Permanent J-code effective January 1, 2024

Genentech
A Member of the Roche Group

GENENTECH PATIENT SUPPORT SERVICES

Access and Reimbursement Support for COLUMVI™ (glofitamab-gxbm)

NCCN
CATEGORY 2A

National Comprehensive Cancer Network® (NCCN®) recommends glofitamab-gxbm (COLUMVI) as a Category 2A treatment option, after at least two prior therapies for adult patients with diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS), or large B-Cell lymphoma (LBCL) arising from follicular lymphoma[1]

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.

NCCN=National Comprehensive Cancer Network.

Genentech-Access.com/COLUMVI

(877) GENENTECH/(877) 436-3683, Monday through Friday, 6 a.m.–5 p.m. PT

Indication

COLUMVI (glofitamab-gxbm) is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL), or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy.

This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Important Safety Information

BOXED WARNING: Cytokine Release Syndrome (CRS), including serious or fatal reactions, can occur in patients receiving COLUMVI. Premedicate before each dose, and initiate treatment with the COLUMVI step-up dosing schedule to reduce the risk of CRS. Withhold COLUMVI until CRS resolves or permanently discontinue based on severity.

Please see the COLUMVI full Prescribing Information for additional Important Safety Information, including **BOXED WARNING**.

COLUMVI™
glofitamab-gxbm
injection for intravenous use 2.5 mg | 10 mg

Inside This Brochure

AIC=alternate infusion center; HOPD=hospital outpatient department.

Genentech Is Here to Support Patients After COLUMVI Has Been Prescribed

At Genentech, we work every day to help patients who have been prescribed COLUMVI, 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

- Contact your Genentech representative if you have any questions about coverage or financial assistance options

Do not have health insurance coverage or have financial concerns and meet 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, **COLUMVI Patient Education and Treatment Resources** provide information about COLUMVI

*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.

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/or the Genentech Patient Foundation and manage your service requests.

Features of My Patient Solutions include:

Messaging—send messages to your Genentech Access Solutions Specialist and receive responses within the system

Paperless enrollment and re-enrollment—enroll and re-enroll your patients 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

Co-pay assistance details—view your enrolled patients' status

Genentech Patient Foundation information—view eligibility and coordinate shipments

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

PATIENT

PATIENTS complete and sign the Patient Consent Form

SERVICE

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 page 28.

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

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 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 page 27 for more information).

D Patients complete this section to enroll in **optional** and free programs from Genentech, including COLUMVI 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
(Both English and Spanish versions)

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(v2.0)

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 1.
Household size (including you): _____ Annual household income: ☐ Under $75,000
☐ $75,000 – $100,000 ☐ $100,001 – $125,000 ☐ $125,001 – $150,000 ☐ Over $150,000

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. 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 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 (3/3) 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.

3 of 3

Tips for Completing the Prescriber Service Form

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

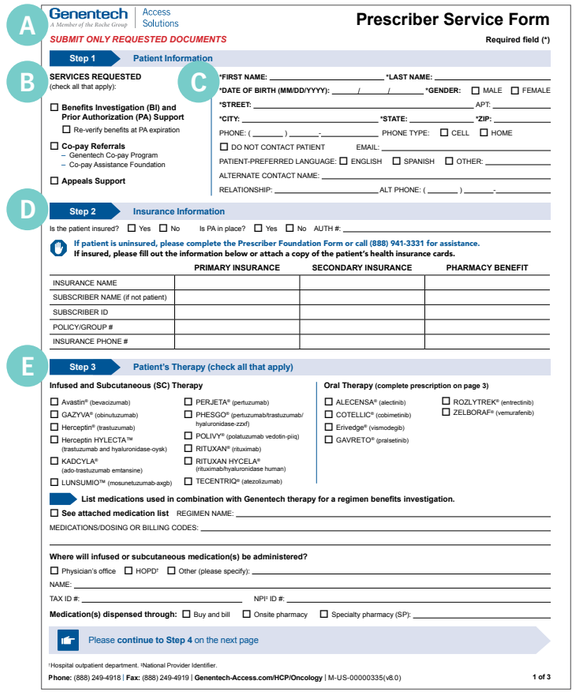
A Only the information requested on this form is required. Providing unrequested documents or information will delay processing.

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 Select COLUMVI as your patient's therapy and provide additional details about their treatment.



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Prescriber Service Form

SUBMIT ONLY REQUESTED DOCUMENTS

Required field (*)

Step 1 Patient Information

B SERVICES REQUESTED (check all that apply):

- ☐ Benefits Investigation (BI) and Prior Authorization (PA) Support
  - ☐ Re-verify benefits at PA expiration
- ☐ Co-pay Referrals
  - – Genentech Co-pay Program
  - – Co-pay Assistance Foundation
- ☐ Appeals Support

C

*FIRST NAME: _____ *LAST NAME: _____

*DATE OF BIRTH (MM/DD/YYYY): ___/___/___ *GENDER: ☐ MALE ☐ FEMALE

*STREET: _____ APT: _____

*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: (___) ___-___

D **Step 2** Insurance Information

Is the patient insured? ☐ Yes ☐ No Is PA in place? ☐ Yes ☐ No AUTH #: _____

If patient is uninsured, please complete the Prescriber Foundation Form or call (888) 941-3331 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	PHARMACY BENEFIT
INSURANCE NAME			
SUBSCRIBER NAME (if not patient)			
SUBSCRIBER ID			
POLICY/GROUP #			
INSURANCE PHONE #			

E **Step 3** Patient's Therapy (check all that apply)

Infused and Subcutaneous (SC) Therapy

- ☐ Avastin® (bevacizumab)
- ☐ GAZYVA® (obinutuzumab)
- ☐ Herceptin® (trastuzumab)
- ☐ Herceptin HYLECTA™ (trastuzumab and hyaluronidase-oysk)
- ☐ KADCYLA® (ado-trastuzumab emtansine)
- ☐ LUNSUMIO™ (mosunetuzumab-axgb)
- ☐ PERJETA® (pertuzumab)
- ☐ PHESGO® (pertuzumab/trastuzumab/hyaluronidase-zzxf)
- ☐ POLIVY® (polatuzumab vedotin-piiq)
- ☐ RITUXAN® (rituximab)
- ☐ RITUXAN HYCELA® (rituximab/hyaluronidase human)
- ☐ TECENTRIQ® (atezolizumab)

Oral Therapy (complete prescription on page 3)

- ☐ ALECENSA® (alectinib)
- ☐ COTELLIC® (cobimetinib)
- ☐ Erivedge® (vismodegib)
- ☐ GAVRETO® (pralsetinib)
- ☐ ROZLYTREK® (entrectinib)
- ☐ ZELBORAF® (vemurafenib)

List medications used in combination with Genentech therapy for a regimen benefits investigation.

☐ See attached medication list REGIMEN NAME: _____

MEDICATIONS/DOSING OR BILLING CODES: _____

Where will infused or subcutaneous medication(s) be administered?

☐ Physician's office ☐ HOPD† ☐ Other (please specify): _____

NAME: _____

TAX ID #: _____ NPI‡ ID #: _____

Medication(s) dispensed through: ☐ Buy and bill ☐ Onsite pharmacy ☐ Specialty pharmacy (SP): _____

Please continue to Step 4 on the next page

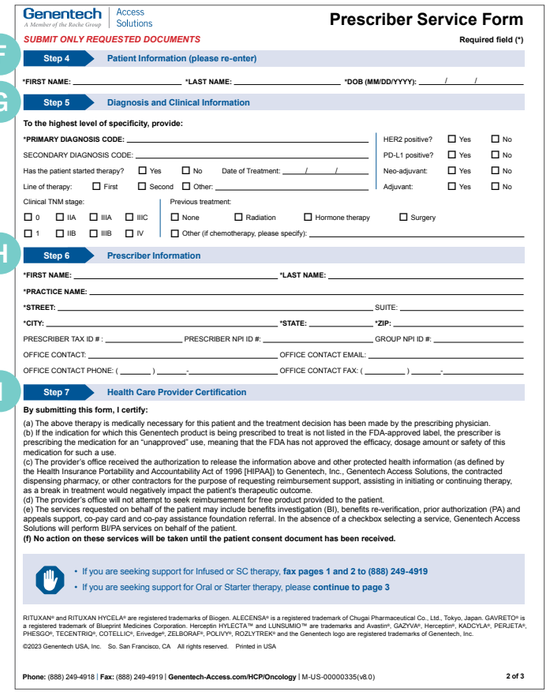
†Hospital outpatient department. ‡National Provider Identifier.

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

G 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/COLUMVI**.

H Complete your practice information. When you complete the Prescriber Service Form via My Patient Solutions® for Health Care Practices, this information is prepopulated (see page 4 for more information).

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



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Prescriber Service Form

SUBMIT ONLY REQUESTED DOCUMENTS

Required field (*)

F **Step 4** Patient Information (please re-enter)

*FIRST NAME: _____ *LAST NAME: _____ *DOB (MM/DD/YYYY): ___/___/___

G **Step 5** Diagnosis and Clinical Information

To the highest level of specificity, provide:

*PRIMARY DIAGNOSIS CODE: _____

SECONDARY DIAGNOSIS CODE: _____

Has the patient started therapy? ☐ Yes ☐ No Date of Treatment: ___/___/___

Line of therapy: ☐ First ☐ Second ☐ Other: _____

Clinical TNM stage:
☐ 0 ☐ IIA ☐ IIIA ☐ IIIC
☐ 1 ☐ IIB ☐ IIIB ☐ IV

Previous treatment:
☐ None ☐ Radiation ☐ Hormone therapy ☐ Surgery
☐ Other (if chemotherapy, please specify): _____

HER2 positive? ☐ Yes ☐ No
PD-L1 positive? ☐ Yes ☐ No
Neo-adjuvant: ☐ Yes ☐ No
Adjuvant: ☐ Yes ☐ No

H **Step 6** Prescriber Information

*FIRST NAME: _____ *LAST NAME: _____

*PRACTICE NAME: _____

*STREET: _____ SUITE: _____

*CITY: _____ *STATE: _____ *ZIP: _____

PRESCRIBER TAX ID # : _____ PRESCRIBER NPI ID #: _____ GROUP NPI ID #: _____

OFFICE CONTACT: _____ OFFICE CONTACT EMAIL: _____

OFFICE CONTACT PHONE: (___) ___-___ OFFICE CONTACT FAX: (___) ___-___

I **Step 7** 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), benefits re-verification, prior authorization (PA) and appeals support, co-pay card and co-pay assistance foundation referral. In the absence of a checkbox selecting a service, Genentech Access Solutions will perform BI/PA services on behalf of the patient.
(f) No action on these services will be taken until the patient consent document has been received.

- If you are seeking support for Infused or SC therapy, **fax pages 1 and 2 to (888) 249-4919**
- If you are seeking support for Oral or Starter therapy, please **continue to page 3**

Finding and submitting the form

Where to Find	Genentech-Access.com/COLUMVI
Options to Submit	Complete online using My Patient Solutions Fax to (888) 249-4919

Sample Billing and Coding for COLUMVI

Diagnosis codes

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

Type	Code	Description
Diagnosis: 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

Other important codes

The Centers for Medicare & Medicaid Services have assigned a **permanent J-code** for COLUMVI for dates of service **effective January 1, 2024**.

Type	Code		Description
NTAP: ICD-10-PCS[2]*	XW033P9		Introduction of glofitamab antineoplastic into peripheral vein, percutaneous approach, new technology group 9
	XW043P9		Introduction of glofitamab antineoplastic into central vein, percutaneous approach, new technology group 9
Drug: HCPCS	J9286		Injection, glofitamab-gxbm, 2.5 mg
HCPCS modifier†	JZ		Zero drug amount discarded/not administered to any patient
Drug: NDC	**10-digit**	**11-digit**	
	50242-125-01	50242-0125-01	2.5 mg/2.5 mL single-dose vial
	50242-127-01	50242-0127-01	10 mg/10 mL single-dose vial
Administration procedures: CPT	96413		Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
	96415		Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug; each additional hour (List separately in addition to code for primary procedure)

Billable Units For COLUMVI, 1 billable unit is equal to 2.5 mg. Payers might have different requirements for billing for COLUMVI. Check with your local payers for specific billing unit information.

