Genentech
A Member of the Roche Group

GENENTECH PATIENT SUPPORT SERVICES

Access and Reimbursement Support for POLIVY® (polatuzumab vedotin-piiq)

NCCN CATEGORY 1 PREFERRED TREATMENT OPTION

National Comprehensive Cancer Network® (NCCN®) recommends polatuzumab vedotin-piiq (POLIVY) + R-CHP (rituximab, cyclophosphamide, doxorubicin, prednisone) as a category 1 preferred treatment option for patients with previously untreated stage II (with extensive mesenteric disease) or stage III-IV diffuse large B-cell lymphoma and IPI ≥2.[1]*

POLIVY + R-CHP is approved for previously untreated DLBCL, NOS or HGBL and IPI ≥2.

NCCN=National Comprehensive Cancer Network.

*NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.

Genentech-Access.com/POLIVY | **(877) GENENTECH**/(877) 436-3683, Monday through Friday, 6 a.m.–5 p.m. PT

Indication Statement

POLIVY in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the treatment of adult patients who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index score of 2 or greater.

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-cell Lymphomas V.2.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed February 17, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

Please see the full **Prescribing Information** and pages 28-29 for additional Important Safety Information.

POLIVY™
polatuzumab vedotin-piiq
INJECTION FOR INTRAVENOUS USE 30 MG | 140 MG

Inside This Brochure

Genentech Is Here to Support Patients Taking POLIVY

At Genentech, we work every day to help patients who have been prescribed POLIVY, so they can focus on what matters most. We offer assistance options for a wide range of patient situations.

If your patients:

Need help understanding health insurance coverage and related financial responsibilities, **Genentech Access Solutions** is here to help

Do not have health insurance coverage or have financial concerns and meet certain eligibility criteria, the **Genentech Patient Foundation** may be able to provide free medicine*

Have health insurance and need help paying for their medicine, **Affordability Options** may be available

- For eligible commercially insured patients: the Genentech Oncology Co-pay Assistance Program†
- For eligible publicly or commercially insured patients: referrals to independent co-pay assistance foundations‡

Want information and resources about their medicine, **POLIVY Patient Education and Treatment Resources** provide answers to their questions

*To be eligible for free Genentech medicine from the Genentech Patient Foundation, insured patients who have coverage for their medicine should try to pursue other forms of financial assistance, if available, and meet certain income requirements. Uninsured patients and insured patients without coverage for their medicine must meet a different set of income requirements. Genentech reserves the right to modify or discontinue the program at any time and to verify the accuracy of information submitted.

†Eligibility criteria apply. Not valid for patients using federal or state government programs to pay for their Genentech medicine. Patients must be taking the Genentech medicine for an FDA-approved indication. Please visit the Co-pay Program website for the full list of Terms and Conditions.

‡Independent co-pay assistance foundations have their own rules for eligibility. Genentech has no involvement or influence in independent foundation decision-making or eligibility criteria and does not know if a foundation will be able to help your patient. We can only refer your patient to a foundation that supports their disease state. Genentech does not endorse or show preference for any particular foundation. The foundations to which we refer your patient may not be the only ones that might be able to help.

Please see the full **Prescribing Information** and pages 28-29 for additional Important Safety Information.

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Enroll Patients and Work With Us Online Using My Patient Solutions® for Health Care Practices

My Patient Solutions is an online tool to help you enroll patients in Genentech Access Solutions and manage your service requests.

Features of My Patient Solutions include:

Messaging—send messages to a Genentech Access Solutions or Genentech Patient Foundation Specialist and receive responses within the system

Genentech Patient Foundation information—view eligibility and coordinate shipments

Co-pay assistance details—view your patient's enrollment status

Paperless enrollment and re-enrollment—enroll and re-enroll your patients in Genentech Access Solutions or the Genentech Patient Foundation entirely online using eSignature and scanned Patient Consent Form attachments or send a link to the paperless Patient Consent Form

Benefits Investigation (BI) Reports—review BI Reports for all your patients enrolled in Genentech Access Solutions

Prior authorization (PA) and appeal follow-up—download the PA form (if available) and request that Genentech Access Solutions follow up with the health insurance plan on behalf of the patient

Log in or register your practice at **Genentech-Access.com/MPS**. For more detailed information about My Patient Solutions, contact your **Field Reimbursement Manager (FRM)** or **Hematology Therapeutic Area Manager (TAM)**.

Enrolling Your Patients in Coverage and Reimbursement Support

PATIENTS complete and sign the Patient Consent Form

PRESCRIBERS complete the Prescriber Service Form

Once we receive these completed forms, your Genentech Specialist can:

- Complete a BI
- Identify necessary PAs
- Provide you with resources for the appeals process, if necessary
- Refer patients to an appropriate financial assistance option, if needed

Be sure to submit the forms together for fast and efficient processing.

For more information about enrolling eligible patients into the Genentech Patient Foundation, see pages 25-27.

Please see the full **Prescribing Information** and pages 28-29 for additional Important Safety Information.

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Tips for Completing the Patient Consent Form

The Patient Consent Form gives permission for Genentech to work with your practice and the patient's health insurance plan.

A Only the information requested on this form is required. Providing additional, unrequested documents or information will delay processing.

B **All fields marked with an asterisk (*) are required.**

C This section is required for Genentech Patient Foundation requests (see pages 25-27 for more information).

D Patients complete this section to enroll in optional and free programs from Genentech, including POLIVY patient education and treatment resources.

E This section is required for all Genentech patient support services, including Genentech Access Solutions and the Genentech Patient Foundation.

- **Be sure the patient signs and dates this section**—we are not able to help patients without a valid signature

Finding and submitting the form

Where to Find	Genentech-Access.com/PatientConsent
Options to Submit	eSubmit at Genentech-Access.com/PatientConsent Upload a scanned copy to My Patient Solutions® for Health Care Practices Text a photo to (650) 877-1111 Fax to (866) 480-7762

A **PATIENT CONSENT FORM**

Genentech — A Member of the Roche Group | Access Solutions

Genentech-Access.com
Phone: (866) 422-2377 **Fax:** (866) 480-7762
6 a.m.–5 p.m. (PT) M-F

Required field (*) M-US-00002802(v3.0)

B **Patient Information** (to be completed by patient or their legally authorized representative)

*First name: _____ *Last name: _____

Home phone: ( ) - _____ Cell phone: ( ) - _____

☐ OK to leave a detailed message? Date of birth (MM/DD/YYYY): __/__/____

Email: _____ Preferred language: ☐ English ☐ Spanish ☐ Other: _____

Alternate Contact (optional) Full name: _____

Relationship: _____ Phone: ( ) - _____

C **1** Financial Eligibility: Complete **only** if you are applying to the Genentech Patient Foundation

By completing this section, I am agreeing to the Terms and Conditions of the Genentech Patient Foundation outlined on page 2.

Household size (including you): _____

Annual household income: _____

D **2** Consent for Patient Resources and Information (**OPTIONAL**)

Genentech offers **optional** and free disease education and other material for patients. This may include information and marketing material about products, services and programs offered by Genentech, its partners and their respective affiliates. If you sign up, you may be contacted using the information you have provided.

☐ By checking this box, I agree to receive **optional** disease education and other material. I understand providing this agreement is voluntary and plays no role in getting Genentech Access Solutions services or my medicine and that it may be necessary to use my sensitive personal information to provide me with relevant material. I also understand that I may opt out of receiving this information at any time by calling **(877) 436-3683** and that this consent will remain active unless I opt out.

Telephone Consumer Protection Act (TCPA) Consent (**OPTIONAL**)

☐ By checking this box, I consent to receive autodialed marketing calls and text messages from and on behalf of Genentech at the phone number(s) I have provided. I understand that consent is not a requirement of any purchase or enrollment. Message frequency may vary. Message and data rates may apply. I may opt out at any time by texting STOP or calling **(877) GENENTECH**/(877) 436-3683.

E **3** By signing this form, I acknowledge that I have provided accurate and complete information and understand and agree to the terms of this form. My signature certifies that I have read, understood, and agree to the release and use of my personal information, including sensitive personal information, pursuant to the Authorization to Use and Disclose Personal Information and as otherwise stated on this form.

