

Effective: October 1, 2023

<b>Guideline Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Non-Formulary <input type="checkbox"/> Step-Therapy <input type="checkbox"/> Administrative
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**Applies to:**

**Public Plans Products**

Tufts Health One Care\* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956  
 \*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

**Senior Products**

Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956  
 Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956  
 Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956  
 Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

**Overview**

**Food and Drug Administration–Approved Indications**

**Columvi (glofitamab-gxbm)** 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 or large B-cell lymphoma 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).

**Clinical Guideline Coverage Criteria**

The plan may authorization coverage of Columvi for Members when all of the following criteria are met:

1. Documented diagnosis of **one (1)** of the following:
  - a. Relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified
  - b. Large B-cell lymphoma arising from follicular lymphoma

**AND**
2. The prescribing physician is an oncologist or hematologist

**AND**

3. Documentation the patient has received at least two prior lines of systemic therapy

**Limitations**

- None

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## Codes

The following code(s) require prior authorization:

**Table 1: HCPCS Codes**

HCPCS Codes	Description
J9286	INJECTION, GLOFITAMAB-GXBM, 2.5 MG

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## References

1. Columvi (glofitamab-gxblm) [prescribing information]. South San Francisco, CA: Genentech, Inc.; 2023 June
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## Approval And Revision History

September 12, 2023: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- December 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
  - January 1, 2024: Administrative updated: Added new J Code J9286 to Medical Necessity Guideline.
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## Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients 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. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.