An up-to-date list of sample codes is available at **Genentech-Access.com/COLUMVI**.

CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; FDA=US Food and Drug Administration; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; ICD-10-PCS=International Classification of Diseases, 10th Revision, Procedure Coding System; IPPS=Inpatient Prospective Payment System; NDC=National Drug Code; NTAP=New Technology Add-on Payment; WAC=wholesale acquisition cost.

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.

*Effective October 1, 2023, Medicare will provide an NTAP for COLUMVI to IPPS-participating acute care hospitals. NTAP cannot be granted if ICD-10-PCS codes are omitted.[3]

†As of July 1, 2023, CMS requires the use of the JZ modifier to indicate there were no units of a drug discarded. For more information, visit CMS.gov.

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 specialty distributors (see pages 20-21)
- Sample billing and coding information (see pages 10-11)
- Referrals to financial assistance options (see pages 23-29)

Our knowledgeable and experienced in-house Specialists are focused on assisting patients and practices who need access to COLUMVI.

Coverage and Reimbursement Resources

Benefits investigations

We can conduct a BI to help you determine:

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

When patients are prescribed a regimen with 1 or more Genentech Oncology agents in combination with other oncology medicines, our Case Managers can perform an optional regimen BI.

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.

*PAs and appeals cannot be completed or submitted by Genentech Access Solutions on your behalf.

Composing a Sample Appeal Letter

When a patient's health insurance plan denies your request for prior authorization (PA) or coverage for COLUMVI, 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 COLUMVI.

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
   - Prescribing Information
   - Pathology reports
   - 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 COLUMVI.

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

Patient: [Patient first and last name]
Subscriber ID #: [Insurance ID #]
Subscriber Group #: [Insurance group #]
Re: COLUMVI™ (glofitamab-gxbm)
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 COLUMVI™ (glofitamab-gxbm) 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 COLUMVI 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 COLUMVI. 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 June 15, 2023, the US Food and Drug Administration (FDA) approved COLUMVI for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL), or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy.

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

Summary
I believe COLUMVI is appropriate and medically necessary for this patient and I request that you 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.

Composing a Sample Letter of Medical Necessity

When submitting a prior authorization (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 COLUMVI.

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.

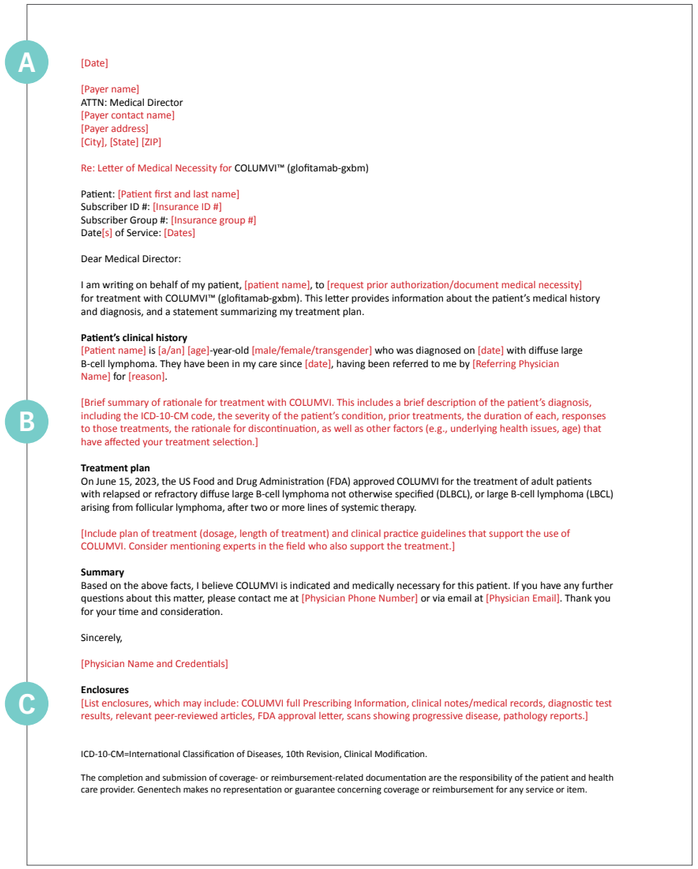
Be detailed and thorough. Recommended information for a letter of medical necessity includes:

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
   - 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 See page 10 for sample ICD-10-CM codes for COLUMVI.

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 COLUMVI™ (glofitamab-gxbm)

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 COLUMVI™ (glofitamab-gxbm). 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 COLUMVI. 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 June 15, 2023, the US Food and Drug Administration (FDA) approved COLUMVI for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL), or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy.

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

Summary
Based on the above facts, I believe COLUMVI 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: COLUMVI 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.

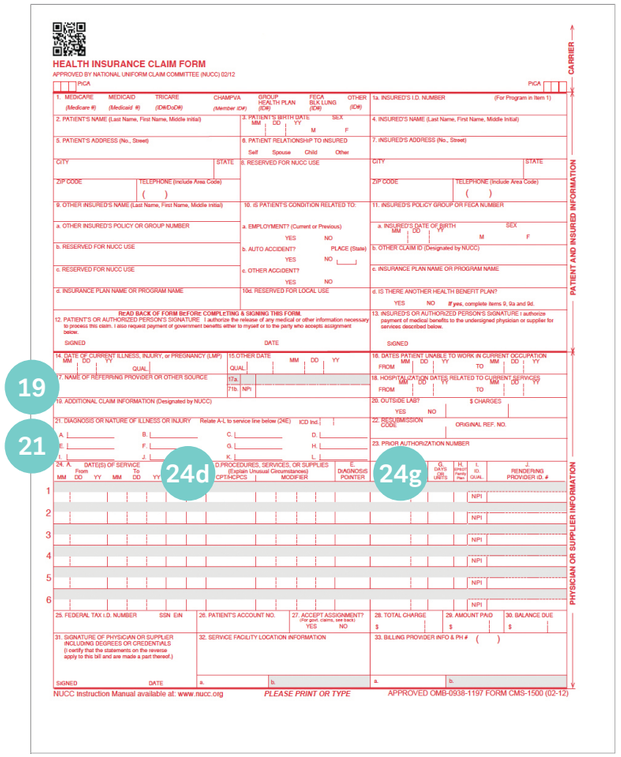
The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and health care provider. Genentech makes no representation or guarantee concerning coverage or reimbursement for any service or item.

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.

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

Sample Claim Form: CMS-1500

The CMS-1500 claim form is used by some payers to bill for services provided in the noninstitutional (physician office) setting.



19 Include the following:

- Drug name (both brand and generic names)
- Dosage
- NDC

Payers may also require:

- Route of administration
- Amount administered
- Drug strength

Note: When submitting claims using the electronic version of the CMS-1500 claim form, make sure the character limits in Box 19 are set to let you include all of the required information. An attachment might be needed if Box 19 is not large enough for the requested information. If necessary, contact your software vendor for assistance.

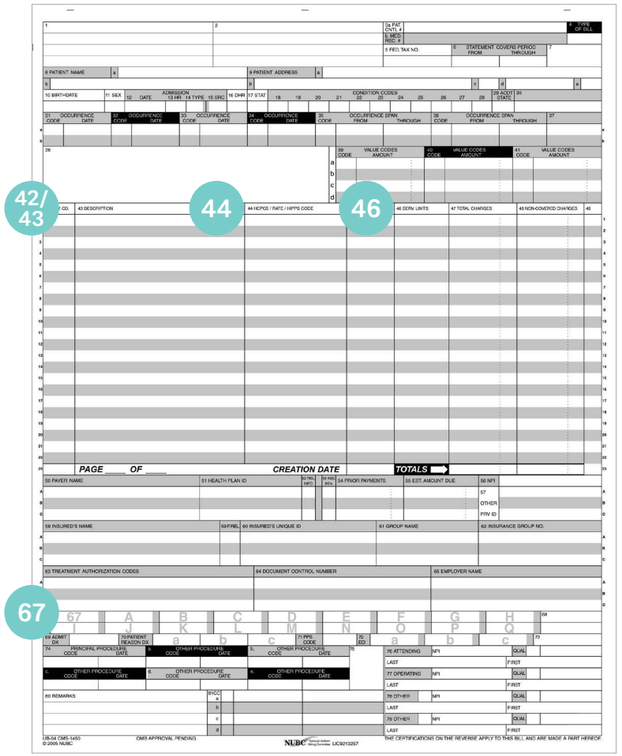
21 Insert appropriate ICD-10-CM diagnosis code(s).

24d Document use of drug with the appropriate HCPCS code on 1 line and the appropriate CPT administration code(s) on a separate line.

24g Include the number of units used for each line item. Unclassified codes do not have “unit values” and are generally reported as “1 unit,” regardless of the amount of drug administered. Check payer guidelines for appropriate reporting of units for an unclassified code.

Sample Claim Form: CMS-1450

The CMS-1450 claim form is used by some payers to bill for services provided in the institutional (hospital) setting.



42/43 Enter the appropriate revenue code(s) and description corresponding to the HCPCS code(s) in field 44.

44 Document use of drug with the appropriate HCPCS code on 1 line and the appropriate CPT administration code(s) on a separate line.

46 Include the number of units used for each line item. Unclassified codes do not have “unit values” and are generally reported as “1 unit,” regardless of the amount of drug administered. Check payer guidelines for appropriate reporting of units for an unclassified code.

67 Insert appropriate ICD-10-CM diagnosis code(s). Enter any pertinent information not shown elsewhere on the form, such as product, dosage, route of administration and NDC.

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.

The forms shown here are for informational purposes only. Completion of other fields on these claim forms or completion of different claim forms might be required. Because COLUMVI uses a miscellaneous HCPCS code, some additional information might be required when submitting claims. Check with individual payers for specific requirements.

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

Authorized Specialty Distributors for COLUMVI*

Genentech has contracted with a network of authorized specialty distributors to service practices choosing to purchase COLUMVI through the buy and bill model. Customers can purchase COLUMVI 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 COLUMVI 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
	Cardinal Health Specialty Distribution	866-677-4844	N/A	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
	Cardinal Health Specialty Distribution	866-677-4844	N/A	www.cardinalhealth.com/en/solutions/specialty-distribution.html
	CuraScript SD (Priority Health)	877-599-7748	800-862-6208	www.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
	Cardinal Health Specialty Distribution	866-677-4844	N/A	www.cardinalhealth.com/en/solutions/specialty-distribution.html
	CuraScript SD (Priority Health)	877-599-7748	800-862-6208	www.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
	Cardinal Health Specialty Distribution	866-677-4844	N/A	www.cardinalhealth.com/en/solutions/specialty-distribution.html
	CuraScript SD (Priority Health)	877-599-7748	800-862-6208	www.curascriptsd.com/Contact-Us
	McKesson Plasma and Biologics (MPB)	877-625-2566	N/A	www.mckesson.com/Pharmaceutical-Distribution/Plasma-Biologics
	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 Puerto Rico	Cardinal Health Puerto Rico	787-625-4200	N/A	www.cardinalhealth.pr
	Cesar Castillo (Puerto Rico)	787-999-1616	787-999-1618	www.cesarcastillo.net

For a list of authorized specialty distributors, visit the Product Distribution page on **Genentech-Access.com/COLUMVI**.

*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.

Assistance if COLUMVI 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 COLUMVI 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 COLUMVI.

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 COLUMVI 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.

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.

$0

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

$25K

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

There are no income requirements

*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 RxBIN and 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)

DoD=Department of Defense; FDA=US Food and Drug Administration; VA=Department of Veterans Affairs.