REQUIRED

Sign and date here: _____ *Signature of Patient/Legally Authorized Representative (A parent or guardian must sign for patients under 18 years of age) | __/__/____ *Date signed (MM/DD/YYYY)

Person signing (if not patient): _____ Print first name | _____ Print last name | _____ Relationship to patient

Once this page (4/4) has been completed, please text a photo of the page to **(650) 877-1111** or fax to **(866) 480-7762**. You can also complete this form online at **Genentech-Access.com/PatientConsent**.

If this is an electronic consent, you understand that by typing your name and the date above and submitting, or taking a picture and sending to us, that you are providing your consent electronically and that it has the same force and effect as if you were signing in person on paper. Genentech reserves the right to rescind, revoke or amend the program without notice at any time.

4 of 4

Please see the full **Prescribing Information** and pages 28-29 for additional Important Safety Information.

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Tips for Completing the Prescriber Service Form

The Prescriber Service Form is used to collect the patient's health insurance and treatment information.

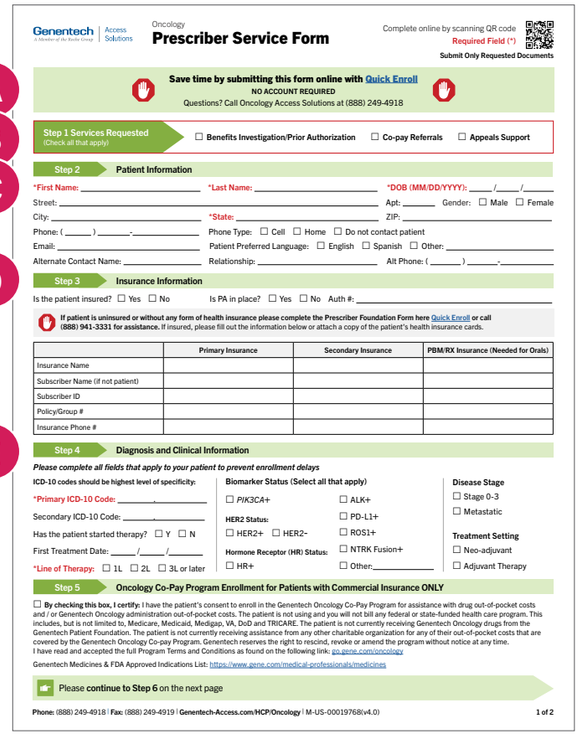
A You can save time by submitting this form online with Quick Enroll. There is no account required.

B Select the service(s) you are requesting. If no services are requested, Genentech Access Solutions will perform a benefits investigation (BI) and provide prior authorization (PA) resources.

C **All fields marked with an asterisk (*) are required.**

D You can either enter the patient's health insurance information onto the form directly or attach a copy of the insurance card(s).

E Be sure to include the code itself, not just the description. Sample coding information can be found on page 10 of this brochure or online at **Genentech-Access.com/POLIVY**.



Genentech | Access Solutions — Oncology

Prescriber Service Form

Complete online by scanning QR code
Required Field (*)
Submit Only Requested Documents

Save time by submitting this form online with Quick Enroll
NO ACCOUNT REQUIRED
Questions? Call Oncology Access Solutions at (888) 249-4918

Step 1 Services Requested (Check all that apply)
☐ Benefits Investigation/Prior Authorization ☐ Co-pay Referrals ☐ Appeals Support

Step 2 Patient Information
*First Name: _____ *Last Name: _____ *DOB (MM/DD/YYYY): ____/____/____
Street: _____ Apt: _____ Gender: ☐ Male ☐ Female
City: _____ *State: _____ ZIP: _____
Phone: (____) ____-____ Phone Type: ☐ Cell ☐ Home ☐ Do not contact patient
Email: _____ Patient Preferred Language: ☐ English ☐ Spanish ☐ Other: _____
Alternate Contact Name: _____ Relationship: _____ Alt Phone: (____) ____-____

Step 3 Insurance Information
Is the patient insured? ☐ Yes ☐ No Is PA in place? ☐ Yes ☐ No Auth #: _____

If patient is uninsured or without any form of health insurance please complete the Prescriber Foundation Form here Quick Enroll or call (888) 941-3333 for assistance. If insured, please fill out the information below or attach a copy of the patient's health insurance cards.

	Primary Insurance	Secondary Insurance	PBM/RX Insurance (Needed for Orals)
Insurance Name			
Subscriber Name (if not patient)			
Subscriber ID			
Policy/Group #			
Insurance Phone #			

Step 4 Diagnosis and Clinical Information
Please complete all fields that apply to your patient to prevent enrollment delays
ICD-10 codes should be highest level of specificity:
*Primary ICD-10 Code: _____.____
Secondary ICD-10 Code: _____.____
Has the patient started therapy? ☐ Y ☐ N
First Treatment Date: ____/____/____
*Line of Therapy: ☐ 1L ☐ 2L ☐ 3L or later
Biomarker Status (Select all that apply)
☐ PIK3CA+ ☐ ALK+
HER2 Status: ☐ HER2+ ☐ HER2- ☐ ROS1+ ☐ PD-L1+
Hormone Receptor (HR) Status: ☐ HR+ ☐ NTRK Fusion+ ☐ Other: _____
Disease Stage: ☐ Stage 0-3 ☐ Metastatic
Treatment Setting: ☐ Neo-adjuvant ☐ Adjuvant Therapy

Step 5 Oncology Co-Pay Program Enrollment for Patients with Commercial Insurance ONLY
☐ **By checking this box, I certify:** I have the patient's consent to enroll in the Genentech Oncology Co-Pay Program for assistance with drug out-of-pocket costs and / or Genentech Oncology administration out-of-pocket costs. The patient is not using and you will not bill any federal or state-funded health care program. This includes, but is not limited to, Medicare, Medicaid, Medigap, VA, DoD and TRICARE. The patient is not currently receiving Genentech Oncology drugs from the Genentech Patient Foundation. The patient is not currently receiving assistance from any other charitable organization for any of their out-of-pocket costs that are covered by the Genentech Oncology Co-pay Program. Genentech reserves the right to rescind, revoke or amend the program without notice at any time. I have read and accepted the full Program Terms and Conditions as found on the following link: go.gene.com/oncology
Genentech Medicines & FDA Approved Indications List: https://www.gene.com/medical-professionals/medicines

Please **continue to Step 6** on the next page

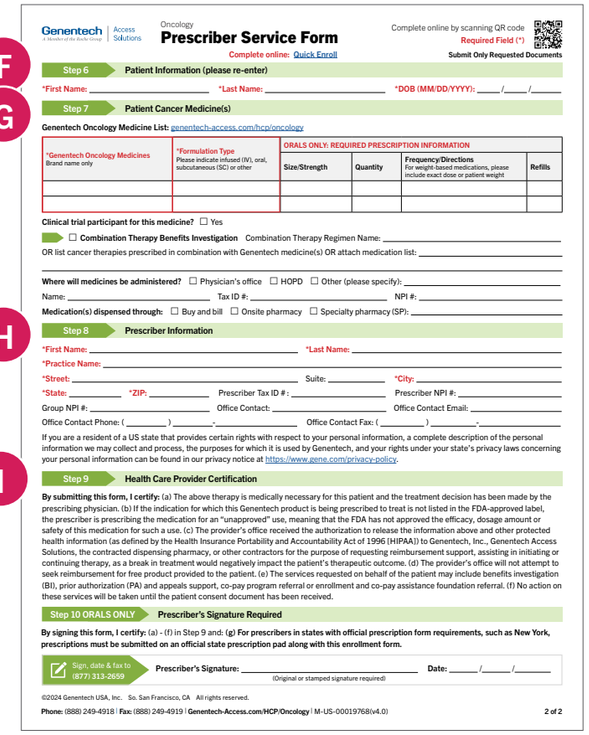
Phone: (888) 249-4918 | **Fax:** (888) 249-4919 | **Genentech-Access.com/HCP/Oncology** | M-US-00019768(v4.0) 1 of 2

F Be sure to re-enter the patient information in case the pages get separated.

G Select POLIVY as your patient's therapy and provide additional details about their treatment regimen.

H Complete your practice information. When you complete the Prescriber Service Form via My Patient Solutions® for Health Care Practices, this information is prepopulated.

I For infused therapies such as POLIVY, a signature is not required.



Genentech | Access Solutions — Oncology

Prescriber Service Form

Complete online by scanning QR code
Complete online: Quick Enroll
Required Field (*)
Submit Only Requested Documents

Step 6 Patient Information (please re-enter)
*First Name: _____ *Last Name: _____ *DOB (MM/DD/YYYY): ____/____/____

Step 7 Patient Cancer Medicine(s)
Genentech Oncology Medicine List: genentech-access.com/hcp/oncology

*Genentech Oncology Medicines Brand name only	*Formulation Type Please indicate infused (IV), oral, subcutaneous (SC) or other	ORALS ONLY: REQUIRED PRESCRIPTION INFORMATION			
		Size/Strength	Quantity	Frequency/Directions For weight-based medications, please include exact dose or patient weight	Refills

Clinical trial participant for this medicine? ☐ Yes
☐ **Combination Therapy Benefits Investigation** Combination Therapy Regimen Name: _____
OR list cancer therapies prescribed in combination with Genentech medicine(s) OR attach medication list: _____
Where will medicines be administered? ☐ Physician's office ☐ HOPD ☐ Other (please specify): _____
Name: _____ Tax ID #: _____ NPI #: _____
Medication(s) dispensed through: ☐ Buy and bill ☐ Onsite pharmacy ☐ Specialty pharmacy (SP): _____

Step 8 Prescriber Information
*First Name: _____ *Last Name: _____
*Practice Name: _____
*Street: _____ Suite: _____ *City: _____
*State: _____ *ZIP: _____ Prescriber Tax ID # : _____ Prescriber NPI #: _____
Group NPI #: _____ Office Contact: _____ Office Contact Email: _____
Office Contact Phone: (____) ____-____ Office Contact Fax: (____) ____-____

If you are a resident of a US state that provides certain rights with respect to your personal information, a complete description of the personal information we may collect and process, the purposes for which it is used by Genentech, and your rights under your state's privacy laws concerning your personal information can be found in our privacy notice at https://www.gene.com/privacy-policy.

Step 9 Health Care Provider Certification
By submitting this form, I certify: (a) The above therapy is medically necessary for this patient and the treatment decision has been made by the prescribing physician. (b) If the indication for which this Genentech product is being prescribed to treat is not listed in the FDA-approved label, the prescriber is prescribing the medication for an "unapproved" use, meaning that the FDA has not approved the efficacy, dosage amount or safety of this medication for such a use. (c) The provider's office received the authorization to release the information above and other protected health information (as defined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA)) to Genentech, Inc., Genentech Access Solutions, the contracted dispensing pharmacy, or other contractors for the purpose of requesting reimbursement support, assisting in initiating or continuing therapy, as a break in treatment would negatively impact the patient's therapeutic outcome. (d) The provider's office will not attempt to seek reimbursement for free product provided to the patient. (e) The services requested on behalf of the patient may include benefits investigation (BI), prior authorization (PA) and appeals support, co-pay program referral or enrollment and co-pay assistance foundation referral. (f) No action on these services will be taken until the patient consent document has been received.

Step 10 ORALS ONLY Prescriber's Signature Required
By signing this form, I certify: (a) - (f) in Step 9 and: **(g) For prescribers in states with official prescription form requirements, such as New York, prescriptions must be submitted on an official state prescription pad along with this enrollment form.**
Sign, date & fax to (877) 313-2659 **Prescriber's Signature:** _____ **Date:** ____/____/____ (Original or stamped signature required)

Phone: (888) 249-4918 | **Fax:** (888) 249-4919 | **Genentech-Access.com/HCP/Oncology** | M-US-00019768(v4.0) 2 of 2

Finding and submitting the form

Where to Find	Genentech-Access.com/POLIVY
Options to Submit	eSubmit using Quick Enroll Complete online using My Patient Solutions® for Health Care Practices Fax to (888) 249-4919

Please see the full **Prescribing Information** and pages 28-29 for additional Important Safety Information.

POLIVY™ polatuzumab vedotin-piiq
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Sample Coding for POLIVY

This coding information may assist you as you complete the payer forms for POLIVY.

Diagnosis codes

	Code	Description
ICD-10-CM	C83.30	Diffuse large B-cell lymphoma, unspecified site
	C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
	C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
	C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
	C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
	C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
	C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
	C83.37	Diffuse large B-cell lymphoma, spleen
	C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
	C83.398	Diffuse large B-cell lymphoma of other extranodal and solid organ sites
HCPCS	J9309	Injection, polatuzumab vedotin-piiq, 1 mg
HCPCS modifier*	JW	Drug amount discarded/not administered to any patient
	JZ	Zero drug amount discarded/not administered to any patient
	10-Digit / **11-Digit**	
NDC	50242-103-01 / 50242-0103-01	30-mg single-dose vial
	50242-105-01 / 50242-0105-01	140-mg single-dose vial
CPT	96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
	96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)
	96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (List separately in addition to code for primary procedure)

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code.

*The JW modifier is required on claims for all single-dose container or single-dose drugs when an amount is discarded. Beginning July 1, 2023, CMS requires the use of the JZ modifier to indicate there were no units of a drug discarded. While not required until July 1, 2023, the JZ modifier is available for use as of January 1, 2023. For more information, visit CMS.gov.

These codes are not all-inclusive; appropriate codes can vary by patient, setting of care and payer. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Genentech does not make any representation or guarantee concerning reimbursement or coverage for any item or service.

Many payers will not accept unspecified codes. If you use an unspecified code, please check with your payer.

Your Resource for Access and Reimbursement Support

Genentech Access Solutions offers a range of access and reimbursement support for your patients and practice.

- Benefits investigations (BIs) and benefits reverification support
- Prior authorization (PA) resources
- Resources for denials and appeals
- Information about authorized distributors (see pages 18-19)
- Sample billing and coding information
- Referrals to financial assistance options (see pages 22-27)

Coverage and reimbursement resources

Benefits investigations

We can conduct a BI to help you determine:

- If POLIVY is covered or denied
- If PAs are required
- The patient's cost share, so you can see if financial assistance might be needed

Prior authorization resources

If a PA is necessary, we can:

- Help identify the required forms and documents for your submission to the health insurance plan
- Offer resources as you request the PA for your patient, including considerations for composing a letter of medical necessity

Denial and appeal resources†

If a plan issues a denial, the denial should be reviewed, along with the health insurance plan's guidelines, to determine what to include in your patient's appeal submission. Your Genentech representative or Genentech Access Solutions Specialist has local payer coverage expertise and can help you determine specific requirements for your patient.

Genentech provides coverage and reimbursement services to patients to help them understand benefits, coverage and reimbursement. Genentech provides these services to patients only after a health care provider has prescribed a Genentech product.

The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and health care provider. Genentech makes no representation or guarantee concerning coverage or reimbursement for any service or item.

†Appeals cannot be completed or submitted by Genentech Access Solutions on your behalf.

Please see the full **Prescribing Information** and pages 28-29 for additional Important Safety Information.

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Composing a Sample Appeal Letter

When a patient's health insurance plan denies your request for prior authorization (PA) or coverage for POLIVY, you may submit an appeal. When submitting an appeal to a patient's health insurance plan, including an Appeal Letter can help explain the rationale and clinical decision-making behind the choice of POLIVY.

Tips for drafting an Appeal Letter

The first step when filing an appeal is to understand the reason for a denial.

- This can be found in the explanation of benefits (EOB) or the denial letter

Coverage can be denied for various reasons, such as:

- Simple errors on the forms, including coding errors
- Failure to obtain or document necessary PAs
- Payer determining that the treatment is not covered

Be sure to identify the payer-specific appeals process and deadlines. If there was a documentation error, contact the payer to adjust or correct the form.

