



Genentech BioOncology Access Solutions

What you need to know about coverage,
reimbursement and patient assistance

Table of contents

What We Do

| | |
|--|---|
| Welcome to Genentech BioOncology Access Solutions..... | 3 |
| Our service structure..... | 4 |
| Genentech BioOncology Access Solutions process flow chart..... | 5 |

Getting Started

| | |
|--|---|
| How to enroll a patient in Genentech BioOncology Access Solutions..... | 6 |
|--|---|

Coverage and Reimbursement Services

| | |
|--|---|
| Benefits investigations, prior authorizations and recertification..... | 7 |
| Denials and appeals..... | 8 |
| Sample appeals letter..... | 9 |

Helping Patients

| | |
|---|-------|
| The Genentech® Access to Care Foundation..... | 10-11 |
| Out-of-pocket cost assistance..... | 12-13 |
| Additional support programs for patients..... | 14-15 |

BioOncologyAccessSolutions.com

| | |
|--|-------|
| Resources for healthcare professionals, patients and caregivers..... | 16-17 |
|--|-------|

2

Additional Programs and Resources

| | |
|---------------------------------------|-------|
| Spoilage and replacement program..... | 18-19 |
| Helpful resources..... | 19 |

What we do



Welcome to Genentech BioOncology Access Solutions

Reimbursement, access and support

At Genentech, we develop therapeutics for serious or life-threatening medical conditions, and we believe they should be accessible for the patients who need them.

Genentech BioOncology Access Solutions helps resolve a wide range of access and reimbursement issues for patients every day. Our in-house, dedicated Specialists help bring patient treatment and practice solutions together.

Committed to helping patients

- Since 1985, when its first product was approved, Genentech has donated approximately \$2.3 billion in free medicine to uninsured patients through the Genentech® Access To Care Foundation (GATCF)
- Since 2005, Genentech has donated more than \$550 million to various independent, non-profit organizations (INOs) that provide co-pay assistance



Genentech BioOncology Access Solutions Contact Information

BioOncologyAccessSolutions.com

Phone: (888) 249-4918

Fax: (888) 249-4919

Genentech BioOncology
Access Solutions

1 DNA Way, Mail Stop #858a
South San Francisco, CA 94080

Model is being used for illustrative purposes only.

What we do

Helping patients access our therapies

We want your patients to get the Genentech therapies you prescribe, regardless of their ability to pay. In 2010, Genentech Access Solutions helped more than 107,000 patients with coverage and reimbursement issues.

The Specialists at Genentech BioOncology Access Solutions can provide expertise regarding access and reimbursement issues for the Genentech therapies your patients need.

Our Service Structure

Coverage and Reimbursement

- Help with benefits and coverage issues
 - Benefits investigation
 - Prior authorization
 - Recertification
- Help with reimbursement issues
 - Denials and appeals
 - Billing and coding information

Patient Assistance

- Genentech® Access to Care Foundation (GATCF) support for qualifying uninsured and rendered uninsured patients
- Referrals to independent, non-profit organizations for co-pay assistance
- CancerCare*
- Patient ambassador programs
- Genentech BioOncology Co-pay Card