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 type or amount of assistance available (if any) offered can vary by foundation
- If the patient is denied assistance by one co-pay assistance foundation, they 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/COLUMVI** 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. This information is provided as a resource for you. Genentech does not endorse or show preference for any particular foundation. The foundations in this list may not be the only ones that might be able to help your patient.

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

The **Genentech Patient Foundation** provides free COLUMVI to people who don't have health insurance coverage or who have financial concerns and meet eligibility criteria.

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†

Genentech reserves the right to modify or discontinue the program at any time and to verify the accuracy of information submitted.

†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-Access.com/COLUMVI

(877) GENENTECH/(877) 436-3683
Monday through Friday, 6 a.m.–5 p.m. PT

Please see the COLUMVI full Prescribing Information for additional Important Safety Information, including **BOXED WARNING**.

COLUMVI™
glofitamab-gxbm
injection for intravenous use 2.5 mg | 10 mg

Tips for Completing the Prescriber Foundation Form

Along with the Patient Consent Form (see pages 6–7), 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 27 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.**

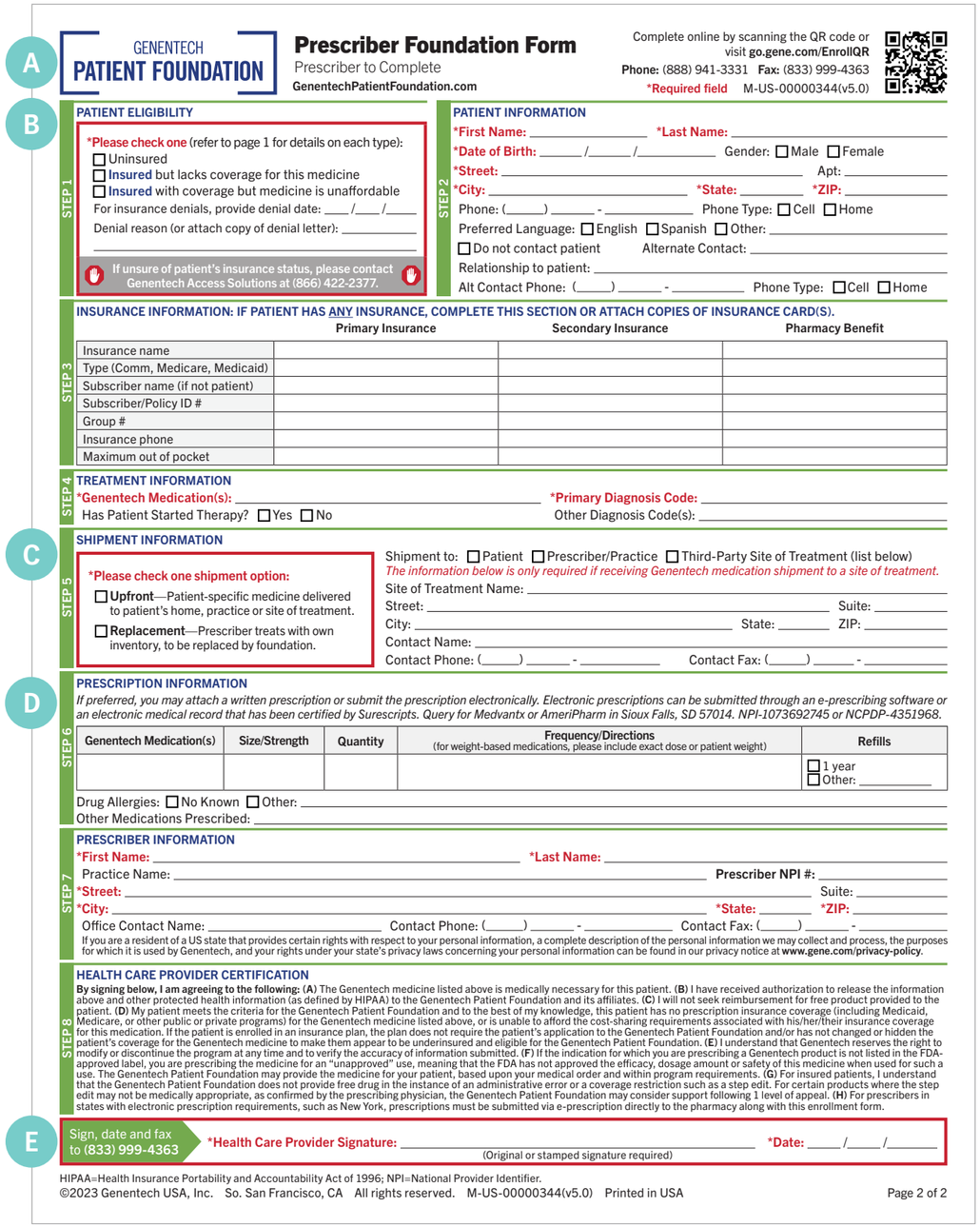
Finding and submitting the form

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



A

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)

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.
 M-US-00000344(v5.0) Printed in USA

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

Genentech-Access.com/COLUMVI

(877) GENENTECH/(877) 436-3683
Monday through Friday, 6 a.m.–5 p.m. PT

Please see the COLUMVI full Prescribing Information for additional Important Safety Information, including **BOXED WARNING**.

COLUMVI™
glofitamab-gxbm
injection for intravenous use 2.5 mg | 10 mg

Connect Directly With Genentech—Call the Genentech Patient Resource Center

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

- General questions about COLUMVI
- Acquiring, storing or administering COLUMVI
- Financial support options and understanding health insurance coverage for COLUMVI
- Connecting to educational programs and resources to support patients
- Product complaints or wastage
- Locating infusion or administration sites
- Connecting to in-person support from a Genentech representative
- Using Genentech online resources including **My Patient Solutions® for Health Care Practices**

Call **(877) GENENTECH**/(877) 436-3683, Monday through Friday, 6 a.m.–5 p.m. PT with questions or to get started.

Important Safety Information

BOXED WARNING: Cytokine Release Syndrome (CRS), including serious or fatal reactions, can occur in patients receiving COLUMVI. Premedicate before each dose, and initiate treatment with the COLUMVI step-up dosing schedule to reduce the risk of CRS. Withhold COLUMVI until CRS resolves or permanently discontinue based on severity.

Warnings and Precautions

Cytokine Release Syndrome (CRS)

COLUMVI can cause serious and fatal CRS.

Among the 145 patients who received COLUMVI, CRS occurred in 70%, with Grade 1 CRS developing in 52% of patients, Grade 2 in 14%, Grade 3 in 2.8% of patients, and Grade 4 in 1.4%. The most common manifestations of CRS included fever, tachycardia, hypotension, chills, and hypoxia.

CRS occurred in 56% of patients after the 2.5 mg dose of COLUMVI, 35% after the 10 mg dose, 29% after the initial 30 mg target dose, and 2.8% after subsequent doses. With the first step-up dose of COLUMVI, the median time to onset of CRS (from the start of infusion) was 14 hours (range: 5 to 74 hours). CRS after any dose resolved in 98% of cases, with a median duration of CRS of 2 days (range: 1 to 14 days). Recurrent CRS occurred in 34% of all patients. CRS can first occur with the 10 mg dose; of 135 patients treated with the 10 mg dose of COLUMVI, 15 patients (11%) experienced their first CRS event with the 10 mg dose, of which 13 events were Grade 1, 1 event was Grade 2, and 1 event was Grade 3.

Administer COLUMVI in a facility equipped to monitor and manage CRS. Initiate therapy according to the COLUMVI step-up dosing schedule to reduce the risk of CRS, administer pretreatment medications, and ensure adequate hydration. Patients should be hospitalized during and for 24 hours after completing infusion of the 2.5 mg step-up dose. Patients who experienced any grade CRS during the 2.5 mg step-up dose should be hospitalized during and for 24 hours after completion of the 10 mg step-up dose. For subsequent doses, patients who experienced Grade ≥2 CRS with their previous infusion should be hospitalized during and for 24 hours after the next COLUMVI infusion.

At the first sign of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care; withhold or permanently discontinue COLUMVI based on severity.

Neurologic Toxicity

COLUMVI can cause serious neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity (ICANS).

Among 145 patients who received COLUMVI, the most frequent neurologic toxicities of any grade were headache (10%), peripheral neuropathy (8%), dizziness or vertigo (7%), and mental status changes (4.8%, including confusional state, cognitive disorder, disorientation, somnolence, and delirium). Grade 3 or higher neurologic adverse reactions occurred in 2.1% of patients and included somnolence, delirium, and myelitis. Cases of ICANS of any grade occurred in 4.8% of patients.

Coadministration of COLUMVI with other products that cause dizziness or mental status changes may increase the risk of neurologic toxicity. Optimize concomitant medications and hydration to avoid dizziness or mental status changes. Institute fall precautions as appropriate.

Monitor patients for signs and symptoms of neurologic toxicity, evaluate, and provide supportive therapy; withhold or permanently discontinue COLUMVI based on severity.

Important Safety Information (cont)

Warnings and Precautions (cont)

Neurologic Toxicity (cont)

Evaluate patients who experience neurologic toxicity such as tremors, dizziness, or adverse reactions that may impair cognition or consciousness promptly, including potential neurology evaluation. Advise affected patients to refrain from driving and/or engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, until the neurologic toxicity fully resolves.

Serious Infections

COLUMVI can cause serious or fatal infections.

Serious infections were reported in 16% of patients, including Grade 3 or 4 infections in 10%, and fatal infections in 4.8% of patients. Grade 3 or higher infections reported in ≥ 2% patients were COVID-19 infection (6%), including COVID-19 pneumonia, and sepsis (4.1%). Febrile neutropenia occurred in 3.4% of patients.

COLUMVI should not be administered to patients with an active infection. Administer antimicrobial prophylaxis according to guidelines. Monitor patients before and during COLUMVI treatment for infection and treat appropriately. Withhold or consider permanent discontinuation of COLUMVI based on severity.

Tumor Flare

COLUMVI can cause serious tumor flare. Manifestations included localized pain and swelling at the sites of the lymphoma lesions and/or dyspnea from new pleural effusions.

Tumor flare was reported in 12% of patients who received COLUMVI, including Grade 2 tumor flare in 4.8% of patients and Grade 3 tumor flare in 2.8%. Recurrent tumor flare occurred in two (12%) of the affected patients. Most tumor flare events occurred during Cycle 1, with a median time to first onset of 2 days (range: 1 to 16 days) after the first dose of COLUMVI. The median duration was 3.5 days (range: 1 to 35 days).

Patients with bulky tumors or disease located in close proximity to airways or a vital organ should be monitored closely during initial therapy. Monitor for signs and symptoms of compression or obstruction due to mass effect secondary to tumor flare, and institute appropriate treatment. Withhold COLUMVI until tumor flare resolves.

Embryo-Fetal Toxicity

Based on its mechanism of action, COLUMVI may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with COLUMVI and for 1 month after the last dose.

Most Common Adverse Reactions

The most common (≥ 20%) adverse reactions, excluding laboratory abnormalities, are CRS (70%), musculoskeletal pain (21%), rash (20%), and fatigue (20%). The most common Grade 3 to 4 laboratory abnormalities (≥ 20%) are lymphocyte count decreased (83%), phosphate decreased (28%), neutrophil count decreased (26%), uric acid increased (23%), and fibrinogen decreased (21%).

Drug Interactions

For certain CYP substrates where minimal concentration changes may lead to serious adverse reactions, monitor for toxicities or drug concentrations of such CYP substrates when coadministered with COLUMVI.

Glofitamab-gxbm causes the release of cytokines that may suppress the activity of CYP enzymes, resulting in increased exposure of CYP substrates. Increased exposure of CYP substrates is more likely to occur after the first dose of COLUMVI on Cycle 1 Day 8 and up to 14 days after the first 30 mg dose on Cycle 2 Day 1 and during and after CRS.

