STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

Columvi (glofitamab-gxbm)
PAM–070

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	01/01/2024
Revision Number:	1	**Last Rev Date:**	07/19/2024
Reviewed By:	Medicaid Medical Director	**Next Rev Date:**	07/18/2025
Approved By:	Medicaid Clinical Advisory Committee	**Approved Date:**	07/19/2024

Overview

Medication:[1]	glofitamab-gxbm
Brand Name:	Columvi™
Pharmacologic Category:	Antineoplastic; bispecific CD20-directed CD3 T-cell engager
FDA-Approved Indication(s):	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).
How Supplied:	Single-dose vial containing either 2.5 mg/2.5 mL (1 mg/mL) or 10 mg/10 mL (1 mg/mL)
Dosage and Administration:	Continue Columvi™ for a maximum of 12 treatment cycles (inclusive of Cycle 1 step-up dosing) or until disease progression or unacceptable toxicity, whichever occurs first.

21-Day Treatment Cycle	Day	COLUMVI Dose	
Cycle 1	Day 1	Obinutuzumab (Gazyva®)*	
	Day 8	Step-up dose 1	2.5 mg
	Day 15	Step-up dose 2	10 mg
Cycle 2	Day 1	Subsequent treatment doses	
Cycles 3 to 12	Day 1	Subsequent treatment doses	

* 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™ to deplete the circulating and lymphoid tissue B cells.

Benefit Category:	Medical

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.

Descriptive Narrative

Diffuse large B-cell lymphoma (DLBCL) is the most common histologic subtype of non-Hodgkin lymphoma (NHL) accounting for approximately 25 percent of NHL cases in the developed world. In the United States, the incidence of DLBCL is approximately 7 cases per 100,000

persons per year. Incidence varies by ethnicity, with White Americans having higher rates than Black, Asian, and American Indian or Alaska Native individuals, in order of decreasing incidence. Like most other NHLs, there is a male predominance with approximately 55 percent of cases occurring in men. Incidence increases with age; the median age at presentation is 64 years for patients as a whole but appears to be younger for Black compared with White Americans.[2]

Guidelines

As new and emerging therapies are rapidly coming to market, oncology treatment recommendations and guidelines are constantly changing. To keep up with these changes, the National Comprehensive Cancer Network (NCCN) publishes guidelines which are developed and updated by 60 individual panels, comprising over 1,660 clinicians and oncology researchers from the 31 NCCN Member Institutions.[3]

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

The information referenced at the time of this policy writing/revision is from:

- NCCN Guidelines® for B-Cell Lymphomas (Version 2.2024 – April 30, 2024)[4]

NCCN Guidelines® recommendation(s) for glofitamab-gxbm (Columvi®)
(1) Diffuse Large B-Cell Lymphoma, third-line and subsequent therapy A. Bispecific antibody therapy (only after at least 2 lines of systemic therapy; including patients with disease progression after transplant or CAR T-cell therapy) i. Glofitamab-gxbm: Category 2A, preferred (2) Histologic Transformation of Indolent Lymphomas to DLBCL A. T-cell engager therapy (only after at least 2 lines of systemic therapy; including patients with disease progression after transplant or CAR T-cell therapy) i. Glofitamab-gxbm: Category 2A, treatment option for third-line therapy

NCCN Categories of Evidence and Consensus (all recommendations are category 2A unless otherwise indicated)	
Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

NCCN Categories of Preference (all recommendations are considered appropriate)	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for select patient populations (defined with recommendation).

Eastern Cooperative Oncology Group (ECOG) Performance Status Scale[5]

Developed by the Eastern Cooperative Oncology Group (ECOG), now part of the ECOG-ACRIN Cancer Research Group, and published in 1982, the ECOG Performance Status Scale describes a patient's level of functioning in terms of their ability to care for themself, daily activity, and physical ability (walking, working, etc.). It is used by doctors and researchers to assess how a patient's disease is progressing, how the disease affects the daily living abilities of the patient and determine appropriate treatment and prognosis.

GRADE	ECOG PERFORMANCE STATUS [Synonyms: WHO/Zubrod score]
0	Fully active, able to carry on all pre-disease performance without restriction.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work.
2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours.
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours.
4	Completely disabled; cannot carry on any self-care; totally confined to bed or chair.
5	Dead.

Criteria

Prior authorization is required.

Columvi™ is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of one of the following
    a. Diffuse large B-cell lymphoma (DLBCL); or
    b. Large B-cell lymphoma arising from follicular lymphoma; **AND**
2. Disease is refractory to or has relapsed after 2 or more lines of systemic therapy; **AND**
3. Member is 18 years of age or older; **AND**
4. Member has an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
5. Prescribed by, or in consultation with, an oncologist; **AND**
6. Member will receive a pre-treatment dose of obinutuzumab (Gazyva®) on Cycle 1, Day 1 (7 days prior to the initiation of Columvi™) to deplete the circulating and lymphoid tissue B cells; **AND**
7. Request meets one of the following (a or b):
    a. Regimen is prescribed on a 21-day treatment cycle and meets one of the following (i or ii):
        i. Cycle 1: Day 8 (step-up dose 1) does not exceed 2.5 mg and Day 15 (step-up dose 2) does not exceed 10 mg; or
        ii. Cycles 2 through 12: dose does not exceed 30 mg on Day 1 of each cycle, for a maximum of 12 cycles; **OR**
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Columvi™ is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy, as demonstrated by tumor response or lack of disease progression, and an acceptable toxicity profile; **AND**
3. Prescribed by, or in consultation with, an oncologist; **AND**
4. Member has received less than 12 cycles of Columvi™; **AND**
5. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 30 mg on Day 1 of a 21-day cycle, for a maximum of 12 cycles; or
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	6 months	Treat until disease progression or unacceptable toxicity, or up to a maximum of 12 treatment cycles (whichever comes first)
Quantity Limits (21-day cycle)	Cycle 1: one 2.5 mg dose and one 10 mg dose Cycles 2 and beyond: one 30 mg dose	One 30 mg dose per cycle (up to a maximum total treatment course of 12 cycles)

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J9286	Injection, glofitamab-gxbm, 2.5 mg [Columvi™]
J9301	Injection, obinutuzumab, 10 mg [Gazyva®]

ICD-10	Description
C83.30 – C83.39	Diffuse large B-cell lymphoma

Medication	NDC (and strength)	Labeler	Dosage	Pkg Size	Pkg Qty	Units/ Pkg
Columvi™	50242-0125-01 (2.5 mg/2.5 mL)	Genentech, Inc. (50242)	2.5 mg	1	EA	1
Columvi™	50242-0127-01 (10 mg/10 mL)	Genentech, Inc. (50242)	2.5 mg	1	EA	4
Gazyva®	50242-0070-01 (1,000 mg/40 mL)	Genentech, Inc. (50242)	10 mg	1	EA	100

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Columvi® prescribing information (06/2023). Genentech, Inc.: South San Francisco, CA. Available online at: www.columvi-hcp.com. Accessed May 24, 2024.

[2] Freedman AS, Aster JC. Epidemiology, clinical manifestations, pathologic features, and diagnosis of diffuse large B cell lymphoma. Rosmarin AG, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed May 28, 2024.

[3] National Comprehensive Cancer Network (NCCN). Development and Update of Guidelines. Available online at www.nccn.org. Accessed October 11, 2023.

[4] Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas (v.2.2024 – April 30, 2024). Accessed June 6, 2024. The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version of the guidelines, go online to NCCN.org.

[5] Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655. PMID 7165009.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
07/19/2024	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee