Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Talvey™ (talquetamab-tgvs)

Effective: January 1, 2026

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

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

☒ 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

Accelerated approval of Talvey was based on the Phase 2 MonumenTAL-1, open-label trial in which 187 patients who received at least four prior lines of therapy and were not exposed to prior T-cell redirection therapy, received Talvey either weekly or biweekly until disease progression or unacceptable toxicity. The overall response rate was 73% with the weekly dose and 74% with the every-other week dosing. The median duration of response was only reached with the weekly dosing and was 9.5 months. Thirty-two patients had previous exposure to bispecific antibody CAR T-cell therapy, mostly B-cell maturation antigen-directed, and had received at least four prior lines of therapy. In these patients, the overall response rate was 72%.

There are no guidelines for sequencing the options that can be used in the fifth line setting for multiple myeloma. Providers will consider patient comorbidities, ability to tolerate side effects, ECOG score, prior exposure to agents, and availability of therapies in the specific area.

Food and Drug Administration–Approved Indications

Talvey (talquetamab-tgvs) is a bispecific GPRC5D-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

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 Talvey for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of relapsed or refractory multiple myeloma

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. Documentation the patient has received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J3055	Injection, talquetamab-tgvs, 0.25 mg

References

1. Talvey (talquetamab-tgvs) [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; 2023 Aug.

Approval And Revision History

November 14, 2023: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- December 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- January 1, 2024: Administrative updated: Added new C Code C9163 to Medical Necessity Guideline.
- April 1, 2024: Administrative update: Removed C Code C9163 and added J Code J3055.
- November 12, 2024: No changes (eff 1/1/25)
- December 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/25).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

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.