Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Glofitamab-gxbm (Columvi®)	MP-RX-FP-122-24	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of Glofitamab-gxbm (Columvi®), a bispecific CD20-directed CD3 T-cell engager approved by the Food and Drug Administration (FDA) 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.

Background Information

Glofitamab-gxbm is a recombinant humanized anti-CD20 anti-CD3ε bispecific immunoglobulin G1 (IgG1) monoclonal antibody. It's unique mechanism of binding to CD20 on B cells and CD3 receptors on T cells activates T cell proteins, enabling them to eliminate cancer cells associated with B cells.

Prescribing information for Columvi includes a black box warning for cytokine release syndrome (CRS), with potential serious or fatal reactions in patients. Premedication before each dose and following the step-up dosing schedule are recommended to mitigate CRS risk. Columvi should be withheld until CRS resolves, or permanent discontinuation may be necessary depending on severity.

Additionally, the prescribing information highlights the following warnings and precautions for Columvi:

- Neurologic toxicity: Serious neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), may occur. Monitoring for neurologic toxicity is advised, with potential withholding or discontinuation based on severity.
- Serious infections: Columvi can lead to severe or fatal infections. Monitoring for signs of infection and appropriate treatment are essential.
- Tumor flare: Serious tumor flare reactions are possible. Monitoring for complications related to tumor flare is recommended.
- Embryo-fetal toxicity: There is a risk of fetal harm, and females of reproductive potential should be informed of this risk. Effective contraception is advised during Columvi treatment.

The adverse reactions associated with Columvi include:

- Common (≥ 20%): Cytokine release syndrome, musculoskeletal pain, rash, and fatigue.
- Grade 3 to 4 laboratory abnormalities
- (≥ 20%): Decreased lymphocyte count, decreased phosphate, decreased neutrophil count, increased uric acid, and decreased fibrinogen.

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Approved Indications

Columvi is approved by the FDA 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. The approval for this indication is granted through accelerated approval, considering factors such as response rate and the duration of response. Ongoing approval for this specific use is subject to confirmation and detailed documentation of clinical benefits in one or more confirmatory trials.

Other Uses

None

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J9286	Injection, glofitamab-gxbm, 2.5 mg

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

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Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Glofitamab-gxbm (Columvi®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual is using for a maximum of 12 cycles; **AND**

ii. Individual is using for one of the following:

A. Relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified;

OR

B. Large B-cell lymphoma arising from follicular lymphoma; **AND**

C. Previously had two or more lines of systemic therapy.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Glofitamab-gxbm (Columvi®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen **and** the maximum duration of therapy (twelve [12] 21-days cycles) has not been exceeded. The following information should be submitted for reauthorization:

A. A current oncology note documenting the patient's response to treatment showing no progression of disease.

B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

C. Authorization Duration

i. Initial Approval Duration: As requested for up to 6 months

ii. Reauthorization Approval Duration: As requested, for up to 6 months, until a maximum of twelve (12) 21-days cycles (9 months) has been reached

D. **Conditions Not Covered**

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

Requests for Columvi (glofitamab-gxbm) may not be approved when the above criteria are not met and for all other indications.

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Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Day	Dose	
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 2-12	Day 1	30 mg	
Exceptions			
• Columvi administration begins with a step-up dosing schedule. • All patients should be pretreated with a single intravenous infusion of 1,000 mg obinutuzumab on Cycle 1 Day 1. This should be done seven days before initiating Columvi with the purpose of depleting circulating and lymphoid tissue B cells effectively.			

Reference Information

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 3, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on J
    a. T-Cell Lymphomas. V2.2022. Revised March 7, 2022.

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Policy Inception	New Medical Policy creation	4/18/2024	6/28/2024

Revised: 01/16/2024