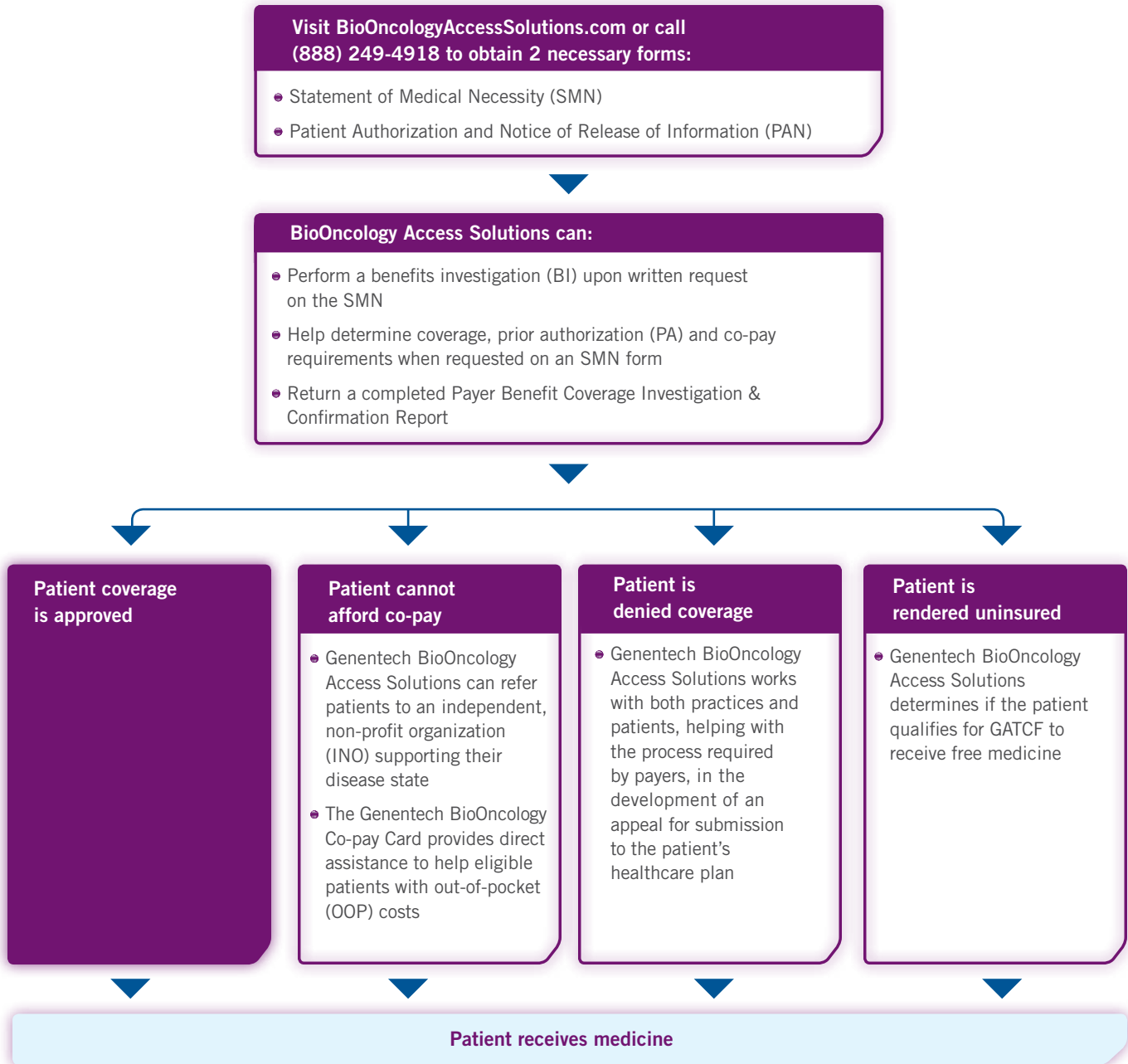
Informational Resources

- BioOncology Field Reimbursement Managers
- Product spoilage and replacement information
- Communication assistance services
 - Translation services
 - Telephone to telephone typewriter (TTY) services
- My Patient Solutions, our online patient management tool
- Medicare/Medicaid search tool
- Glossary of access and reimbursement terms

*CancerCare is a leading national non-profit organization offering counseling, education and practical help free of charge to anyone affected by cancer.

What we do

Genentech BioOncology Access Solutions process flow chart



Getting started

How to enroll a patient in Genentech BioOncology Access Solutions

BioOncology Field Reimbursement Managers

BioOncology Field Reimbursement Managers are experts in all Genentech BioOncology Access Solutions services. They can provide personalized, in-office support to physician practices, helping to facilitate patients' access to the Genentech therapies they need.