Use in Specific Populations

Lactation

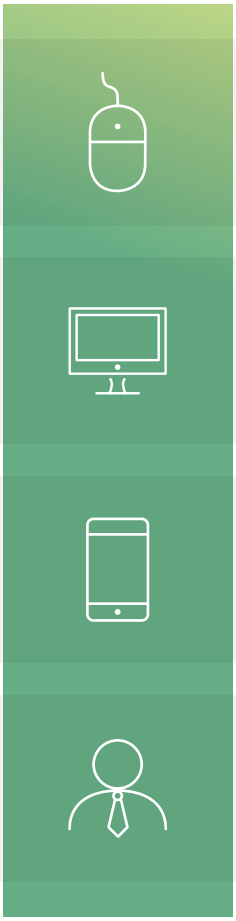
There are no data on the presence of glofitamab-gxbm in human milk or the effects on the breastfed child or milk production. Because human IgG is present in human milk, and there is potential for glofitamab-gxbm absorption leading to B-cell depletion, advise women not to breastfeed during treatment with COLUMVI and for 1 month after the last dose of COLUMVI.

Geriatric Use

Of the 145 patients with relapsed or refractory LBCL who received COLUMVI in study NP30179, 55% were 65 years of age or older, and 23% were 75 years of age or older. There was a higher rate of fatal adverse reactions, primarily from COVID-19, in patients 65 years of age or older compared to younger patients. No overall differences in efficacy were observed between patients 65 years of age or older and younger patients.

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.

Choose How You Connect With Us



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Reference: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-cell Lymphomas V.5.2023. ©National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Published July 7, 2023. Accessed August 4, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. **2.** Centers for Medicare & Medicaid Services. 2024 ICD-10-PCS codes file. Accessed September 6, 2023. https://www.cms.gov/files/zip/2024-icd-10-pcs-order-file-long-and-abbreviated-titles.zip **3.** Centers for Medicare and Medicaid Services. Medicare Program; proposed hospital inpatient prospective payment systems for acute care hospitals and the long-term care hospital prospective payment system and policy changes and fiscal year 2024 rates; quality programs and Medicare promoting interoperability program requirements for eligible hospitals and critical access hospitals; rural emergency hospital and physician-owned hospital requirements; and provider and supplier disclosure of ownership. *Fed Regist.* 2023;88(83);26658-27309. Published May 1, 2023. Accessed September 6, 2023. https://www.govinfo.gov/content/pkg/FR-2023-05-01/pdf/2023-07389.pdf

Genentech
A Member of the Roche Group

COLUMVI™
glofitamab-gxbm
injection for intravenous use 2.5 mg | 10 mg

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use COLUMVI® safely and effectively. See full prescribing information for COLUMVI.

COLUMVI (glofitamab-gxbm) injection, for intravenous use
Initial U.S. Approval: 2023

WARNING: CYTOKINE RELEASE SYNDROME

See full prescribing information for complete boxed warning

Cytokine Release Syndrome (CRS), including serious or fatal reactions, can occur in patients receiving COLUMVI. Premedicate before each dose, and initiate treatment with the COLUMVI step-up dosing schedule to reduce the risk of CRS. Withhold COLUMVI until CRS resolves or permanently discontinue based on severity. (2.1, 2.2, 2.3, 2.4, 5.1)

RECENT MAJOR CHANGES

Dosage and Administration (2.1, 2.3, 2.5, 2.6, 2.7)	10/2025

INDICATIONS AND USAGE

COLUMVI is a bispecific CD20-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy.

This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). (1)

DOSAGE AND ADMINISTRATION

- Pretreat with a single 1,000 mg dose of obinutuzumab intravenously 7 days before initiation of COLUMVI (Cycle 1 Day 1). (2.2)
- Administer premedications as recommended. (2.3)
- Administer only as an intravenous infusion. (2.1)
- Recommended dosage (2.2):

Treatment Cycle[a]	Day	Dose of COLUMVI	
Cycle 1	Day 1	Obinutuzumab 1,000 mg	
	Day 8	Step-up dose 1	2.5 mg
	Day 15	Step-up dose 2	10 mg
Cycle 2 to 12	Day 1	30 mg	

[a] Cycle = 21 days

- Administer in a facility equipped to monitor and manage CRS. (2.1, 2.2)
- Patients should be hospitalized for the 2.5 mg step-up dose and for subsequent infusions as recommended. (2.1, 2.2)
- See Full Prescribing Information for instructions on preparation and administration. (2.5, 2.6, 2.7)

DOSAGE FORMS AND STRENGTHS

Injection:
- 2.5 mg/2.5 mL (1 mg/mL) in a single-dose vial. (3)
- 10 mg/10 mL (1 mg/mL) in a single-dose vial. (3)

CONTRAINDICATIONS

None. (4)

WARNINGS AND PRECAUTIONS

- Neurologic Toxicity: Can cause serious neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). Monitor for neurologic toxicity; withhold or permanently discontinue based on severity. (5.2)
- Serious Infections: Can cause serious or fatal infections. Monitor patients for signs and symptoms of infection and treat appropriately. (5.3)
- Tumor Flare: Can cause serious tumor flare reactions. Monitor patients at risk for complications of tumor flare. (5.4)
- Embryo-Fetal Toxicity: May cause fetal harm. Advise females of reproductive potential of the potential risk to the fetus and to use effective contraception. (5.5, 8.1, 8.3)

ADVERSE REACTIONS

The most common (≥ 20%) adverse reactions, excluding laboratory abnormalities, are cytokine release syndrome, musculoskeletal pain, rash, and fatigue. The most common (≥ 20%) Grade 3 to 4 laboratory abnormalities are lymphocyte count decreased, phosphate decreased, neutrophil count decreased, uric acid increased, and fibrinogen decreased. (6.1)

USE IN SPECIFIC POPULATIONS

Lactation: Advise not to breastfeed. (8.2)

To report SUSPECTED ADVERSE REACTIONS, contact Genentech at 1-888-835-2555 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 10/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME

Cytokine Release Syndrome (CRS), including serious or fatal reactions, can occur in patients receiving COLUMVI. Premedicate before each dose, and initiate treatment with the COLUMVI step-up dosing schedule to reduce the risk of CRS. Withhold COLUMVI until CRS resolves or permanently discontinue based on severity *[see Dosage and Administration (2.1, 2.2, 2.3, and 2.4) and Warnings and Precautions (5.1)]*.

1 INDICATIONS AND USAGE

COLUMVI is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy.

This indication is approved under accelerated approval based on response rate and durability of response *[see Clinical Studies (14.1)]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 DOSAGE AND ADMINISTRATION

2.1 Important Dosing Information

- Administer only as an intravenous infusion through a dedicated infusion line that includes a sterile 0.2-micron in-line filter.
- Administer COLUMVI diluted solution via intravenous bag infusion. The 2.5 mg dose may alternatively be administered via intravenous syringe infusion *[see Dosage and Administration (2.5, 2.6, 2.7)]*.
- COLUMVI should only be administered by a healthcare professional with immediate access to appropriate medical support, including supportive medications to manage severe CRS *[see Dosage and Administration (2.4)]*.
- Ensure adequate hydration before administering COLUMVI.
- Premedicate before each dose *[see Dosage and Administration (2.3)]*.
- Following pretreatment with obinutuzumab, administer COLUMVI according to the step-up dosing schedule in Table 1 with appropriate premedication, including dexamethasone, to reduce the incidence and severity of CRS *[see Dosage and Administration (2.3)]*.
- Due to the risk of CRS, patients should be hospitalized during and for 24 hours after completion of infusion of step-up dose 1 (2.5 mg on Cycle 1 Day 8) *[see Dosage and Administration (2.2) and Warnings and Precautions (5.1)]*.
- Patients who experienced any grade CRS during step-up dose 1 should be hospitalized during and for 24 hours after completion of step-up dose 2 (10 mg on Cycle 1 Day 15). CRS with step-up dose 2 can occur in patients who did not experience CRS with step-up dose 1 *[see Dosage and Administration (2.2) and Warnings and Precautions (5.1)]*.
- For subsequent doses, patients who experienced Grade ≥ 2 CRS with their previous infusion should be hospitalized during and for 24 hours after the completion of the next COLUMVI infusion.

2.2 Recommended Dosage

Pretreatment with Obinutuzumab

Pretreat all patients with a single 1,000 mg dose of obinutuzumab administered as an intravenous infusion on Cycle 1 Day 1, 7 days prior to initiation of COLUMVI (see Table 1) to deplete the circulating and lymphoid tissue B cells.

Obinutuzumab should be administered as an intravenous infusion at 50 mg/hour. The rate of infusion can be escalated in 50 mg/hour increments every 30 minutes to a maximum of 400 mg/hour. Refer to the obinutuzumab prescribing information for complete dosing information.

COLUMVI Step-up Dose Schedule

COLUMVI dosing begins with a step-up dose schedule. Following completion of pretreatment with obinutuzumab on Cycle 1 Day 1, administer COLUMVI as an intravenous infusion according to the step-up dose schedule in Table 1. Administer premedications for each dose of COLUMVI as described in Table 3 *[see Dosage and Administration (2.3)]*.

Table 1: COLUMVI Dosing Schedule (21-Day Treatment Cycles)

Treatment cycle	Day	Dose of COLUMVI		Duration of infusion
Cycle 1	Day 1	Obinutuzumab[1]		
	Day 8	Step-up dose 1	2.5 mg	4 hours[2]
	Day 15	Step-up dose 2	10 mg	
Cycle 2	Day 1	30 mg		4 hours[2]
Cycle 3 to 12	Day 1	30 mg		2 hours[3]

[1] Refer to "*Pretreatment with obinutuzumab*" described above.

[2] For patients who experience CRS with their previous dose of COLUMVI, the time of infusion may be extended up to 8 hours.

[3] If the patient experienced CRS with the previous dose, the duration of infusion should be maintained at 4 hours.

Continue COLUMVI for a maximum of 12 cycles (inclusive of Cycle 1 step-up dosing) or until disease progression or unacceptable toxicity, whichever occurs first.

Monitoring for Cytokine Release Syndrome *[see Warnings and Precautions (5.1)]*

- Administer the COLUMVI infusions intravenously in a healthcare setting with immediate access to medical support to manage CRS, including severe CRS.
- For the first COLUMVI step-up dose (2.5 mg on Cycle 1 Day 8), patients should be hospitalized during and for 24 hours after completion of the COLUMVI infusion.
- Patients who experienced any grade CRS during step-up dose 1 should be hospitalized during and for 24 hours after completion of step-up dose 2 (10 mg on Cycle 1 Day 15). CRS with step-up dose 2 can occur in patients who did not experience CRS with step-up dose 1.
- For subsequent infusions (30 mg on Day 1 of Cycle 2 or subsequent cycles), patients who experienced Grade ≥ 2 CRS with their previous infusion should be hospitalized during and for 24 hours after completion of the next COLUMVI infusion.
- For monitoring after delayed or missed doses of COLUMVI, follow the recommendations in Table 2.

Delayed or Missed Doses

If a dose of COLUMVI is delayed, restart therapy based on the recommendations made in Table 2, then resume the treatment schedule accordingly.

For repeat of the 2.5 mg dose patients should be hospitalized during and for 24 hours after completion of the COLUMVI infusion. For the repeat of the 10 mg dose, patients should be hospitalized during and for 24 hours after completion of the COLUMVI infusion if any grade CRS occurred during the most recent 2.5 mg dose.