Be detailed and thorough. Recommended information for an Appeal Letter includes:

1. Patient information:
   - Full name
   - Insurance group number
   - Date of birth
   - Case ID number
   - Insurance ID number
2. An introduction stating the purpose of the Appeal Letter (i.e., the reason for the denial) that indicates you are familiar with the health insurance plan's policy.
3. A summary of the patient's diagnosis and the indication for the Genentech medicine being prescribed. Be sure to include: The diagnosis code(s) (ICD-10-CM), the severity of the patient's condition, prior treatment(s) including the duration of each and the patient's response to each treatment.
4. The clinical rationale for treatment, including clinical trial data supporting the FDA approval of this drug, administration and dosing information.
5. An explanation of why the plan's preferred formulary treatments may not be appropriate for the patient.
6. A summary of your recommendation.
7. Additional enclosures, including:
   - The Letter of Medical Necessity
   - Pathology reports
   - Prescribing information
   - Relevant peer-reviewed articles
   - Clinical notes/medical records
   - Clinical practice guidelines
   - Diagnostic test results
   - FDA approval letter
   - Scans for showing progressive disease

A Use the physician's letterhead to print the letter.

B Learn the reasons for the denial by reviewing the EOB or denial letter.

C See page 10 for sample ICD-10-CM codes for POLIVY.

D Visit Forms and Documents at **Genentech-Access.com** to find the full Prescribing Information and a link to the FDA approval letter.

A
[Payer name]
ATTN: APPEALS
[Payer contact name]
[Payer address]
[City], [State] [ZIP]

Patient: [Patient first and last name]
Subscriber ID #: [Insurance ID #]
Subscriber Group #: [Insurance group #]
Re: POLIVY® (polatuzumab vedotin-piiq)
Date[s] of Service: [Include all denied dates of service]

Dear Appeals Reviewer:

B
I am writing to request [appeal/redetermination/reconsideration] of the above denial[s] of POLIVY® (polatuzumab vedotin-piiq) for my patient [patient name]. I understand from your denial letter that the denials were based on [denial reason]. I would like to address [that reason/those reasons] now. A prompt review of the enclosed information demonstrating medical necessity and coverage for POLIVY is appreciated.

Patient's diagnosis, medical history and treatment plan

[Patient name] is [a/an] [age]-year-old [male/female/transgender] who was diagnosed on [date] with diffuse large B-cell lymphoma. They have been in my care since [date], having been referred to me by [Referring Physician Name] for [reason].

C
[Brief summary of rationale for treatment with POLIVY. This includes a brief description of the patient's diagnosis, including the ICD-10-CM code, the severity of the patient's condition, prior treatments, the duration of each, responses to those treatments, the rationale for discontinuation, as well as other factors (e.g., underlying health issues, age) that have affected your treatment selection.]

Treatment plan

On April 19, 2023, the US Food and Drug Administration (FDA) approved POLIVY in combination with rituximab, cyclophosphamide, doxorubicin and prednisone (R-CHP) for the first-line treatment of diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index score of 2 or greater.

[Include plan of treatment (dosage, length of treatment) and clinical practice guidelines that support the use of POLIVY. Consider mentioning experts in the field who also support the treatment.]

Summary

I believe POLIVY is appropriate and medically necessary for this patient and will provide coverage for this treatment. If you have any further questions about this matter, please contact me at [Physician Phone Number] or via email at [Physician Email]. Thank you for your time and consideration.

Sincerely,

[Physician Name and Credentials]

D
Enclosures
[List enclosures, which may include: the Letter of Medical Necessity, prescribing information, clinical notes/medical records, diagnostic test results, relevant peer-reviewed articles, clinical practice guidelines, FDA approval letter, scans showing progressive disease, pathology reports.]

ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification.

The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and health care provider. Genentech makes no representation or guarantee concerning coverage or reimbursement for any service or item.

Please remember to keep complete records, including a copy of the materials that you send and a log of telephone calls made to the patient's health insurance plan.

FDA=US Food and Drug Administration; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification.

Please see the full **Prescribing Information** and pages 28-29 for additional Important Safety Information.

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INJECTION FOR INTRAVENOUS USE 30 MG | 140 MG

Composing a Sample Letter of Medical Necessity

When submitting a PA request to a patient's health insurance plan, including a Letter of Medical Necessity can help explain the rationale and clinical decision-making behind the choice of POLIVY.

Tips for drafting a Letter of Medical Necessity

To help avoid denials when you submit the PA request to the payer, familiarize yourself with the plan's specific guidelines (e.g., obtain any necessary referrals, determine if treatment must be given in a particular setting).

Be sure to know and meet all deadlines for submitting the PA form and other required documents. Once you have received the PA, check with the payer to determine the length of the authorization, as this can vary.

Be detailed and thorough. Recommended information for a Letter of Medical Necessity includes:

1. Patient information:
   - Full name
   - Insurance group number
   - Date of birth
   - Case ID number
   - Insurance ID number
2. The patient's diagnosis and the indication for the Genentech medicine being prescribed.
3. The severity of the patient's condition.
4. A summary of the patient's previous treatments, the duration of each and the rationale for discontinuation. Include coding information for prior treatments/services to help the health insurance plan conduct their research in a timely manner.
5. The clinical rationale for treatment, including clinical trial data supporting the FDA approval of this drug, administration and dosing information.
6. A summary of your recommendation.
7. Additional enclosures, including:
   - Prescribing information
   - Pathology reports
   - Clinical notes/medical records
   - Relevant peer-reviewed articles
   - Diagnostic test results
   - FDA approval letter
   - Scans for showing progressive disease

A Use the physician's letterhead to print the letter.

B See page 10 for sample ICD-10-CM codes for POLIVY.

C Visit Forms and Documents at **Genentech-Access.com** to find the full Prescribing Information and a link to the FDA approval letter.

A [Date]

[Payer name]
ATTN: Medical Director
[Payer contact name]
[Payer address]
[City], [State] [ZIP]

Re: Letter of Medical Necessity for POLIVY® (polatuzumab vedotin-piiq)
Patient: [Patient first and last name]
Subscriber ID #: [Insurance ID #]
Subscriber Group #: [Insurance group #] Date[s] of Service: [Dates]

Dear Medical Director:

I am writing on behalf of my patient, [patient name], to [request prior authorization/document medical necessity] for treatment with POLIVY® (polatuzumab vedotin-piiq). This letter provides information about the patient's medical history and diagnosis, and a statement summarizing my treatment plan.

Patient's clinical history

[Patient name] is [a/an] [age]-year-old [male/female/transgender] who was diagnosed on [date] with diffuse large B-cell lymphoma. They have been in my care since [date], having been referred to me by [Referring Physician Name] for [reason].

B [Brief summary of rationale for treatment with POLIVY. This includes a brief description of the patient's diagnosis, including the ICD-10-CM code, the severity of the patient's condition, prior treatments, the duration of each, responses to those treatments, the rationale for discontinuation, as well as other factors (e.g., underlying health issues, age) that have affected your treatment selection. This may include:]

Treatment plan

On April 19, 2023, the US Food and Drug Administration (FDA) approved POLIVY in combination with rituximab, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the first-line treatment of diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index score of 2 or greater.

[Include plan of treatment (dosage, length of treatment) and clinical practice guidelines that support the use of POLIVY. Consider mentioning experts in the field who also support the treatment.]

Summary

Based on the above facts, I believe POLIVY is indicated and medically necessary for this patient. If you have any further questions about this matter, please contact me at [Physician Phone Number] or via email at [Physician Email]. Thank you for your time and consideration.

Sincerely,

[Physician Name and Credentials]

C **Enclosures**

[List enclosures, which may include: POLIVY full Prescribing Information, clinical notes/medical records, diagnostic test results, relevant peer-reviewed articles, FDA approval letter, scans showing progressive disease, pathology reports.]

ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification.

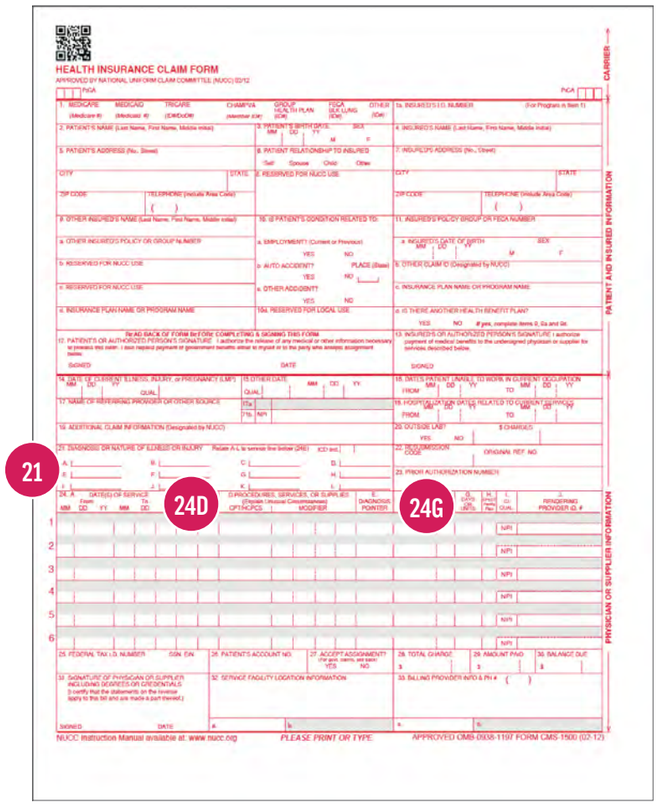
The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and health care provider. Genentech makes no representation or guarantee concerning coverage or reimbursement for any service or item.

Please remember to keep complete records, including a copy of the materials that you send and a log of telephone calls made to the patient's health insurance plan.

Please see the full **Prescribing Information** and pages 28-29 for additional Important Safety Information.

POLIVY™ polatuzumab vedotin-piiq
INJECTION FOR INTRAVENOUS USE 30MG | 140MG

Example CMS-1500 Claim Form: Physician Office Setting



Tips for completing the form

The CMS-1500 claim form is used to bill for services provided in a noninstitutional setting. Accurate completion of this form can help prevent potential reimbursement problems.

21 **Diagnosis code (field 21):** Insert appropriate ICD-10-CM diagnosis code(s).

24D **Procedure and product codes (field 24D):** Document use of POLIVY with J9309 (injection, polatuzumab vedotin-piiq, 1 mg) on one line and the appropriate CPT administration code on a separate line.

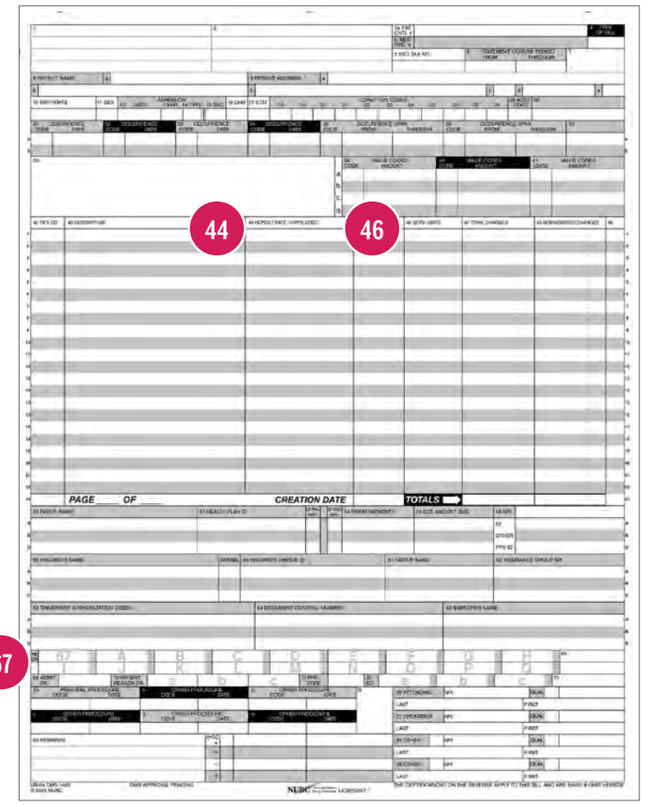
24G **Units administered (field 24G):** Enter the number of units used for each line item. For more information, please refer to POLIVY full Prescribing Information.

Also remember to:

- Check your billable units
- Double-check to make sure all coding information, including modifier language, is accurate (see page 10 for sample coding information for POLIVY)
- Review each claim to avoid simple errors, such as misspellings
- File claim promptly after the service has been rendered
- Follow up with insurers in the interest of timely claim processing

Note: Some payers may require that you bill spoilage separately. Please check with your payer. Payers may require the NDC in addition to the J-code.

Example CMS-1450 Claim Form: HOPD and Alternate Infusion Center Settings



Tips for completing the form

The CMS-1450 claim form is used to bill for services provided in the institutional (e.g., HOPD) setting. Accurate completion of this form can help prevent potential reimbursement problems.

44 **Procedure and product codes (field 44):** Document use of POLIVY with J9309 (injection, polatuzumab vedotin-piiq, 1 mg) on one line and the appropriate CPT administration code on a separate line.

46 **Units administered (field 46):** Enter the number of units used for each line item. For more information, please refer to the POLIVY full Prescribing Information.

67 **Diagnosis code (field 67):** Insert appropriate ICD-10-CM diagnosis code(s).

For more information on dosing, please refer to the accompanying full Prescribing Information.

CPT=Current Procedural Terminology; HOPD=hospital outpatient department; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code.

Please see the full **Prescribing Information** and pages 28-29 for additional Important Safety Information.

POLIVY™ polatuzumab vedotin-piiq INJECTION FOR INTRAVENOUS USE 30 MG | 140 MG

Authorized Specialty Distributors for POLIVY*

Genentech has contracted with a network of authorized specialty distributors to service practices choosing to purchase POLIVY through the buy and bill model. Customers can purchase POLIVY through authorized specialty distributors and wholesalers that have made a commitment to product integrity. These partners have agreed to distribute only products purchased directly from Genentech and not to distribute POLIVY through secondary channels.

	Specialty Distributors	Telephone	Fax	Web Orders
Distributors for Federal Accounts	ASD Healthcare (Cencora)	800-746-6273	800-547-9413	www.asdhealthcare.com
	Besse Medical (Cencora)	800-543-2111	800-543-8695	www.besse.com/home
	Cardinal Health Specialty Distribution	866-677-4844	N/A	https://www.cardinalhealth.com/en/solutions/specialty-distribution.html
	Dakota Drug	866-210-5887	763-421-0661	www.dakdrug.com/ContactUs.aspx
	DMS Pharmaceutical	877-788-1100	847-518-1105	www.dmspharma.com/contact-us
	McKesson Plasma and Biologics (MPB)	877-625-2566	N/A	www.mckesson.com/Pharmaceutical-Distribution/Plasma-Biologics/
	Metro Medical (Cardinal Health)	800-768-2002	615-256-4194	www.metromedicalorder.com
	Oncology Supply (Cencora)	800-633-7555	800-248-8205	www.oncologysupply.com/
Distributors for Hospitals	ASD Healthcare (Cencora)	800-746-6273	800-547-9413	www.asdhealthcare.com
	Besse Medical (Cencora)	800-543-2111	800-543-8695	www.besse.com/home
	Cardinal Health Specialty Distribution	866-677-4844	N/A	https://www.cardinalhealth.com/en/solutions/specialty-distribution.html
	CuraScript SD (Priority Health)	877-599-7748	800-862-6208	curascriptsd.com/Contact-Us
	McKesson Plasma and Biologics (MPB)	877-625-2566	N/A	www.mckesson.com/Pharmaceutical-Distribution/Plasma-Biologics/
	Metro Medical (Cardinal Health)	800-768-2002	615-256-4194	www.metromedicalorder.com
	Morris & Dickson Specialty Distribution	800-710-6100	318-524-3096	www.mdspecialtydist.com
	Oncology Supply (Cencora)	800-633-7555	800-248-8205	www.oncologysupply.com/
Distributors for Physician Offices and Federally Qualified Health Centers	ASD Healthcare (Cencora)	800-746-6273	800-547-9413	www.asdhealthcare.com
	Besse Medical (Cencora)	800-543-2111	800-543-8695	www.besse.com/home
	Cardinal Health Specialty Distribution	866-677-4844	N/A	https://www.cardinalhealth.com/en/solutions/specialty-distribution.html
	CuraScript SD (Priority Health)	877-599-7748	800-862-6208	curascriptsd.com/Contact-Us
	McKesson Specialty Health (McKesson Specialty Care Distribution Corporation)	800-482-6700	N/A	www.mckesson.com/specialty/
	Metro Medical (Cardinal Health)	800-768-2002	615-256-4194	www.metromedicalorder.com
	Oncology Supply (Cencora)	800-633-7555	800-248-8205	www.oncologysupply.com/
Distributors for Authorized Specialty Pharmacies	ASD Healthcare (Cencora)	800-746-6273	800-547-9413	www.asdhealthcare.com
	Besse Medical (Cencora)	800-543-2111	800-543-8695	www.besse.com/home
	Cardinal Health Specialty Distribution	866-677-4844	N/A	https://www.cardinalhealth.com/en/solutions/specialty-distribution.html
	CuraScript SD (Priority Health)	877-599-7748	800-862-6208	www.curascriptsd.com
	McKesson Plasma and Biologics (MPB)	877-625-2566	N/A	www.mckesson.com/Pharmaceutical-Distribution/Plasma-Biologics/
	Metro Medical (Cardinal Health)	800-768-2002	615-256-4194	www.metromedicalorder.com
	Oncology Supply (Cencora)	800-633-7555	800-248-8205	www.oncologysupply.com/
Distributors for Puerto Rico	Cardinal Health Puerto Rico	787-625-4200	N/A	https://cardinalhealth.pr/
	Cesar Castillo (Puerto Rico)	787-999-1616	787-999-1618	cesarcastillo.net/welcome/