BioOncology Field Reimbursement Managers can provide:

- Patient-level issue resolution management
- Local market coverage and reimbursement expertise
- Genentech BioOncology Access Solutions expertise, payer policy and process education

Important forms

6

To begin the enrollment process for Genentech BioOncology Access Solutions, complete the following 2 forms:

- **Statement of Medical Necessity (SMN)**— a form with basic patient, insurance and prescription information used when contacting patients' healthcare plans to determine their reimbursement coverage



- **Patient Authorization and Notice of Release of Information (PAN)**— a form signed and dated by your patients giving written permission for Genentech BioOncology Access Solutions to discuss their case with you and the patients' healthcare plans



3 ways to get these forms:

1. Visit BioOncologyAccessSolutions.com and click on the “Frequently Used Forms” link in the lower right corner of the page.
2. Use the search function on BioOncologyAccessSolutions.com and search for “SMN Form” or “PAN Form.”
3. Call (888) 249-4918 and speak to one of our Specialists.

Both forms can be faxed to Genentech BioOncology Access Solutions at (888) 249-4919. Once Genentech BioOncology Access Solutions has processed the enrollment, an acknowledgment letter will be faxed to your office within 24 hours.

Coverage and reimbursement services



Benefits investigations, prior authorizations and recertification

Once we have received the completed SMN and PAN forms, a dedicated Specialist can:

- Complete an initial benefits investigation (BI), if requested
- Identify necessary prior authorizations (PAs)
- Help you obtain recertification for your patients if their coverage has lapsed
- Guide you through the appeals process, should it become necessary

Benefits investigations

Benefits investigations can:

- Help patients understand what is covered before they begin treatment
- Determine if a patient assistance program may be needed

Genentech BioOncology Access Solutions Specialists can help you facilitate BIs on behalf of your patients. A BI can only be initiated once the prescribing healthcare professional has requested this service on the SMN form.*

Prior authorizations

Our Specialists can help you determine if a PA is necessary. All they need is a completed SMN form requesting our services and a signed and dated PAN form. If a PA is required, a Specialist can help you obtain one by:

- Helping you compile required forms and documents for submission to the healthcare plan
- Determining the next steps if your patient's request for a PA is not granted

If a PA is approved by your patient's healthcare plan, Genentech therapies can be acquired through "buy and bill" or a specialty pharmacy.

Recertification

When a medical treatment is authorized for a specific and limited time, it will generally require recertification. Genentech BioOncology Access Solutions can help you obtain recertification for your patients so they can get coverage for continued treatment.

If the payer *approves* the patient's request for recertification, medicine can be dispensed to your patient. If the payer *denies* the request for recertification, an appeal may be filed with the payer.

*This description is provided for informational purposes only. The submission and completion of coverage- or reimbursement-related documentation are the responsibility of the patient and healthcare provider. Genentech, Inc. makes no representation or guarantee concerning coverage or reimbursement for any service or item.

Coverage and reimbursement services

Denials and appeals

If your patient's healthcare plan has issued a denial for a Genentech therapy, your BioOncology Field Reimbursement Manager or your Specialist can guide you in the process as you prepare an appeal submission, as per your patient's plan requirements.*

Each appeal may require different information, so your BioOncology Field Reimbursement Manager or Specialist has plan-specific knowledge to help you navigate the process.

Denials and appeals process flow

Understand the reason for the denial, which will be in either:

- The explanation of benefits (EOB)
- A denial letter

Compile an appeals package, consisting of:

- Appeal letter
- Letter of medical necessity
- Denial documentation
- Medical documentation
- Other necessary documentation (eg, journal articles, textbook excerpts, practice guidelines, etc)

A Genentech BioOncology Access Solutions Specialist can guide you as you put together an appeals package

Submit the appeals package, remembering to:

- Check the payer's deadline for appeals
- Keep a copy of the package for your records
- Send the package via certified mail to ensure and track receipt

Follow up with the appeals department:

- Within 1 week of submitting the appeals package
- Every 1 or 2 weeks for a status update

A Genentech BioOncology Access Solutions Specialist can guide you through the follow-up process

Find out the result of the appeal

Coverage and reimbursement services



Sample appeals letter

A 1-page letter used when contacting a patient's health insurance plan to provide a brief clinical history of the patient and your professional rationale for pursuing treatment with a Genentech BioOncology therapeutic.

Date

ATTN: Medical Review/Appeals process

Payer Name

Payer Address

Patient: [type in patient's first and last name]

Subscriber ID#:

Provider: [type in physician name and provider number]

RE: Genentech Therapy Denials

Dates of Service: [include all denied dates of service]

Dear Appeals Reviewer,

This letter is regarding my patient, [patient name], who has a history of [cancer type]. I am requesting reconsideration of the [Genentech therapy] denials on the above dates of service.

