICE OR CALL US AT THE PHONE NUMBER LISTED AT THE TOP OF THIS PAGE.

1. Information to Be Disclosed or Used

This signed form lets my doctors and health care plans send my PHI to Genentech BioOncology Access Solutions and/or GATCF. This includes:

- All my health records relating to my treatment
- Information about my health care plan benefits
- The dollar balance left on the total of the lifetime payments covered by my health care plan policy (if this applies to my plan)
- Any information having a bearing on my health or my adherence to my treatment

All of the above is considered part of my PHI. I know this could include information about:

- Sexually transmitted diseases
- Mental health conditions
- Genetic test results

We are not looking for this information. It might be part of the medical record sent to us.

2. Who May Disclose My PHI

My PHI may be released by my doctor. It may also be released by my health care plan or others who might hold my PHI.

3. Who May See My Personal Health Information (PHI)

My PHI may be seen by Genentech BioOncology Access Solutions and/or GATCF. These are programs sponsored by Genentech. Its address is 1 DNA Way, Mail Stop #858a, South San Francisco, CA 94080-4990. It may also be seen by anyone helping Genentech BioOncology Access Solutions perform services including Genentech employees and any of Genentech's partners.

4. How My PHI May Be Used

My PHI may be used only in these ways:

- Helping with my health care plan coverage for Genentech products
- Applying to GATCF
- Tracking my use of Genentech products
- Measuring the help offered by Genentech BioOncology Access Solutions

5. Expiration Date

This release is in effect for 1 year once I have signed it. I may also withdraw it in writing at any time.

6. Notices

Once I sign this form, I know my PHI might not be covered by any federal law about the use of my PHI or how it is disclosed. There is no guarantee my PHI might not be released to a third party. This third party might not need to follow the conditions of this release.

I know I can refuse to sign this form. I may withdraw it at any time and for any reason. This won't affect the start or continuing of my treatment. It will have no effect on the quality of my treatment.

I know this release stays in effect for 1 year or until I withdraw it in writing. To withdraw it, I must send a written notice to Genentech. It can be sent by fax or by mail to the address at the bottom of this page. This withdrawal goes into effect once it is received by Genentech. It will have no impact on my treatment by my doctor.

If I don't sign this form or withdraw it, I may be responsible for the costs of my treatment.

7. Distribution Acceptance

If I receive free product from GATCF, I will use Genentech products as my doctor has prescribed them to me. I will not sell or distribute Genentech products. I understand it is unlawful to do this. I am responsible for ensuring any Genentech product is sent to a secure address when it is shipped to me. I know it is my duty to control any Genentech product while it stays in my possession.

SECTION 8 ON THE NEXT PAGE IS REQUIRED.

This written notice must be signed, dated and mailed or faxed to:

Genentech BioOncology Access Solutions
1 DNA Way, Mail Stop #858a
South San Francisco, CA 94080-4990

Fax: (888) 249-4919

8. Signature and Date (REQUIRED)

I have read and understand the terms of this release form. I have had the chance to ask questions about the use of my personal health information (PHI) and who may see it. By signing this form below, I know I am releasing my PHI as discussed in this form. **(Please fill in all information below. Be sure to sign and date this form. If you don't, it could hold up the process for helping you.)**

You must sign and date here

Signature of Patient or Guardian* ______ Description of Authority ______ Date ______

You must print your name here

Print Patient's Name ______

Patient/Guardian Address ______

*If the patient is an unemancipated minor or otherwise incapacitated (physically or mentally).

9. Financial Information

Fill out this section only if you want to apply for help from GATCF.

Household Adjusted Gross Income: ☐ $0-$25,000/yr ☐ $25,001-$50,000/yr ☐ $50,001-$75,000/yr ☐ $75,001-$100,000/yr ☐ Other: ______

I know that to qualify for free medicine, my household adjusted gross income may not be more than $100,000 per year. I certify the above statement of my income for last year is true. I certify I have no health plan coverage for Genentech BioOncology products. This includes Medicare, Medicaid or other public programs. I do not have the financial resources to pay for Genentech BioOncology products. I agree to give GATCF proof of my income. This may be a copy of my IRS 1040 form from last year. It may be other proof of my income as well. I will send this to GATCF within 45 days after this form is submitted. I know if I fail to supply this, GATCF won't be able to keep helping me.

Sign and date here (if needed)

Signature of Patient or Guardian ______ Date ______

10. An Optional and Free Patient Support Program

I want to enroll in an optional and free patient support program from Genentech. I understand my PHI is needed for me to be a part of this program. I also know my PHI will be shared with Genentech BioOncology Access Solutions and the patient support program. I may choose to be contacted by mail, email or phone. I understand my PHI won't be shared outside of Genentech or by its agents. I agree to let Genentech or its agents contact me in the future about this program. The Genentech privacy policy can be found at BioOncologyAccessSolutions.com. I understand I do not have to sign this part of the form. It plays no role in getting my medicine. It is not part of receiving help from Genentech BioOncology Access Solutions. I also know I may cancel this enrollment in the patient support program at any time. To cancel, I can call (877) 436-3683.

Preferred way to contact me (please check the boxes that apply and fill in your information. You can check more than one box.):

☐ Email: ______ ☐ Phone Number: ______ Okay to leave a message? ☐ Yes ☐ No

☐ Address: ______

Choose to enroll by signing here

Signature of Patient (you must sign here to enroll in the patient support program). ______ Date ______

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