An up-to-date list of authorized distributors is available at **Genentech-Access.com/POLIVY**.

*Genentech does not influence or advocate the use of any one specialty distributor. We make no representation or guarantee of service or coverage of any item.

Please see the full **Prescribing Information** and pages 28-29 for additional Important Safety Information.

POLIVY™ polatuzumab vedotin-piiq INJECTION FOR INTRAVENOUS USE 30MG | 140MG

Assistance If POLIVY Is Spoiled or Damaged

The **Genentech Spoilage Replacement Program** provides for replacement of infused, injected and self-administered products, which are prescribed and prepared for a labeled indication, yet not administered due to unforeseen patient clinical circumstances, subject to certain limitations and conditions set forth by Genentech. The purpose of the program is to support our commitment to protecting patient safety by preventing the use of spoiled, damaged or contaminated products.

Important points to remember:

- Replacement is on a case-by-case basis at the sole discretion of Genentech
- Genentech does not ship replacement product if any portion of the product has been administered
- The online Spoilage Form allows you to make corrections to previously submitted forms and save a draft to complete requests at a later date

Please contact Genentech Customer Service at **(800) 551-2231** or visit **www.spoilage.gene.com** to submit a request for replacement of spoiled product or to obtain additional information about the program.

Financial Assistance Options

At Genentech, we understand patients may have financial concerns related to their treatment. We are dedicated to helping ensure POLIVY is accessible for the patients who have been prescribed it.

Several options are available to help eligible patients with the out-of-pocket (OOP) costs of POLIVY.

For patients with commercial health insurance

The **Genentech Oncology Co-pay Assistance Program*** provides financial assistance to eligible commercially insured patients to help with their co-pays, co-insurance or other OOP costs.

For patients with public or commercial health insurance

We offer referrals to **independent co-pay assistance foundations**† for eligible patients who are commercially or publicly insured, including those covered by Medicare and Medicaid.

For patients who don't have insurance coverage or who have financial concerns and meet eligibility criteria

The **Genentech Patient Foundation**‡ provides eligible patients their POLIVY free of charge.

*Eligibility criteria apply. Not valid for patients using federal or state government programs to pay for their Genentech medicine. Patients must be taking the Genentech medicine for an FDA-approved indication. Please visit the Co-pay Program website for the full list of Terms and Conditions.

†Independent co-pay assistance foundations have their own rules for eligibility. Genentech has no involvement or influence in independent foundation decision-making or eligibility criteria and does not know if a foundation will be able to help your patient. We can only refer your patient to a foundation that supports their disease state. Genentech does not endorse or show preference for any particular foundation. The foundations to which we refer your patient may not be the only ones that might be able to help.

‡To be eligible for free Genentech medicine from the Genentech Patient Foundation, insured patients who have coverage for their medicine should try to pursue other forms of financial assistance, if available, and meet certain income requirements. Uninsured patients and insured patients without coverage for their medicine must meet a different set of income requirements. Genentech reserves the right to modify or discontinue the program at any time and to verify the accuracy of information submitted.

Please see the full **Prescribing Information** and pages 28-29 for additional Important Safety Information.

POLIVY™
polatuzumab vedotin-piiq
INJECTION FOR INTRAVENOUS USE 30 MG | 140 MG

Genentech Oncology Co-pay Assistance Program

If eligible commercially insured patients need help with their co-pays, the **Genentech Oncology Co-pay Assistance Program** may be able to help.

Eligible patients pay as little as $0 for their prescribed Genentech Oncology product(s).

The program covers the rest of the patient's co-pay, up to a $25,000 annual benefit.

There are no income requirements.

DoD=Department of Defense; VA=Department of Veterans Affairs.

The Co-pay Program ("Program") is valid ONLY for patients with commercial (private or non-governmental) insurance who have a valid prescription for a Food and Drug Administration (FDA)-approved indication of a Genentech medicine. Patients using Medicare, Medicaid or any other federal or state government program (collectively, "Government Programs") to pay for their Genentech medicine are not eligible.

Under the Program, the patient may be required to pay a co-pay. The final amount owed by a patient may be as little as $0 for the Genentech medicine (see Program specific details available at the Program website). The total patient out-of-pocket cost is dependent on the patient's health insurance plan. The Program assists with the cost of the Genentech medicine only. It does not assist with the cost of other medicines, procedures or office visit fees. After reaching the maximum annual Program benefit amount, the patient will be responsible for all remaining out-of-pocket expenses. The Program benefit amount cannot exceed the patient's out-of-pocket expenses for the Genentech medicine.

All participants are responsible for reporting the receipt of all Program benefits as required by any insurer or by law. The Program is only valid in the United States and U.S. Territories, is void where prohibited by law and shall follow state restrictions in relation to AB-rated generic equivalents (e.g., MA, CA) where applicable. No party may seek reimbursement for all or any part of the benefit received through the Program. The value of the Program is intended exclusively for the benefit of the patient. The funds made available through the Program may only be used to reduce the out-of-pocket costs for the patient enrolled in the Program. The Program is not intended for the benefit of third parties, including without limitation third party payers, pharmacy benefit managers, or their agents. If Genentech determines that a third party has implemented a program that adjusts patient cost-sharing obligations based on the availability of support under the Program and/or excludes the assistance provided under the Program from counting towards the patient's deductible or out-of-pocket cost limitations, Genentech may impose a per fill cap on the cost-sharing assistance available under the Program. Submission of true and accurate information is a requirement for eligibility and Genentech reserves the right to disqualify patients who do not comply from Genentech programs. Genentech reserves the right to rescind, revoke or amend the Program without notice at any time.

Additional terms and conditions apply. Please visit the Co-pay Program website for the full list of Terms and Conditions.

Oncology CO-PAY ASSISTANCE Program

Additional details

- $0 co-pay applies for FDA-approved Genentech combination products
- Retroactive requests for assistance from the Genentech Oncology Co-pay Assistance Program may be honored for qualifying patients if the infusion or prescription fill occurred within 180 days prior to enrollment and the patient meets all eligibility criteria at the time of infusion
- Claims must be submitted within 365 days from the date of service (DOS) for consideration
- No physical card needed; patients simply need their Member ID

Eligibility

In order to qualify for the Genentech Oncology Co-pay Assistance Program, patients must meet the following criteria:

- Covered by commercial (also known as private) insurance
- Not a participant in a federal or state-funded health care program, including but not limited to Medicare, Medicaid, VA/DoD, TRICARE and Medigap
- Are 18 years of age or older, or have a legal guardian 18 years of age or older to manage the program
- Live in and receive treatment in the United States or U.S. Territories
- Receiving a Genentech Oncology product for an FDA-approved indication
- Not receiving assistance through the Genentech Patient Foundation or any other co-pay charitable organization

Visit **CopayAssistanceNow.com** Call **(855) MY-COPAY** (855-692-6729)

Please see the full **Prescribing Information** and pages 28-29 for additional Important Safety Information.