Clinical History

[Provide rationale for the treatment. This includes a brief description of the patient's disease state, prior treatments and response to those treatments, as well as other underlying health issues that impact the treatment selection. Consider mentioning alternative treatments and why you are not choosing them.]

Rationale for [Genentech Therapy]

[Provide information about the mode of action of the treatment and how it is beneficial for the patient's condition. Include other benefits of the treatment for your patient (eg, well tolerated, will not exacerbate underlying conditions). Include medical documentation that supports your argument for coverage (eg, physician notes and appropriate lab/test results that support the choice of treatment). If a medication was administered, include the infusion record.]

Conclusion

[Summarize the major points in your letter and restate what you want of the payer. If your patient has already received treatment and experienced a good response, mention that. Include journal articles, abstracts, textbook excerpts, practice guidelines and compendia indications that support the use of the treatment for your patient's condition. Consider mentioning experts in the field who support the treatment.] Thank you for your time and attention in reviewing this Genentech treatment for approval.

Sincerely,

[Physician name and credentials]

Enclosures [suggested]

- Lab report indicating CD20 level
- Genentech FDA approval letter

*Appeals cannot be submitted by Genentech BioOncology Access Solutions on your behalf. We can offer guidance on what needs to be done so you can submit an appeal.

Helping patients

The Genentech Access to Care Foundation: Free medicine for qualified patients

At Genentech, we are committed to connecting your patients to their medicine. One way we do this is through the Genentech Access to Care Foundation (GATCF). GATCF was established to help patients with unmet medical needs receive proper medical treatment.

Key points about GATCF

- Patients are eligible for free medicine for 1 year and must reapply annually
- Patient assistance support may be given before treatment or up to 1 year post-treatment
- GATCF assists with medical costs only, not administration costs

GATCF eligibility screening

If you are concerned that your patient will not be covered for their Genentech therapy at the time you initiate a BI, you may request a GATCF Eligibility Screening. This helps you assess whether your patient may meet GATCF criteria.

To begin the GATCF Eligibility Screening process, check the appropriate box under *Services Requested* on the SMN form and have your patients verify their income on the PAN form. GATCF will then review your patient's eligibility and fax a letter notifying you of the outcome within 24 hours of receiving the forms.*

In 2010 alone, GATCF provided medicine to approximately 47,000 uninsured patients who needed our products.



Helping patients

Genentech Access to Care Foundation process flow

GATCF verifies the patient's eligibility criteria

| Insurance criteria | Financial criteria | Medical criteria |
|---|--|--|
| <p>GATCF verifies the patient's insurance status to confirm the patient:</p> <ul style="list-style-type: none">• Is uninsured• Lacks coverage through prior authorization, claim or appeal denial <p>OR</p> <ul style="list-style-type: none">• Lacks coverage because the payer policy clearly states non-coverage | <p>GATCF assesses the patient's financial eligibility based on annual household adjusted gross income (AGI) of ≤\$100,000[†]:</p> <ul style="list-style-type: none">• GATCF follows up directly with the patient to explain and obtain income documentation• Financial documentation (eg, current IRS 1040) is required within 45 days of enrollment | <p>GATCF assesses the patient's medical eligibility according to guidelines set by the GATCF Clinical Advisory Board</p> |

GATCF notifies the practice of the patient's eligibility and, if the patient is approved, will:

- Verify the prescription with the office (must have original physician signature)
- Coordinate shipment of the prescribed therapy with the practice
- Ship the subsequent (or replacement) supply only after treatment documentation is received by GATCF
—If the Patient Authorization and Notice of Release of Information (PAN) financial information section is completed and the patient meets the criteria, the patient's medicine may be shipped within 48 hours



We want any information you need about coverage and reimbursement to be as easy to gather as possible.

