Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Columvi™ (glofitamab-gxbm)

Effective: October 1, 2024

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

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

Columvi (glofitamab-gxbm) is a bispecific CD20-directed CD3 T-cell engager. Accelerated approval of Columvi was based on response rate and durability of response (DOR) in a Phase 1/2 trial in which the overall response rate (ORR) was 56% and the DOR was 18.4 months. Furthermore, 43% of patients achieved a complete response (CR) and 68.5% of patients who responded to Columvi continued to respond for at least 9 months. The median time to a CR was 42 days (95% confidence interval [CI]: 42 to 44). Seventy eight percent of patients with CR were ongoing at 12 months. The 12-month progression-free survival (PFS) was 37% (95% CI: 28 to 46). 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.

This trial enrolled patients who previously received CAR T-cell therapy. Specifically, 33% of patients had previously received CAR T-cell therapy. Of the patients who had previously received CAR T-cell therapy, 83% had received CAR T-cell therapy after a second or subsequent relapse and 17% after a first relapse. In addition, 89% of patients were refractory to CAR T-cell therapy. The rate of CR with Columvi was 35% in patients previously treated with CAR T-cell therapy and 42% in patients who had not previously received CAR T-cell therapy.

Food and Drug Administration–Approved Indications

Columvi (glofitamab-gxbm) is 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 authorize 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

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9286	Injection, glofitamab-gxbm, 2.5 mg

References

1. Columvi (glofitamab-gxbm) [prescribing information]. South San Francisco, CA: Genentech, Inc.; 2023 June

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.
- August 13, 2024: No changes (eff 10/1/24).
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24).

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

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