POLIVY™ polatuzumab vedotin-piiq INJECTION FOR INTRAVENOUS USE 30 MG | 140 MG

Referrals to Independent Co-pay Assistance Foundations

We offer **referrals to independent co-pay assistance foundations*** for eligible patients who are commercially or publicly insured, including those covered by Medicare and Medicaid.

Key points to remember about independent co-pay assistance foundation referrals:

- Eligibility requirements, all aspects of the application process, turnaround times and the amount of assistance offered can vary by foundation
- If the patient is denied assistance by one co-pay assistance foundation, he or she can be referred to a different foundation, if one is available
- Patients referred for co-pay assistance need not be enrolled in Genentech Access Solutions and can simply call for a referral
- Patients can call the foundation directly to request assistance

Potential independent co-pay assistance foundations for hematology

- CancerCare Co-Payment Assistance Foundation
- Patient Access Network Foundation (PANF)
- The HealthWell Foundation
- The Leukemia and Lymphoma Society

These organizations may be able to help your patients. Please check their websites for up-to-date information on the assistance they provide.

Visit **Genentech-Access.com/POLIVY** for a list of potential independent co-pay assistance foundations.

*Independent co-pay assistance foundations have their own rules for eligibility. Genentech has no involvement or influence in independent foundation decision-making or eligibility criteria and does not know if a foundation will be able to help your patient. We can only refer your patient to a foundation that supports their disease state. Genentech does not endorse or show preference for any particular foundation. The foundations to which we refer your patient may not be the only ones that might be able to help.

Help for Eligible Patients Who Lack Insurance Coverage or Have Financial Concerns

The **Genentech Patient Foundation** provides free POLIVY to people who don't have insurance coverage or who have financial concerns and meet eligibility criteria, shown on the next page.

GENENTECH
PATIENT FOUNDATION

ELIGIBILITY CRITERIA

UNINSURED PATIENTS
With incomes under $150,000†

OR

INSURED PATIENTS WITHOUT COVERAGE for a Genentech medicine
With incomes under $150,000†

OR

INSURED PATIENTS WITH COVERAGE for a Genentech medicine‡

- With an out-of-pocket maximum (set by the health insurance plan) that is more than 7.5% of the patient's yearly income
- With household size and income within the guidelines listed below

HOUSEHOLD SIZE	ANNUAL INCOME
1	Less than $75,000
2	Less than $100,000
3	Less than $125,000
4	Less than $150,000†

†For all patient types, add $25,000 for each extra person in households larger than 4 people.
‡We encourage insured patients to pursue other financial assistance options prior to applying for help from the Genentech Patient Foundation, if possible.
Genentech reserves the right to modify or discontinue the program at any time and to verify the accuracy of information submitted.

Please see the full **Prescribing Information** and pages 28-29 for additional Important Safety Information.

POLIVY™
polatuzumab vedotin-piiq
INJECTION FOR INTRAVENOUS USE 30 MG | 140 MG

Tips for Completing the Prescriber Foundation Form

Along with the Patient Consent Form (see page 6), the Prescriber Foundation Form is used to enroll eligible patients in the Genentech Patient Foundation.

Note: This is a different form than the Prescriber Service Form for Genentech Access Solutions.

Use this form for direct enrollment in the Genentech Patient Foundation

A All fields marked with an asterisk (*) are required.

B To learn more about determining patient eligibility, see page 25 of this brochure or the first page of the form:

- If your patient is insured, be sure to attach the patient's health insurance information and pharmacy benefit or attach a copy of the patient's insurance card(s)

C Practices are encouraged to select one option (upfront or replacement) for all shipments.

D Complete this section only if requesting upfront shipments:

- You may attach a written prescription or send an electronic prescription if you prefer

E Original or stamped signatures are required for all requests.

Finding and submitting the form

Where to Find

GenentechPatientFoundation.com

Options to Submit

- eSubmit using Quick Enroll
- Complete online using My Patient Solutions® for Health Care Practices
- Fax to (833) 999-4363

Only the information requested on these forms is required. Providing unrequested documents or information will delay processing.

GENENTECH
PATIENT FOUNDATION

Prescriber Foundation Form
Prescriber to Complete
GenentechPatientFoundation.com

Complete online by scanning the QR code or visit **go.gene.com/EnrollQR**
Phone: (888) 941-3331 **Fax:** (833) 999-4363
*Required field M-US-00000344(v5.0)

A

B

STEP 1 — PATIENT ELIGIBILITY

*Please check one (refer to page 1 for details on each type):
☐ Uninsured
☐ **Insured** but lacks coverage for this medicine
☐ **Insured** with coverage but medicine is unaffordable
For insurance denials, provide denial date: ____/____/____
Denial reason (or attach copy of denial letter): _____

If unsure of patient's insurance status, please contact Genentech Access Solutions at (866) 422-2377.

STEP 2 — PATIENT INFORMATION

*First Name: _____ *Last Name: _____
*Date of Birth: ____/____/____ Gender: ☐ Male ☐ Female
*Street: _____ Apt: _____
*City: _____ *State: _____ *ZIP: _____
Phone: (____) _____ - _____ Phone Type: ☐ Cell ☐ Home
Preferred Language: ☐ English ☐ Spanish ☐ Other: _____
☐ Do not contact patient Alternate Contact: _____
Relationship to patient: _____
Alt Contact Phone: (____) _____ - _____ Phone Type: ☐ Cell ☐ Home

STEP 3 — INSURANCE INFORMATION: IF PATIENT HAS ANY INSURANCE, COMPLETE THIS SECTION OR ATTACH COPIES OF INSURANCE CARD(S).

	Primary Insurance	Secondary Insurance	Pharmacy Benefit
Insurance name			
Type (Comm, Medicare, Medicaid)			
Subscriber name (if not patient)			
Subscriber/Policy ID #			
Group #			
Insurance phone			
Maximum out of pocket			

STEP 4 — TREATMENT INFORMATION

*Genentech Medication(s): _____ *Primary Diagnosis Code: _____
Has Patient Started Therapy? ☐ Yes ☐ No Other Diagnosis Code(s): _____

C

STEP 5 — SHIPMENT INFORMATION

*Please check one shipment option:
☐ **Upfront**—Patient-specific medicine delivered to patient's home, practice or site of treatment.
☐ **Replacement**—Prescriber treats with own inventory, to be replaced by foundation.

Shipment to: ☐ Patient ☐ Prescriber/Practice ☐ Third-Party Site of Treatment (list below)
The information below is only required if receiving Genentech medication shipment to a site of treatment.
Site of Treatment Name: _____
Street: _____ Suite: _____
City: _____ State: _____ ZIP: _____
Contact Name: _____
Contact Phone: (____) _____ - _____ Contact Fax: (____) _____ - _____

D

STEP 6 — PRESCRIPTION INFORMATION

If preferred, you may attach a written prescription or submit the prescription electronically. Electronic prescriptions can be submitted through an e-prescribing software or an electronic medical record that has been certified by Surescripts. Query for Medvantx or AmeriPharm in Sioux Falls, SD 57014. NPI-1073692745 or NCPDP-4351968.

Genentech Medication(s)	Size/Strength	Quantity	Frequency/Directions (for weight-based medications, please include exact dose or patient weight)	Refills
				☐ 1 year ☐ Other: _____

Drug Allergies: ☐ No Known ☐ Other: _____
Other Medications Prescribed: _____

STEP 7 — PRESCRIBER INFORMATION

*First Name: _____ *Last Name: _____
Practice Name: _____ Prescriber NPI #: _____
*Street: _____ Suite: _____
*City: _____ *State: _____ *ZIP: _____
Office Contact Name: _____ Contact Phone: (____) _____ - _____ Contact Fax: (____) _____ - _____

If you are a resident of a US state that provides certain rights with respect to your personal information, a complete description of the personal information we may collect and process, the purposes for which it is used by Genentech, and your rights under your state's privacy laws concerning your personal information can be found in our privacy notice at **www.gene.com/privacy-policy**.

STEP 8 — HEALTH CARE PROVIDER CERTIFICATION

By signing below, I am agreeing to the following: (A) The Genentech medicine listed above is medically necessary for this patient. **(B)** I have received authorization to release the information above and other protected health information (as defined by HIPAA) to the Genentech Patient Foundation and its affiliates. **(C)** I will not seek reimbursement for free product provided to the patient. **(D)** My patient meets the criteria for the Genentech Patient Foundation and to the best of my knowledge, this patient has no prescription insurance coverage (including Medicaid, Medicare, or other public or private programs) for the Genentech medicine listed above, or is unable to afford the cost-sharing requirements associated with his/her/their insurance coverage for this medication. If the patient is enrolled in an insurance plan, the plan does not require the patient's application to the Genentech Patient Foundation and/or has not changed or hidden the patient's coverage for the Genentech medicine to make them appear to be underinsured and eligible for the Genentech Patient Foundation. **(E)** I understand that Genentech reserves the right to modify or discontinue the program at any time and to verify the accuracy of information submitted. **(F)** If the indication for which you are prescribing a Genentech product is not listed in the FDA-approved label, you are prescribing the medicine for an "unapproved" use, meaning that the FDA has not approved the efficacy, dosage amount or safety of this medicine when used for such a use. The Genentech Patient Foundation may provide the medicine for your patient, based upon your medical order and within program requirements. **(G)** For insured patients, I understand that the Genentech Patient Foundation does not provide free drug in the instance of an administrative error or a coverage restriction such as a step edit. For certain products where the step edit may not be medically appropriate, as confirmed by the prescribing physician, the Genentech Patient Foundation may consider support following 1 level of appeal. **(H)** For prescribers in states with electronic prescription requirements, such as New York, prescriptions must be submitted via e-prescription directly to the pharmacy along with this enrollment form.

E

Sign, date and fax to **(833) 999-4363**

*Health Care Provider Signature: _____ *Date: ____/____/____
(Original or stamped signature required)

HIPAA=Health Insurance Portability and Accountability Act of 1996; NPI=National Provider Identifier.
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Please see the full **Prescribing Information** and pages 28-29 for additional Important Safety Information.

POLIVY™
polatuzumab vedotin-piiq
INJECTION FOR INTRAVENOUS USE 30MG | 140MG

Connect Directly With Genentech—Call Our Patient Resource Center

People who call the **Genentech Patient Resource Center** can connect to a variety of assistance options, including:

- General questions about POLIVY
- Acquiring, storing or administering POLIVY
- Financial support options and understanding insurance coverage for POLIVY
- Patient educational materials and resources
- Product complaints, questions or wastage

Important Safety Information

Peripheral Neuropathy

POLIVY can cause severe peripheral neuropathy. Peripheral neuropathy occurs as early as the first cycle of treatment and is cumulative. POLIVY may exacerbate preexisting peripheral neuropathy.

In POLARIX, of 435 patients treated with POLIVY plus R-CHP, 53% reported new or worsening peripheral neuropathy, with a median time to onset of 2.3 months. Peripheral neuropathy was Grade 1 in 39% of patients, Grade 2 in 12%, and Grade 3 in 1.6%. Peripheral neuropathy resulted in dose reduction in 4% of treated patients and treatment discontinuation in 0.7%. Among patients with peripheral neuropathy after POLIVY, 58% reported resolution after a median of 4 months.

The peripheral neuropathy is predominantly sensory; however, motor and sensorimotor peripheral neuropathy also occur. Monitor for symptoms of peripheral neuropathy such as hypoesthesia, hyperesthesia, paresthesia, dysesthesia, neuropathic pain, burning sensation, weakness, or gait disturbance. Patients experiencing new or worsening peripheral neuropathy may require a delay, dose reduction, or discontinuation of POLIVY.

Infusion-Related Reactions

POLIVY can cause severe infusion reactions. Delayed infusion-related reactions as late as 24 hours after receiving POLIVY have occurred. With premedication, 13% of patients (58/435) in POLARIX reported infusion-related reactions after the administration of POLIVY plus R-CHP. The reactions were Grade 1 in 4.4% of patients, Grade 2 in 8%, and Grade 3 in 1.1%.

Symptoms occurring in ≥1% of patients included chills, dyspnea, pyrexia, pruritus, rash, and chest discomfort. Administer an antihistamine and an antipyretic prior to the administration of POLIVY, and monitor patients closely throughout the infusion. If an infusion-related reaction occurs, interrupt the infusion and institute appropriate medical management.

Myelosuppression

Treatment with POLIVY can cause serious or severe myelosuppression, including neutropenia, thrombocytopenia, and anemia. In POLARIX, 90% of patients treated with POLIVY plus R-CHP had primary prophylaxis with granulocyte colony-stimulating factor (G-CSF). Grade 3-4 hematologic adverse reactions included lymphopenia (44%), neutropenia (39%), febrile neutropenia (15%), anemia (14%), and thrombocytopenia (8%).

Monitor complete blood counts throughout treatment. Cytopenias may require a delay, dose reduction, or discontinuation of POLIVY. Administer prophylactic G-CSF for neutropenia.

Serious and Opportunistic Infections

Fatal and/or serious infections, including opportunistic infections such as sepsis, pneumonia (including *Pneumocystis jiroveci* and other fungal pneumonia), herpesvirus infection, and cytomegalovirus infection, have occurred in patients treated with POLIVY.

In POLARIX, Grade 3-4 infections occurred in 14% (61/435) of patients treated with POLIVY plus R-CHP and infection related deaths were reported in 1.1% of patients.

Closely monitor patients during treatment for signs of infection. Administer prophylaxis for *Pneumocystis jiroveci* pneumonia and herpesvirus. Administer prophylactic G-CSF for neutropenia as recommended.

Progressive Multifocal Leukoencephalopathy (PML)

Monitor for new or worsening neurological, cognitive, or behavioral changes. Hold POLIVY and any concomitant chemotherapy if PML is suspected, and permanently discontinue if the diagnosis is confirmed.

Tumor Lysis Syndrome

POLIVY may cause tumor lysis syndrome. Patients with high tumor burden and rapidly proliferating tumors may be at increased risk of tumor lysis syndrome. Monitor closely and take appropriate measures, including tumor lysis syndrome prophylaxis.

Hepatotoxicity

Serious cases of hepatotoxicity that were consistent with hepatocellular injury, including elevations of transaminases and/or bilirubin, have occurred in patients treated with POLIVY.

In recipients of POLIVY plus R-CHP, Grade 3–4 elevation of ALT and AST developed in 1.4% and 0.7% of patients, respectively.

Preexisting liver disease, elevated baseline liver enzymes, and concomitant medications may increase the risk of hepatotoxicity. Monitor liver enzymes and bilirubin level.

Embryo-Fetal Toxicity

Based on the mechanism of action and findings from animal studies, POLIVY can cause fetal harm when administered to a pregnant woman. When administered to rats, the small molecule component of POLIVY, monomethyl auristatin E, caused adverse developmental outcomes, including embryo-fetal mortality and structural abnormalities, at exposures below those occurring clinically at the recommended dose.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with POLIVY and for 3 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with POLIVY and for 5 months after the last dose.

The Most Common Adverse Reactions

The most common adverse reactions (≥20%), excluding laboratory abnormalities, are peripheral neuropathy, nausea, fatigue, diarrhea, constipation, alopecia, and mucositis. Grade 3 to 4 laboratory abnormalities (≥10%) are lymphopenia, neutropenia, hyperuricemia, and anemia.

Lactation

Advise women not to breastfeed during treatment with POLIVY and for 2 months after the last dose.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555.

Please see the full **Prescribing Information** for additional Important Safety Information.

POLIVY™
polatuzumab vedotin-piiq
INJECTION FOR INTRAVENOUS USE 30 MG | 140 MG

Patient Resources

Choose How You Connect With Us

Visit **Genentech-Access.com/POLIVY**

Call our Specialists at
(877) GENENTECH/(877) 436-3683

Get support from a
Genentech reimbursement representative

Manage your patients online with
My Patient Solutions® for Health Care Practices

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Please see the full **Prescribing Information** and pages 28-29 for additional Important Safety Information.

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