- Visit BioOncologyAccessSolutions.com or call (888) 249-4918 from 6 AM - 5 PM PT, Monday to Friday, to speak live with one of our Specialists

*A GATCF Eligibility Screening approval letter does **not** guarantee acceptance into GATCF; it only states the patient *appears* to meet GATCF's **medical** and **financial** criteria based upon review of the SMN and PAN forms. GATCF will still need to confirm the complete lack of insurance coverage for the Genentech therapy and verify medical and financial qualifications based on documentation provided by the patient.

[†] Special consideration can be given to patients with unique circumstances.

Helping patients

Enhanced assistance for out-of-pocket costs

Genentech BioOncology Co-pay Card

At Genentech, we know that out-of-pocket (OOP) costs can be a financial burden on patients, even if they have health insurance. That's why we've enhanced the Genentech BioOncology Co-pay Card. The card now features more coverage for more patients and a simplified enrollment process.



Recent changes to the card

- **More coverage:** Patients no longer have to pay the first \$100 of the OOP costs for each treatment
- **More patients are eligible:** Patients are eligible regardless of their income* or the amount of their OOP costs per treatment
- **Simplified enrollment:** Patients do not need to provide financial documentation to enroll,[†] just a verbal statement verifying their income

12

Eligibility

| Eligible | Not eligible |
|---|---|
| <ul style="list-style-type: none"> • Covered by commercial insurance (non-governmental) • Age 18 years or older | <ul style="list-style-type: none"> • Participating in Medicare, Medicaid, Medigap, VA, DoD or Tricare (or any other federally- or state-funded benefit programs, including government employee plans) • Uninsured (refer to Genentech® Access to Care Foundation [GATCF]) or currently participating in GATCF • Currently residing or receiving services in Massachusetts or Vermont |

*Patients who make a household income of >\$100,000 per year have a yearly limit of \$1,500.

[†]Patients only need to provide a verbal statement to verify their income when they enroll. Proof of documentation at a later date may be required.

[‡]Genentech BioOncology Access Solutions does not influence or control the operations of these INOs, but Genentech BioOncology Access Solutions can assist patients in navigating the process of seeking co-pay assistance by making an appropriate referral based on a patient's diagnosis and by assisting with the application process. We cannot guarantee co-pay assistance once a patient has been referred by Genentech BioOncology Access Solutions. The INOs to which we refer patients each have their own criteria for patient eligibility, including financial eligibility.

Helping patients

Co-pay coverage

| What the card covers | |
|--------------------------|--|
| Card covers | 80% of your patients' out-of-pocket costs for their Genentech cancer therapy |
| Patients' responsibility | 20% of out-of-pocket costs for their Genentech cancer therapy |
| Card limit | Up to \$4,000 per year*† |



If you want to enroll your patients or have any questions,

Call **855-MYCOPAY (855-692-6729)** from 9 AM - 8 PM ET, Monday to Friday or visit www.CopayAssistanceNow.com



Scanning this QR code with your smartphone will take you to www.CopayAssistanceNow.com where you can find out more about the Genentech BioOncology Co-pay Card. Several free QR code scanner apps are available online.

Co-pay coverage through independent, non-profit organizations

At Genentech, it is our goal to help ease the financial burden some patients and their families may experience while gaining access to our therapies. Genentech has made significant and ongoing charitable donations to various independent, non-profit organizations (INOs)[‡] in support of co-pay assistance.

If insured patients are having trouble paying for their Genentech therapy co-pay, co-insurance or another expense, Genentech BioOncology Access Solutions can refer them to an INO supporting their disease state. Patients enrolled

in Medicare Part D may be eligible to apply for co-pay assistance, including fees associated with true out-of-pocket (TrOOP) expenses.

In 2007, Genentech referred approximately **18,000 patients** for co-pay assistance.

Key points about co-pay referrals

- If a patient is denied by one INO, he or she can be referred to a different INO
- A Specialist follows up weekly with both the patient and the INO until a resolution is reached
- INO turnaround time can vary from 2 weeks to 30 days

Helping patients

Additional support programs for patients

Specialty pharmacies

Specialty pharmacies have highly trained staff, including oncology-trained professionals who can:

- Individualize care
- Assist in clinical case management
- Facilitate reimbursement
- Manage special handling and shipping needs

Most specialty pharmacies also provide extensive patient education to reinforce the instructions of the healthcare provider and encourage patients to adhere to their therapy.

CancerCare

Our Specialists can help your patients and their caregivers get assistance by simply transferring them to a social worker at CancerCare.

CancerCare is a leading national non-profit organization that offers counseling, education and practical help free of charge to anyone affected by cancer. This includes patients, family and other loved ones. CancerCare also offers financial assistance for qualified patients.

Your patients can call CancerCare directly at (800) 813-HOPE (800-813-4673).

To learn more about CancerCare's services, please visit cancercares.org.



To get a partial list of specialty pharmacies that supply Genentech oral therapies, please visit BioOncologyAccessSolutions.com or contact a Specialist.

Helping patients

More support programs

Patient Support Link

At Genentech BioOncology Access Solutions, we know helping patients access their medicine is only part of the battle. Each patient may have additional support needs related to their treatment. That's why we offer Patient Support Link,* a personalized service that connects patients to external organizations.†

These organizations may be able to provide assistance with:

- Medical bills, including OOP costs for infusion administration
- Medical supplies and legal services
- Food, groceries and nutritional supplements
- Mortgage, rent and utility bills
- Transportation to and from medical appointments, including by air

When your patients contact Genentech BioOncology Access Solutions to request OOP cost assistance, they may also register for Patient Support Link. Then, through this service, patients can obtain:

- A personalized search for local organizations providing additional support specific to patients' needs
- Customized search results within 3 business days, along with instructions to the patients about how to request assistance from the organizations

Communication assistance services

As part of our commitment to patients, Genentech BioOncology Access Solutions offers multiple language translations and hearing-impaired services for callers to ensure individual communication needs are not a barrier to accessing our patient support services.

- Translation services are available for most languages
- Telephone to telephone typewriter services are available for hearing-impaired patients



There may be additional support programs for specific Genentech therapies that may help you or your patients.

- To learn more about these programs, visit BioOncologyAccessSolutions.com or call (888) 249-4918 from 6 AM - 5 PM PT, Monday to Friday

*All or part of this service might not be available in some areas of the United States. While patients do not need to qualify through Genentech, they could need to meet certain qualification criteria for the individual organizations providing assistance. Patients may opt into this service when co-pay referral assistance is requested.

† We do not influence or control the operations of the organizations in the Patient Support Link program, but Genentech BioOncology Access Solutions may assist patients in navigating the process of seeking assistance by making an appropriate referral based on a patient's diagnosis and by assisting with the application process. We cannot guarantee assistance once a patient has been referred by Genentech BioOncology Access Solutions. The organizations to which we refer patients each have their own criteria for patient eligibility.

Simplify the process for you and your patients

BioOncologyAccessSolutions.com provides easy access to information that can help you connect your patients to the medicine they need. A wealth of Genentech BioOncology Access Solutions expertise is available online whenever you need it. See below for the look and feel of the site:

- A** Dawn, our virtual guide at BioOncologyAccessSolutions.com, will provide you with an overview of our home page.
- B** BioOncologyAccessSolutions.com helps you refine your searches by organizing site visitors by whether you are a “Patient/Caregiver” or “Healthcare Professional,” and by what Genentech therapy you are interested in.

- C** The “Frequently Used Forms” link is an easy way to access SMN, PAN and other important documents you may need as you try and help your patients access Genentech therapies.

Resources for patients and caregivers

At Genentech BioOncology Access Solutions, we know that sometimes patients and caregivers like to take an active role in their treatment and access decisions. That’s why we created a separate section of the Web site designed just for patients, with easy-to-understand content so they can access the information and resources they need.





Tools you can use to help your patients

Resources for healthcare professionals

Given your busy schedule, we know how important it is to have treatment and access knowledge at your fingertips. At BioOncologyAccessSolutions.com, you can get detailed information on our many patient assistance programs.

With a quick search or click, you can:

- Explore each program's eligibility
- Learn how to enroll your eligible patients
- See illustrated process flows of our programs
- View a list of independent, non-profit organizations providing co-pay assistance to eligible patients

MyPatientSolutions.com

My Patient Solutions is our online patient management tool, which is linked from BioOncologyAccessSolutions.com. It was designed to help manage patient cases in a way that works for you.