Table 2: Recommendations for Restarting COLUMVI After Dose Delay

Last Dose Administered	Time Since Last Dose Administered	Action for Next Dose(s)[a]
Obinutuzumab pretreatment (Cycle 1 Day 1)	≤ 2 weeks	• Administer COLUMVI 2.5 mg (Cycle 1 Day 8)[b], then resume the planned treatment schedule.
	> 2 weeks	• Repeat obinutuzumab 1,000 mg pretreatment (Cycle 1 Day 1). • Then administer COLUMVI 2.5 mg (Cycle 1 Day 8)[b] and resume the planned treatment schedule.
COLUMVI 2.5 mg (Cycle 1 Day 8)	≤ 2 weeks	• Administer COLUMVI 10 mg (Cycle 1 Day 15)[c], then resume the planned treatment schedule.
	> 2 to ≤ 4 weeks	• Repeat COLUMVI 2.5 mg (Cycle 1 Day 8)[b]. • Then administer COLUMVI 10 mg (Cycle 1 Day 15)[c] and resume the planned treatment schedule.
	> 4 weeks	• Repeat obinutuzumab 1,000 mg pretreatment (Cycle 1 Day 1) and COLUMVI 2.5 mg (Cycle 1 Day 8)[b]. • Then administer COLUMVI 10 mg (Cycle 1 Day 15)[c] and resume the planned treatment schedule.
COLUMVI 10 mg (Cycle 1 Day 15)	≤ 2 weeks	• Administer COLUMVI 30 mg (Cycle 2 Day 1), then resume the planned treatment schedule.
	> 2 to ≤ 6 weeks	• Repeat COLUMVI 10 mg (Cycle 1 Day 15).[c] • Then administer COLUMVI 30 mg (Cycle 2 Day 1) and resume the planned treatment schedule.
	> 6 weeks	• Repeat obinutuzumab 1,000 mg pretreatment (Cycle 1 Day 1), COLUMVI 2.5 mg (Cycle 1 Day 8)[b], and COLUMVI 10 mg (Cycle 1 Day 15)[c]. • Then administer COLUMVI 30 mg (Cycle 2 Day 1) and resume the planned treatment schedule.
COLUMVI 30 mg (Cycle 2 onwards)	≤ 6 weeks	• Administer COLUMVI 30 mg, then resume the planned treatment schedule.
	> 6 weeks	• Repeat the Cycle 1 regimen described in Table 1: obinutuzumab 1,000 mg pretreatment (Day 1), COLUMVI 2.5 mg (Day 8)[b], and COLUMVI 10 mg (Day 15)[c]. • Then administer COLUMVI 30 mg (Day 1 of next cycle) and resume the planned treatment schedule.

[a] Administer premedication as per Table 3 for all patients.

[b] Patients should be hospitalized during and for 24 hours after completing infusion of the 2.5 mg dose.

[c] Patients should be hospitalized during and for 24 hours after completing infusion of the 10 mg dose if CRS occurred during the most recent 2.5 mg dose.

2.3 Recommended Premedication and Prophylactic Medications

Premedication

Administer the following premedications to reduce the risk of CRS and infusion-related reactions *[see Warnings and Precautions (5.1)]*.

Table 3: Premedications to be Administered for COLUMVI Infusion

Day of Treatment Cycle	Patients requiring premedication	Premedication	Administration
Cycle 1, Day 8 and Day 15; Cycle 2; Cycle 3	All patients	Dexamethasone 20 mg intravenously*	Completed at least 1 hour prior to COLUMVI infusion.
		Acetaminophen 500 mg to 1,000 mg orally	At least 30 minutes before COLUMVI infusion.
		Antihistamine (diphenhydramine 50 mg orally or intravenously or equivalent)	Completed at least 30 minutes before COLUMVI infusion.
All subsequent infusions	All patients	Acetaminophen 500 mg to 1,000 mg orally	At least 30 minutes before COLUMVI infusion.
		Antihistamine (diphenhydramine 50 mg orally or intravenously or equivalent)	Completed at least 30 minutes before COLUMVI infusion.
	Patients who experienced any grade CRS with the previous dose	Dexamethasone 20 mg intravenously*	Completed at least 1 hour prior to COLUMVI infusion.

* If dexamethasone is not available, administer prednisone 100 mg, prednisolone 100 mg, or methylprednisolone 80 mg intravenously.

Tumor Lysis Syndrome Prophylaxis

Before starting COLUMVI, administer anti-hyperuricemics to patients at risk of tumor lysis syndrome, ensure adequate hydration status, and monitor as appropriate *[see Adverse Reactions (6.1)]*.

Infection Prophylaxis

Before starting COLUMVI, consider initiation of antiviral prophylaxis to prevent herpes virus reactivation. Consider prophylaxis for cytomegalovirus infection, pneumocystis jirovecii pneumonia (PJP), and other opportunistic infections in patients at increased risk *[see Warnings and Precautions (5.3)]*.

2.4 Dosage Modifications for Adverse Reactions

No dosage reduction for COLUMVI is recommended.

Cytokine Release Syndrome

Identify CRS based on clinical presentation *[see Warnings and Precautions (5.1)]*. Evaluate for and treat other causes of fever, hypoxia, and hypotension.

If CRS is suspected, withhold COLUMVI and manage according to the recommendations in Table 4 and current practice guidelines. Administer supportive care for CRS, which may include intensive care for severe or life-threatening cases.

Table 4: Recommendations for Management of Cytokine Release Syndrome

Grade[a]	Presenting Symptoms	Actions
Grade 1	Temperature ≥ 100.4°F (38°C)[b]	• Withhold COLUMVI and manage per current practice guidelines. ○ If symptoms resolve, restart infusion at a slower rate.[c] • Ensure CRS symptoms are resolved for at least 72 hours before next dose.[d] • Consider slower infusion rate for next dose.
Grade 2	Temperature ≥ 100.4°F (38°C)[b] with: Hypotension not requiring vasopressors and/or Hypoxia requiring low-flow oxygen[e] by nasal cannula or blow-by	• Withhold COLUMVI and manage per current practice guidelines. ○ If symptoms resolve, restart infusion at a slower rate.[c] • Ensure CRS symptoms are resolved for at least 72 hours before next dose.[d] • For the next dose, consider a slower infusion rate, monitor more frequently, and consider hospitalization. • For recurrent Grade 2 CRS, manage per Grade 3 CRS.
Grade 3	Temperature ≥ 100.4°F (38°C)[b] with: Hypotension requiring vasopressor (with or without vasopressin) and/or Hypoxia requiring high-flow oxygen[e] by nasal cannula, face mask, non-rebreather mask, or Venturi mask	• Withhold COLUMVI and manage per current practice guidelines, which may include intensive care. • Ensure CRS symptoms are resolved for at least 72 hours before next dose.[d] • Hospitalize for the next dose, monitor more frequently, and consider a slower infusion rate.[c] • For recurrent Grade 3 CRS, permanently discontinue COLUMVI.
Grade 4	Temperature ≥ 100.4°F (38°C)[b] with: Hypotension requiring multiple vasopressors (excluding vasopressin) and/or Hypoxia requiring oxygen by positive pressure (e.g., CPAP, BiPAP, intubation, and mechanical ventilation)	• Permanently discontinue COLUMVI and manage per current practice guidelines, which may include intensive care.

[a] American Society for Transplantation and Cellular Therapy (ASTCT) 2019 consensus grading criteria.

[b] Premedication may mask fever. Therefore, if clinical presentation is consistent with CRS, follow these management guidelines.

Grade[a]	Presenting Symptoms	Actions

[c] Duration of infusion may be extended up to 8 hours, as appropriate for that cycle (see Table 1).

[d] Refer to Table 2 for information on restarting COLUMVI after dose delays *[see Dosage and Administration (2.2)]*.

[e] Low-flow oxygen defined as oxygen delivered at < 6 L/minute, high-flow oxygen defined as oxygen delivered at ≥ 6 L/minute.

Neurologic Toxicity, Including ICANS

Management recommendations for neurologic toxicity, including ICANS, is summarized in Table 5. At the first sign of neurologic toxicity, including ICANS, consider neurology evaluation and withholding COLUMVI based on the type and severity of neurotoxicity. Rule out other causes of neurologic symptoms. Provide supportive therapy, which may include intensive care.

Table 5: Recommended Dosage Modification for Neurologic Toxicity (Including ICANS)

Adverse Reaction	Severity[1,2]	Actions
Neurologic Toxicity[1] (including ICANS[2]) *[see Warnings and Precautions (5.2)]*	Grade 1	• Continue COLUMVI and monitor neurologic toxicity symptoms. • If ICANS, manage per current practice guidelines.
	Grade 2	• Withhold COLUMVI until neurologic toxicity symptoms improve to Grade 1 or baseline.[3, 4] • Provide supportive therapy, and consider neurologic evaluation. • If ICANS, manage per current practice guidelines.
	Grade 3	• Withhold COLUMVI until neurologic toxicity symptoms improve to Grade 1 or baseline for at least 7 days.[4, 5] • For Grade 3 neurologic events lasting more than 7 days, consider permanently discontinuing COLUMVI. • Provide supportive therapy, and consider neurology evaluation. • If ICANS, manage per current practice guidelines.
	Grade 4	• Permanently discontinue COLUMVI. • Provide supportive therapy, which may include intensive care, and consider neurology evaluation. • If ICANS, manage per current practice guidelines.

[1] Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.03.

[2] Based on ASTCT 2019 grading for ICANS.

[3] Consider the type of neurologic toxicity before deciding to withhold COLUMVI.

[4] See *Dosage and Administration (2.2)* on restarting COLUMVI after dose delays.

[5] Evaluate benefit-risk before restarting COLUMVI.

Other Adverse Reactions

Table 6: Recommended Dosage Modifications for Other Adverse Reactions

Adverse Reactions[1]	Severity[1]	Actions
Infections *[see Warnings and Precautions (5.3)]*	Grades 1 – 4	• Withhold COLUMVI in patients with active infection until the infection resolves.[2] • For Grade 4, consider permanent discontinuation of COLUMVI.
Tumor flare *[see Warnings and Precautions (5.4)]*	Grade 1	• Monitor for signs and symptoms of compression or obstruction due to mass effect secondary to tumor flare.
	Grades 2 – 4	• Monitor for signs and symptoms of compression or obstruction due to mass effect secondary to tumor flare, and institute appropriate treatment including antihistamine and corticosteroids. • Withhold COLUMVI until tumor flare resolves.[2]
Neutropenia	Absolute neutrophil count less than 0.5 x 10^9/L	• Withhold COLUMVI until absolute neutrophil count is 0.5 x 10^9/L or higher.[2]
Thrombocytopenia	Platelet count less than 50 x 10^9/L	• Withhold COLUMVI until platelet count is 50 x 10^9/L or higher.[2]
Other Adverse Reactions *[see Adverse Reactions (6.1)]*	Grade 3 or higher	• Withhold COLUMVI until the toxicity resolves to Grade 1 or baseline.[2]

[1] Based on NCI CTCAE, version 4.03.

[2] See *Dosage and Administration (2.2)* on restarting COLUMVI after dose delays.

2.5 Preparation into an Intravenous Bag

This section describes preparation of all doses of COLUMVI into an intravenous bag. For preparation instructions for the 2.5 mg dose into an intravenous syringe, see subsection 2.6 *[see Dosage and Administration (2.6)]*.

Preparation

- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. COLUMVI is a colorless clear solution. Discard the vial if the solution is cloudy, discolored, or contains visible particles.
- Use aseptic technique when preparing the COLUMVI diluted solution for intravenous infusion.

Dilution for Intravenous Bag Infusion

- Determine the dose, total volume of COLUMVI solution, and the number of COLUMVI vials needed (see Table 7).
- Select an appropriate size infusion bag of 0.9% Sodium Chloride Injection or 0.45% Sodium Chloride Injection (see Table 7).
    - COLUMVI diluted with 0.9% Sodium Chloride Injection is compatible with intravenous infusion bags composed of polyvinyl chloride (PVC), polyethylene (PE), polypropylene (PP) or polyolefin.
    - COLUMVI diluted with 0.45% Sodium Chloride Injection is compatible with intravenous infusion bags composed of PVC.

- Prepare the infusion bag by withdrawing and discarding the volume from the infusion bag according to Table 7.
- Withdraw the required volume of COLUMVI from the vial(s) using a sterile needle and syringe and dilute into the infusion bag to a final concentration of 0.1 mg/mL to 0.6 mg/mL according to Table 7.