With MyPatientSolutions.com, you can access:

- Your open patient cases, closed cases and pending cases
- Easy enrollment of new cases, with your practice information automatically populated
- E-mail and online alerts for your open cases
- Notifications about the latest news and developments from Genentech BioOncology Access Solutions
- Quick links to the forms you need most often



Important note: Although My Patient Solutions allows you to save and edit forms online, the SMN and PAN forms still must be signed, dated and faxed to (888) 249-4919 or given to your BioOncology Field Reimbursement Manager.



To register for My Patient Solutions, your practice must sign the Office Agreement and fax it to (877) 319-4520. We will then send a confirmation fax back. Administrative Managers and Authorized Users can then register at MyPatientSolutions.com. Each person who registers will receive a separate user name, a link to create a password and challenge questions. The process can take anywhere from a few hours to 4 business days depending on how quickly you register.

Additional programs and resources

Spoilage and replacement program

If the BioOncology product you prescribed for a labeled indication was spoiled or unable to be administered, the BioOncology Spoilage and Replacement Program may be able to provide you with a new supply.*

If the BioOncology product has expired after your office has received it, please call us at (800) 551-2231. Genentech allows the return of spoiled BioOncology products under certain circumstances.

Prerequisites for replacement†

The BioOncology product is eligible for replacement if it has been reconstituted and has not been administered, billed or reimbursed and is unusable due to one of the following events:

- Product was reconstituted and patient missed appointment
- Product was accidentally dropped or mishandled while in transit
- Product was not appropriately refrigerated or was frozen
- Product incurred an admixture error

18



Please contact Genentech Medical Communications (800) 821-8590 for all quality-related issues and Genentech Customer Service at (800) 551-2231 for expired product returns.

*Subject to certain limitations and conditions.

† Genentech retains the right to discontinue its entire Spoilage and Replacement Program for a particular account/physician who it determines in its sole discretion has misused this policy. Genentech has the right to modify or discontinue this program at any time without notice.

‡ Includes debit memo number, DEA number of sender, return authorization number, product name, quantity, product size, reason for return, expiration date and lot number.

Replacement procedure

- Retain all BioOncology product infusion containers (physical proof or certification of spoilage is required)
- Contact Genentech Customer Service at (800) 551-2231 to obtain a BioOncology Spoilage Replacement Form
- If the vial is broken, it should not be returned. If the vial is intact, it is to be returned with the Return Authorization (RA) Number provided by Customer Service to:
Genco Pharmaceuticals
[Assigned RA Number]
6101 North 64th Street
Milwaukee, WI 53218
(800) 950-5479
- Replacement product vials will be shipped upon receipt of both the completed BioOncology Spoilage Replacement Form and the spoiled product or the Certification Form for replacement of destroyed product
- The completed Certification Form must be faxed to (877) 329-6737

Procedure for returning products

For expired products, as identified within this policy, contact Genco Pharmaceuticals at (800) 950-5479



Genco Pharmaceuticals will provide an RA Number



Product returns must include all information necessary for processing‡

For all other product return requests, including damaged or overstocked product, contact your Genentech Clinical Oncology Specialist.

Additional programs and resources



Additional spoilage and replacement information

- Genentech (not Genco Pharmaceuticals) will process return credits
- All products returned must have an RA Number
- All products returned, including unauthorized returns, will be destroyed
- Customers are responsible for the cost of shipping to Genco Pharmaceuticals and are liable for the product until Genco Pharmaceuticals or Genentech identifies it as an appropriate product return
- Returns for reasons related to product quality (eg, solution is cloudy) will continue to be processed by Genentech. Please contact Genentech Medical Communications at (800) 821-8590
- Returns due to expiration will be credited or replaced if product is 2 months prior to expiration or 6 months past expiration

Non-returnable products

Under the following conditions, the product is non-returnable, regardless of expiration date:

- Products damaged by fire or water
- Repackaged products
- Products obtained illegally or from an unauthorized source
- Partially filled vial
- Products with no lot numbers, expiration dates or readable labels
- Products purchased for research or clinical trials

Removable card that you can share with your practice





Genentech
A Member of the Roche Group