Table 7: Dilution of COLUMVI into an intravenous infusion bag

Dose of COLUMVI	Size of 0.9% Sodium Chloride Injection or 0.45% Sodium Chloride Injection infusion bag	Volume to be withdrawn and discarded from the infusion bag	Volume of COLUMVI to be added to the infusion bag	Total volume to be infused
2.5 mg	50 mL	27.5 mL	2.5 mL	25 mL
10 mg	50 mL	10 mL	10 mL	50 mL
	100 mL	10 mL	10 mL	100 mL
30 mg	50 mL	30 mL	30 mL	50 mL
	100 mL	30 mL	30 mL	100 mL

- Discard any unused COLUMVI left in the vial.
- Gently invert the infusion bag to mix the solution, in order to avoid excess foaming. Do not shake.

2.6 Preparation of 2.5 mg Dose into an Intravenous Syringe

This section describes the alternative method of preparation of the 2.5 mg dose of COLUMVI into an intravenous syringe. For preparation instructions for all doses into an intravenous infusion bag, see subsection 2.5 *[see Dosage and Administration (2.5)]*.

Preparation

- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. COLUMVI is a colorless clear solution. Discard the vial if the solution is cloudy, discolored, or contains visible particles.
- Use aseptic technique when preparing the COLUMVI diluted solution for intravenous syringe infusion.

Dilution for Intravenous Syringe Infusion (Alternative Method for 2.5 mg Dose Only)

- Draw 22.5 mL of 0.9% Sodium Chloride Injection or 0.45% Sodium Chloride Injection into a 30 mL syringe composed of PP (see Table 8).
- Withdraw 2.5 mL of COLUMVI from the vial using a sterile needle into a second syringe (see Table 8). Discard any unused COLUMVI left in the vial.
- Attach a connector to the two syringes and transfer COLUMVI into the 30 mL syringe. The final concentration of COLUMVI should be 0.1 mg/mL.

Table 8: Dilution of COLUMVI into an intravenous syringe

Dose of COLUMVI	Volume of 0.9% Sodium Chloride Injection or 0.45% Sodium Chloride Injection to be added to the syringe	Volume of COLUMVI to be added to the syringe	Total volume to be infused
2.5 mg	22.5 mL	2.5 mL	25 mL

- Disconnect the syringes. Draw air into the syringe containing the COLUMVI diluted solution and close.
- Gently invert the syringe to mix the solution, in order to avoid excessive foaming. Do not shake.

- Remove air bubbles from the syringe before administration.

2.7 Storage and Administration

Storage of Diluted Product

Immediately use diluted COLUMVI solution. If not used immediately, the diluted solution can be stored:

- Refrigerated at 2°C to 8°C (36°F to 46°F) for up to 64 hours, or
- At room temperature up to 25°C (77°F) for up to 4 hours.

Do not freeze the diluted infusion solution.

Discard diluted infusion solution if storage time exceeds these limits.

COLUMVI Administration

- Administer COLUMVI as an intravenous infusion only through a dedicated infusion line that includes a sterile 0.2-micron in-line filter using an intravenous infusion pump or syringe pump. Prime the infusion line with the diluted infusion solution.
- No incompatibilities have been observed with infusion sets with product-contacting surfaces of polyurethane (PUR), PVC, PE, polybutadiene (PBD), polyetherurethane (PEU), polycarbonate (PC), silicone, polytetrafluoroethylene (PTFE), or acrylonitrile butadiene styrene (ABS), and in-line filter membranes composed of polyethersulfone (PES) or polysulfone.
- See Table 1 for duration of infusion. The maximum time for the administration of the diluted infusion solution may be extended up to 8 hours (see Table 4).
- To ensure the entire dose of COLUMVI is administered, replace the empty infusion bag or syringe with an infusion bag or syringe containing 0.9% Sodium Chloride Injection or 0.45% Sodium Chloride Injection connected to the same infusion line. Continue the infusion at the same rate until the recommended infusion duration is reached according to Table 1.
- Do not mix COLUMVI with other drugs.

3 DOSAGE FORMS AND STRENGTHS

Injection:

- 2.5 mg/2.5 mL (1 mg/mL) clear, colorless solution in a single-dose vial.
- 10 mg/10 mL (1 mg/mL) clear, colorless solution in a single-dose vial.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Cytokine Release Syndrome

COLUMVI can cause serious and fatal cytokine release syndrome (CRS) *[see Adverse Reactions (6.1)]*.

Among 145 patients who received COLUMVI, CRS occurred in 70%, with Grade 1 CRS developing in 52% of all patients, Grade 2 in 14%, Grade 3 in 2.8%, and Grade 4 in 1.4%. The most common manifestations of CRS included fever, tachycardia, hypotension, chills, and hypoxia.

CRS occurred in 56% of patients after the 2.5 mg dose of COLUMVI, 35% after the 10 mg dose, 29% after the initial 30 mg target dose, and 2.8% after subsequent doses. With the first step-up dose of COLUMVI, the median time to onset of CRS (from the start of infusion) was 14 hours (range: 5 to 74 hours). CRS after any

dose resolved in 98% of cases, with a median duration of CRS of 2 days (range: 1 to 14 days). Recurrent CRS occurred in 34% of all patients. CRS can first occur with the 10 mg dose; of 135 patients treated with the 10 mg dose of COLUMVI, 15 patients (11%) experienced their first CRS event with the 10 mg dose, of which 13 events were Grade 1, 1 event was Grade 2, and 1 event was Grade 3.

Administer COLUMVI in a facility equipped to monitor and manage CRS. Initiate therapy according to the COLUMVI step-up dosing schedule to reduce the risk of CRS, administer pretreatment medications, and ensure adequate hydration *[Dosage and Administration (2.3)]*. Patients should be hospitalized during and for 24 hours after completing infusion of the 2.5 mg step-up dose. Patients who experienced any grade CRS during the 2.5 mg step-up dose should be hospitalized during and for 24 hours after completion of the 10 mg step-up dose. For subsequent doses, patients who experienced Grade ≥ 2 CRS with the previous infusion should be hospitalized during and for 24 hours after the next COLUMVI infusion *[see Dosage and Administration (2.1 and 2.2)]*.

At the first sign of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care; withhold or permanently discontinue COLUMVI based on severity *[see Dosage and Administration (2.4)]*.

5.2 Neurologic Toxicity

COLUMVI can cause serious and fatal neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity (ICANS) *[see Adverse Reactions (6.1)]*.

Among 145 patients who received COLUMVI, the most frequent neurologic toxicities of any grade were headache (10%), peripheral neuropathy (8%), dizziness or vertigo (7%), and mental status changes (4.8%, including confusional state, cognitive disorder, disorientation, somnolence, and delirium). Grade 3 or higher neurologic adverse reactions occurred in 2.1% of patients and included somnolence, delirium, and myelitis. Cases of ICANS of any grade occurred in 4.8% of patients.

Coadministration of COLUMVI with other products that cause dizziness or mental status changes may increase the risk of neurologic toxicity. Optimize concomitant medications and hydration to avoid dizziness or mental status changes. Institute fall precautions as appropriate.

Monitor patients for signs and symptoms of neurologic toxicity, evaluate, and provide supportive therapy; withhold or permanently discontinue COLUMVI based on severity *[see Dosage and Administration (2.4)]*.

Evaluate patients who experience neurologic toxicity such as tremors, dizziness, or adverse reactions that may impair cognition or consciousness promptly, including potential neurology evaluation. Advise affected patients to refrain from driving and/or engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, until the neurologic toxicity fully resolves.

5.3 Serious Infections

COLUMVI can cause serious or fatal infections *[see Adverse Reactions (6.1)]*.

Serious infections were reported in 16% of patients, including Grade 3 or 4 infections in 10%, and fatal infections in 4.8% of patients. Grade 3 or higher infections reported in ≥ 2% of patients were COVID-19 infection (6%), including COVID-19 pneumonia, and sepsis (4.1%). Febrile neutropenia occurred in 3.4% of patients.

COLUMVI should not be administered to patients with an active infection. Administer antimicrobial prophylaxis according to guidelines. Monitor patients before and during COLUMVI treatment for infection and treat appropriately. Withhold or consider permanent discontinuation of COLUMVI based on severity *[see Dosage and Administration (2.4)]*.

5.4 Tumor Flare

COLUMVI can cause serious tumor flare *[see Adverse Reactions (6.1)]*. Manifestations include localized pain and swelling at the sites of the lymphoma lesions and/or dyspnea from new pleural effusions.

Tumor flare was reported in 12% of patients who received COLUMVI, including Grade 2 tumor flare in 4.8% of patients and Grade 3 tumor flare in 2.8%. Recurrent tumor flare occurred in two (12%) of the affected patients. Most tumor flare events occurred during Cycle 1, with a median time to first onset of 2 days (range: 1 to 16 days) after the first dose of COLUMVI. The median duration was 3.5 days (range: 1 to 35 days).

Patients with bulky tumors or disease located in close proximity to airways or a vital organ should be monitored closely during initial therapy. Monitor for signs and symptoms of compression or obstruction due to mass effect secondary to tumor flare, and institute appropriate treatment. Withhold COLUMVI until tumor flare resolves *[see Dosage and Administration (2.4)]*.

5.5 Embryo-Fetal Toxicity

Based on its mechanism of action, COLUMVI may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with COLUMVI and for 1 month after the last dose *[see Use in Specific Populations (8.1, 8.3)]*.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Cytokine Release Syndrome *[see Warnings and Precautions (5.1)]*
- Neurologic Toxicity *[see Warnings and Precautions (5.2)]*
- Serious Infections *[see Warnings and Precautions (5.3)]*
- Tumor Flare *[see Warnings and Precautions (5.4)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Relapsed or Refractory DLBCL, NOS or LBCL Arising from Follicular Lymphoma

Study NP30179

The safety of COLUMVI was evaluated in Study NP30179, a multi-cohort, multicenter, single-arm clinical trial that included 154 adult patients with relapsed or refractory large B-cell lymphoma (LBCL) after two or more lines of systemic therapy *[see Clinical Studies (14.1)]*. The trial required an ECOG performance status of 0 or 1, absolute neutrophil count ≥ 1,500/µL, platelet count ≥ 75,000/µL independent of transfusion, serum creatinine ≤ 1.5 x upper limit of normal (ULN) or creatinine clearance (CLcr) ≥ 50 mL/min, and hepatic transaminases ≤ 3 x ULN. The trial excluded patients with active or previous central nervous system (CNS) lymphoma or CNS disease, acute infection, recent infection requiring intravenous antibiotics, or prior allogeneic hematopoietic stem cell transplantation (HSCT).

Patients received pretreatment with a single dose of obinutuzumab on Day 1 of Cycle 1 (seven days prior to start of COLUMVI). Following premedication, COLUMVI was administered by intravenous infusion according to the step-up dosing schedule with 2.5 mg on Day 8 of Cycle 1, and 10 mg on Day 15 of Cycle 1. Patients received the 30 mg COLUMVI dose by intravenous infusion on Day 1 of subsequent cycles for a maximum of 12 cycles (including step-up dosing). Each cycle was 21 days. Patients were hospitalized during and for 24 hours following completion of at least the first step-up dose.

Of the 154 patients who initiated study treatment, 145 received COLUMVI; nine patients (6%) did not receive COLUMVI due to infection, progressive disease, or patient decision. Patients received a median of 5 cycles of COLUMVI with 30% receiving all 12 cycles of COLUMVI.

Of patients who received COLUMVI, the median age was 66 years (range: 21 to 90 years); 66% were male; 77% were White, 4.8% were Asian, 1.4% were Black or African American, 6% were Hispanic or Latino. The main diagnoses were DLBCL, NOS and LBCL arising from follicular lymphoma.

Serious adverse reactions occurred in 48% of patients who received COLUMVI. Serious adverse reactions in ≥ 2% of patients included CRS, COVID-19 infection, sepsis, and tumor flare. Fatal adverse reactions occurred in 5% of patients from COVID-19 infection (3.4%), sepsis (1.4%), and delirium (0.6%).

Adverse reactions led to permanent discontinuation of COLUMVI in 7% of patients, including from infection, delirium, neutropenia, and CRS. Adverse reactions led to dose interruptions of COLUMVI in 19% of patients, most frequently (≥ 2%) from neutropenia and thrombocytopenia.

The most common (≥ 20%) adverse reactions, excluding laboratory terms, were CRS, musculoskeletal pain, rash, and fatigue. The most common Grade 3 to 4 laboratory abnormalities (≥ 20%) were lymphocyte count decreased, phosphate decreased, neutrophil count decreased, uric acid increased, and fibrinogen decreased.

Table 9 summarizes adverse reactions observed in Study NP30179.

Table 9: Select Adverse Reactions (≥ 10%) in Patients with Relapsed or Refractory LBCL Who Received COLUMVI in Study NP30179

Adverse Reactions	COLUMVI N=145	
	All grades (%)	Grade 3 or 4 (%)
Immune system disorders		
Cytokine release syndrome	70	4.1
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain[a]	21	2.1
General disorders		
Fatigue[b]	20	1.4
Pyrexia	16	0
Edema[c]	10	0
Skin and subcutaneous tissue disorders		
Rash[d]	20	1.4
Gastrointestinal disorders		
Constipation	14	0
Diarrhea	14	0
Nausea	10	0
Abdominal pain[e]	10	0
Neoplasms		
Tumor flare	12	2.8
Neurologic Disorders		
Headache	10	0

The table includes a combination of grouped and ungrouped terms. Adverse reactions were graded using NCI CTCAE version 4.03, with the exception of CRS, which was graded per ASTCT consensus criteria in most cases.

[a] Includes musculoskeletal pain, back pain, bone pain, flank pain, myalgia, neck pain, and pain in extremity.

[b] Includes fatigue and asthenia.

[c] Includes edema, edema peripheral, swelling face, and face edema.

[d] Includes rash, rash pruritic, rash maculo-papular, dermatitis, dermatitis acneiform, dermatitis exfoliative, erythema, palmar erythema, pruritus, and rash erythematous.

[e] Includes abdominal pain, abdominal discomfort, and abdominal pain upper.

Clinically relevant adverse reactions occurring in < 10% of patients who received COLUMVI included infusion-related reaction, peripheral neuropathy, pneumonia, mental status changes, vomiting, tumor lysis syndrome, febrile neutropenia, upper respiratory tract infection, sepsis, herpes zoster infection, gastrointestinal hemorrhage, tremor, myelitis, and colitis.

Table 10 summarizes laboratory abnormalities in Study NP30179.

Table 10: Select Laboratory Abnormalities (≥ 20%) That Worsened from Baseline in Patients with Relapsed or Refractory LBCL Who Received COLUMVI in Study NP30179

Laboratory Abnormality	COLUMVI[a]	
	All Grades (%)	Grade 3 or 4 (%)
Hematology		
Lymphocytes decreased	90	83
Hemoglobin decreased	72	8
Neutrophils decreased	56	26[b]
Platelets decreased	56	8
Chemistry		
Fibrinogen decreased	84	21
Phosphate decreased	69	28
Sodium decreased	49	7
Calcium decreased	48	2.1
Gamma-glutamyl transferase increased	33	9
Potassium decreased	32	6
Uric acid increased	23	23

[a] The denominator used to calculate the rate varied from 137 to 145 based on the number of patients with a baseline value and at least one post-treatment value.

[b] Grade 4 neutrophil decrease occurred in 9% of patients.

7 DRUG INTERACTIONS

For certain CYP substrates where minimal concentration changes may lead to serious adverse reactions, monitor for toxicities or drug concentrations of such CYP substrates when coadministered with COLUMVI.

Glofitamab-gxbm causes the release of cytokines *[see Clinical Pharmacology (12.2)]* that may suppress the activity of CYP enzymes, resulting in increased exposure of CYP substrates. Increased exposure of CYP substrates is more likely to occur after the first dose of COLUMVI on Cycle 1 Day 8 and up to 14 days after the first 30 mg dose on Cycle 2 Day 1 and during and after CRS *[see Warnings and Precautions (5.1)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on its mechanism of action COLUMVI may cause fetal harm when administered to a pregnant woman *[see Clinical Pharmacology (12.1)]*. There are no available data on the use of COLUMVI in pregnant women to evaluate for a drug-associated risk. No animal reproductive and developmental toxicity studies have been conducted with glofitamab-gxbm.

Glofitamab-gxbm causes T-cell activation and cytokine release; immune activation may compromise pregnancy maintenance. In addition, based on expression of CD20 on B cells and the finding of B-cell depletion in non-pregnant animals, glofitamab-gxbm can cause B-cell lymphocytopenia in infants exposed to glofitamab-gxbm in-utero. Human immunoglobulin G (IgG) is known to cross the placenta; therefore, COLUMVI has the potential to be transmitted from the mother to the developing fetus. Advise women of the potential risk to the fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

8.2 Lactation

Risk Summary

There are no data on the presence of glofitamab-gxbm in human milk or the effects on the breastfed child or milk production. Because human IgG is present in human milk, and there is potential for glofitamab-gxbm absorption leading to B-cell depletion, advise women not to breastfeed during treatment with COLUMVI and for 1 month after the last dose of COLUMVI.

8.3 Females and Males of Reproductive Potential

COLUMVI may cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations (8.1)]*.

Pregnancy Testing

Verify pregnancy status in females of reproductive potential prior to initiating COLUMVI.

Contraception

Females

Advise female patients of reproductive potential to use effective contraception during treatment with COLUMVI and for 1 month after the last dose of COLUMVI *[see Use in Specific Populations (8.1)]*.

8.4 Pediatric Use

The safety and efficacy of COLUMVI in pediatric patients have not been established.

8.5 Geriatric Use

Of the 145 patients with relapsed or refractory LBCL who received COLUMVI in study NP30179, 55% were 65 years of age or older, and 23% were 75 years of age or older. There was a higher rate of fatal adverse reactions, primarily from COVID-19, in patients 65 years of age or older compared to younger patients *[see Adverse Reactions (6.1)]*. No overall differences in efficacy were observed between patients 65 years of age or older and younger patients.

11 DESCRIPTION

Glofitamab-gxbm is a bispecific CD20-directed CD3 T-cell engager. It is a recombinant humanized anti-CD20 anti-CD3ε bispecific immunoglobulin G1 (IgG1) monoclonal antibody produced in Chinese hamster ovary (CHO) cells. Glofitamab-gxbm has an approximate molecular weight of 197 kDa.

COLUMVI (glofitamab-gxbm) injection is a sterile, preservative-free, colorless, clear solution supplied in single-dose vials for intravenous infusion.

COLUMVI is supplied in 2.5 mg/2.5 mL and 10 mg/10 mL single-dose vials at a concentration of 1 mg/mL. Each mL of solution contains 1 mg glofitamab-gxbm, histidine (0.63 mg), histidine hydrochloride monohydrate (3.34 mg), methionine (1.49 mg), polysorbate 20 (0.5 mg), sucrose (82.15 mg), and Water for Injection, USP, at pH 5.5.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Glofitamab-gxbm is a bispecific antibody that binds to CD20 expressed on the surface of B cells, and to CD3 receptor expressed on the surface of T cells. Glofitamab-gxbm causes T-cell activation and proliferation, secretion of cytokines, and the lysis of CD20-expressing B cells. Glofitamab-gxbm showed anti-tumor activity in vivo in mouse models of DLBCL.

12.2 Pharmacodynamics

Circulating B Cell Count

Peripheral B cell counts decreased to undetectable levels (< 5 cells/microliter) in 86.5% of patients by Cycle 1 Day 7 after obinutuzumab pretreatment of 1,000 mg on Cycle 1 Day 1, and in 88.2% of patients by Cycle 1 Day 10 after the first glofitamab-gxbm dose of 2.5 mg on Cycle 1 Day 8.

Cytokine Concentrations

Plasma concentrations of cytokines (IL-2, IL-6, IL-10, TNF-α, and IFN-γ) were measured and transient elevation of cytokines was observed at doses of 0.045 mg and above. After administration of the recommended dosage of COLUMVI, the highest elevation of cytokines was generally observed within 6 hours after the first glofitamab-gxbm dose of 2.5 mg on Cycle 1 Day 8. The elevated cytokine levels generally returned to baseline within 48 hours after the first 30 mg dose on Cycle 2 Day 1.

12.3 Pharmacokinetics

The pharmacokinetics of glofitamab-gxbm was determined following pretreatment with a single dose of obinutuzumab of 1,000 mg and the pharmacokinetic parameters are presented as geometric mean (CV%) unless otherwise specified. Glofitamab-gxbm exposure increased dose-proportionally over the dose range from 0.005 to 30 mg (0.000167 to 1 time the recommended treatment dosage). Glofitamab-gxbm exposure parameters are summarized in Table 11 for the approved recommended dosage of COLUMVI.

Table 11: Exposure Parameters of Glofitamab-gxbm Following Pretreatment with a Single Dose of Obinutuzumab of 1,000 mg

	AUC_{tau} (day·mcg/mL)	**C_{max} (mcg/mL)**	**C_{trough} (mcg/mL)**
First full 30 mg dose	44.5 (55%)	9.41 (27%)	0.52 (83%)
Steady state[1] 30 mg dose	48.6 (33%)	9.44 (26%)	0.59 (67%)

Data presented as geometric mean (CV%). AUC_{tau} = area under the concentration-time curve over one 21-day cycle; C_{max} = maximum glofitamab-gxbm concentration; C_{trough} = glofitamab-gxbm concentration prior to next dose; CV = geometric coefficient of variation.

[1] Steady state values are approximated at Cycle 6 (week 18).

Distribution

The glofitamab-gxbm total volume of distribution is 5.6 L (24%).

Elimination

At steady state, the glofitamab-gxbm terminal half-life is 7.6 days (24%) and the clearance is 0.617 L/day (33%).

Metabolism

Glofitamab-gxbm is expected to be metabolized into small peptides by catabolic pathways.

Specific Populations

No clinically significant changes in the pharmacokinetics of glofitamab-gxbm were observed based on age (21 to 90 years), body weight (31 to 148 kg), sex, mild to moderate renal impairment (CLcr 30 to < 90 mL/min as estimated by Cockcroft-Gault formula) and mild hepatic impairment (total bilirubin > ULN to ≤ 1.5 x ULN or AST > ULN).

The effects of severe renal impairment (CLcr 15 to < 30 mL/min), end-stage renal disease (CLcr < 15 mL/min), or moderate to severe hepatic impairment (total bilirubin > 1.5 x ULN and any AST), and race/ethnicity on the pharmacokinetics of glofitamab-gxbm are unknown.

Drug Interaction Studies

No clinical studies evaluating the drug interaction potential of glofitamab-gxbm have been conducted.

12.6 Immunogenicity

The observed incidence of antidrug antibodies (ADA) is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of ADA in the study described below with the incidence of ADA in other studies, including those of glofitamab-gxbm.

During treatment in Study NP30179 (up to 9 months) *[see Clinical Studies (14.1)]*, using an enzyme-linked immunosorbent assay (ELISA), the incidence of anti-glofitamab antibody formation was 1.1% (5/448) in patients treated with COLUMVI. Because of the low occurrence of ADAs, the effect of these antibodies on the pharmacokinetics, pharmacodynamics, safety, and/or effectiveness of glofitamab-gxbm is unknown.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No carcinogenicity or genotoxicity studies have been conducted with glofitamab-gxbm.

Fertility studies have not been conducted with glofitamab-gxbm.

14 CLINICAL STUDIES

14.1 Relapsed or Refractory DLBCL, NOS or LBCL Arising from Follicular Lymphoma

The efficacy of COLUMVI was evaluated in Study NP30179 (NCT03075696), an open-label, multicenter, multicohort, single-arm clinical trial that included patients with relapsed or refractory LBCL after two or more lines of systemic therapy. The trial required an ECOG performance status of 0 or 1, absolute neutrophil count ≥ 1,500/µL, platelet count ≥ 75,000/µL independent of transfusion, serum creatinine ≤ 1.5 x ULN or CLcr ≥ 50 mL/min, and hepatic transaminases ≤ 3 x ULN. The trial excluded patients with active or previous CNS lymphoma or CNS disease, acute infection, recent infection requiring intravenous antibiotics, or prior allogeneic HSCT.

Following pretreatment with obinutuzumab on Cycle 1 Day 1, patients received COLUMVI by intravenous infusion, starting with a 2.5 mg step-up dose on Cycle 1 Day 8, followed by a 10 mg step-up dose on Cycle 1 Day 15, then 30 mg on Cycle 2 Day 1 and on Day 1 of each subsequent cycle. The cycle length was 21 days. COLUMVI was administered for up to 12 cycles unless patients experienced progressive disease or unacceptable toxicity.

The efficacy population consists of 132 patients with *de novo* DLBCL, NOS (80%) or LBCL arising from follicular lymphoma (20%) who received at least one dose of COLUMVI. The median age was 67 years (range: 21 to 90 years), 64% were male, 77% were White, 4.5% were Asian, 0.8% were Black or African American, 5% were Hispanic or Latino. The median number of prior lines of systemic therapy was 3 (range: 2 to 7). Most patients (83%) had refractory disease to the last therapy, 55% had primary refractory disease, 30% had received CAR-T cell therapy, and 19% had received autologous HSCT.

Efficacy was based on objective response rate (ORR) and duration of response (DOR), as determined by an Independent Review Committee (IRC) using the 2014 Lugano criteria.

Efficacy results are summarized in Table 12. The median time to first response was 42 days (range: 31 to 178 days). Among responders, the estimated median follow-up for DOR was 11.6 months.

Table 12: IRC-Assessed Efficacy in Patients with Relapsed or Refractory DLBCL, NOS or LBCL Arising from Follicular Lymphoma

Outcome per IRC	**COLUMVI N=132**
Overall Response Rate, n (%) (95% CI)	74 (56) (47, 65)
Complete Response, n (%) (95% CI)	57 (43) (35, 52)
Partial Response, n (%) (95% CI)	17 (13) (8, 20)
Duration of Response[a]	N = 74
Median DOR, months (95% CI)[b]	18.4 (11.4, NE)
9-month estimate, % (95% CI)[b]	68.5 (56.7, 80.3)

CI = confidence interval; NE = not estimable

[a] From date of first response (PR or CR) until disease progression or death due to any cause.

[b] Kaplan-Meier estimate.

16 HOW SUPPLIED/STORAGE AND HANDLING

COLUMVI (glofitamab-gxbm) injection is a sterile, preservative-free, colorless, clear solution for intravenous infusion.

COLUMVI is supplied as:

Carton Contents	NDC
One 2.5 mg/2.5 mL (1 mg/mL) single-dose vial	NDC 50242-125-01
One 10 mg/10 mL (1 mg/mL) single-dose vial	NDC 50242-127-01

Store refrigerated at 2°C to 8°C (36°F to 46°F) in original carton to protect from light. Do not freeze. Do not shake.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Cytokine Release Syndrome

Inform patients of the risk of CRS. Advise patients to seek immediate medical attention if they experience signs and symptoms of CRS (fever, hypoxia, hypotension, chills and tachycardia) *[see Warnings and Precautions (5.1)]*.

Provide patients with the Patient Wallet Card that they should carry with them at all times. This card describes symptoms of CRS which, if experienced, should prompt the patient to seek immediate medical attention.

Neurologic Toxicity

Discuss the signs and symptoms associated with neurologic toxicity, including ICANS, headache, peripheral neuropathy, dizziness, or mental status changes. Advise patients to immediately contact their healthcare provider if they experience any signs or symptoms of neurologic toxicity. Advise patients who experience neurologic toxicity that impairs consciousness to refrain from driving or operating heavy or potentially dangerous machinery until neurologic toxicity resolves *[see Warnings and Precautions (5.2)]*.

Serious Infections

Advise patients that COLUMVI can cause serious infections. Advise patients to notify their healthcare provider immediately if they develop any signs of infection (e.g., fever, chills, weakness) *[see Warnings and Precautions (5.3)]*.

Tumor Flare

Inform patients of the potential risk of tumor flare reaction and to report any signs and symptoms associated with this event (e.g., localized pain and swelling) to their healthcare provider for evaluation *[see Warnings and Precautions (5.4)]*.

Embryo-Fetal Toxicity

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to inform their healthcare provider if they are pregnant or become pregnant. Advise females of reproductive potential to use effective contraception during treatment with COLUMVI and for 1 month after the last dose *[see Warnings and Precautions (5.5) and Use in Specific Populations (8.1, 8.3)]*.

Advise women not to breastfeed while receiving treatment with COLUMVI and for 1 month after the last dose *[see Use in Specific Populations (8.2)]*.

COLUMVI® [glofitamab-gxbm]

Manufactured by:

Genentech, Inc.

A Member of the Roche Group

1 DNA Way

South San Francisco, CA 94080-4990

U.S. License No.: 1048

COLUMVI® is a registered trademark of Genentech, Inc.

MEDICATION GUIDE
COLUMVI® (ko-loom-vee)
(glofitamab-gxbm)
injection, for intravenous infusion

What is the most important information I should know about COLUMVI?

COLUMVI can cause Cytokine Release Syndrome (CRS), a serious side effect that is common during treatment with COLUMVI, and can also be serious and lead to death.

- **Call your healthcare provider or get emergency medical help right away if you develop any signs or symptoms of CRS, including:**
  - fever of 100.4°F (38°C) or higher
  - chills or shaking
  - fast or irregular heartbeat
  - dizziness or light-headedness
  - trouble breathing
  - shortness of breath
- **Due to the risk of CRS, you will receive COLUMVI on a "step-up dosing schedule".**
  - A single dose of a medicine called obinutuzumab will be given to you on the first day of your first treatment cycle (Day 1 of Cycle 1).
  - You will start the COLUMVI step-up dosing schedule a week after the obinutuzumab dose. The step-up dosing schedule is when you receive smaller "step-up" doses of COLUMVI on Day 8 and Day 15 of Cycle 1. This is to help reduce your risk of CRS. You should be hospitalized during your infusion and for 24 hours after receiving the first step-up dose on Day 8. You should be hospitalized during your infusion and for 24 hours after receiving the second step-up dose on Day 15 if you experienced CRS during the first step-up dose.
  - You will receive your first full dose of COLUMVI a week after the second step-up dose (this will be Day 1 of Cycle 2).
  - If your dose of COLUMVI is delayed for any reason, you may need to repeat the "step-up dosing schedule".
  - If you had more than mild CRS with your previous dose of COLUMVI, you should be hospitalized during and for 24 hours after receiving your next dose of COLUMVI.
  - Before each dose of COLUMVI, you will receive medicines to help reduce your risk of CRS and infusion-related reactions.
  - See **"How will I receive COLUMVI?"** for more information about how you will receive COLUMVI.
- Your healthcare provider will monitor you for CRS during treatment with COLUMVI and may treat you in a hospital if you develop signs and symptoms of CRS. Your healthcare provider may temporarily stop or completely stop your treatment with COLUMVI if you have severe side effects.
- **Carry the COLUMVI Patient Wallet Card with you at all times and show it to all of your healthcare providers.** The COLUMVI Patient Wallet Card lists the signs and symptoms of CRS you should get emergency medical help for right away.

See **"What are the possible side effects of COLUMVI?**" for more information about side effects.

What is COLUMVI?

COLUMVI is a prescription medicine used to treat adults with certain types of diffuse large B-cell lymphoma (DLBCL) or large B-cell lymphoma (LBCL) that has come back (relapsed) or that did not respond to previous treatment (refractory), and who have received 2 or more prior treatments for their cancer.

It is not known if COLUMVI is safe and effective in children.

Before receiving COLUMVI, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection
- have kidney problems
- are pregnant or plan to become pregnant. COLUMVI may harm your unborn baby.
  Females who are able to become pregnant:
  - Your healthcare provider should do a pregnancy test before you start treatment with COLUMVI.
  - You should use effective birth control (contraception) during treatment and for 1 month after your last dose of COLUMVI. Talk to your healthcare provider about what birth control method is right for you during this time.
  - Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with COLUMVI.
- are breastfeeding or plan to breastfeed. It is not known if COLUMVI passes into your breastmilk. Do not breastfeed during treatment and for 1 month after your last dose of COLUMVI**.**

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive COLUMVI?

- COLUMVI will be given to you by your healthcare provider by infusion through a needle placed in your vein (intravenous infusion).
- Your COLUMVI treatment schedule is divided into cycles that are 21 days (3 weeks) long.

- On Day 1 of Cycle 1, your healthcare provider will give you a single dose of a medicine called obinutuzumab by intravenous infusion. You will then receive COLUMVI on Day 8 and Day 15 of Cycle 1. Starting with Cycle 2, you will receive COLUMVI 1 time every three weeks.

Your healthcare provider will decide how many treatment cycles you will receive of COLUMVI. See **"What is the most important information I should know about COLUMVI?"** for more information about how you will receive COLUMVI.

What should I avoid while receiving COLUMVI?

Do not drive, operate heavy machinery, or do other dangerous activities if you develop dizziness, confusion, shaking (tremors), sleepiness, or any other symptoms that impair consciousness until your signs and symptoms go away. These may be signs and symptoms of neurologic problems.

See "**What are the possible side effects of COLUMVI?"** for more information about signs and symptoms of neurologic problems.

What are the possible side effects of COLUMVI?

COLUMVI may cause serious side effects, including:

- **Cytokine Release Syndrome**. See **"What is the most important information I should know about COLUMVI?"**
- **Neurologic problems.** COLUMVI can cause serious neurologic problems that may lead to death. Your healthcare provider will monitor you for neurologic problems during treatment with COLUMVI. Your healthcare provider may also refer you to a healthcare provider who specializes in neurologic problems. Tell your healthcare provider right away if you develop any signs or symptoms of neurologic problems, including:
  - headache
  - confusion and disorientation
  - difficulty paying attention or understanding things
  - trouble speaking
  - sleepiness
  - memory problems
  - numbness, tingling, or weakness of the hands or feet
  - dizziness
  - shaking (tremors)
- **Serious infections.** COLUMVI can cause serious infections that may lead to death. Your healthcare provider will monitor you for signs and symptoms of infection and treat you as needed. Tell your healthcare provider right away if you develop any signs of infection, including: fever, chills, weakness, cough, shortness of breath, or sore throat.
- **Growth in your tumor or worsening of tumor related problems (tumor flare).** Tell your healthcare provider if you get any of these signs or symptoms of tumor flare:
  - tender or swollen lymph nodes
  - pain or swelling at the site of the tumor
  - chest pain
  - cough
  - trouble breathing

Your healthcare provider may temporarily stop or completely stop treatment with COLUMVI if you develop certain side effects.

The most common side effects of COLUMVI include: CRS, muscle and bone pain, rash, and tiredness.

The most common severe abnormal lab test results with COLUMVI include: decreased white blood cells, decreased phosphate (an electrolyte), increased uric acid levels, and decreased fibrinogen (a protein that helps with blood clotting).

These are not all the possible side effects of COLUMVI.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of COLUMVI.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your healthcare provider or pharmacist for information about COLUMVI that is written for health professionals.

What are the ingredients in COLUMVI?

Active ingredient: glofitamab-gxbm

Inactive ingredients: histidine, histidine hydrochloride monohydrate, methionine, polysorbate 20, sucrose, and Water for injection.

Manufactured by: **Genentech, Inc.**, A Member of the Roche Group, 1 DNA Way, South San Francisco, CA 94080-4990
U.S. License No.: 1048
For more information, go to www.COLUMVI.com or call 1-877-436-3683.
This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 6/2025