

Clinical Policy: Talquetamab-tgvs (Talvey)

Reference Number: PA.CP.PHAR.649

Effective Date: 12/2023

Last Review Date: 10/2025

Description

Talquetamab-tgvs (Talvey[®]) is bispecific GPRC5D-directed CD3 T-cell engager.

FDA Approved Indication(s)

Talvey is 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).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness[®] that Talvey is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Multiple Myeloma (must meet all):

1. Diagnosis of MM;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age \geq 18 years;
4. Disease is relapsed or refractory;
5. One of the following (a or b):
 - a. Member has measurable disease as evidenced by one of the following assessed within the last 30 days (i, ii, or iii):
 - i. Serum M-protein \geq 0.5 g/dL;
 - ii. Urine M-protein \geq 200 mg/24 h;
 - iii. Serum free light chain (FLC) assay: involved FLC level \geq 10 mg/dL (100 mg/L) provided serum FLC ratio is abnormal;
 - b. Member has progressive disease, as defined by the IMWG response criteria (see *Appendix D*), assessed within 60 days following the last dose of the last anti-myeloma drug regimen received;
6. Prescribed in one of the following ways (a or b):
 - a. In combination with Tecvayli[®]: Member has received \geq 3 prior lines of therapy;
 - b. As a single agent: Member has received or has documented intolerance to \geq 4 prior lines of therapies* (see *Appendix B*) that include all of the following (i, ii, and iii):
 - i. One proteasome inhibitor (e.g., bortezomib, Kyprolis[®], Ninlaro[®])

- ii. One immunomodulatory drug (e.g., Thalomid[®], lenalidomide, pomalidomide)
 - iii. One anti-CD38 monoclonal antibody (e.g., Darzalex[®], Sarclisa[®])
**Prior authorization may be required*
7. Request meets one of the following (a, b or c):
- a. For weekly dosing: dose does not exceed 0.4 mg/kg once weekly after day 6;
 - b. For biweekly dosing: dose does not exceed 0.8 mg/kg every 2 weeks after day 9;
 - c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Multiple Myeloma (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b, or c):
 - a. For weekly dosing: dose does not exceed 0.4 mg/kg once weekly after day 6;
 - b. For biweekly dosing: dose does not exceed 0.8 mg/kg every 2 weeks after day 9;
 - c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

FLC: free light chain

IMWG: International Myeloma Working Group

MM: multiple myeloma

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
MM: regimens containing proteasome inhibitors, immunomodulatory agents and/or anti-CD38 monoclonal antibodies (examples – NCCN)		
bortezomib / lenalidomide (Revlimid [®]) or pomalidomide or Thalomid [®] (thalidomide) / dexamethasone	Varies	Varies
Kyprolis [®] (carfilzomib – weekly or twice weekly) / dexamethasone	Varies	Varies
Kyprolis [®] (carfilzomib) / lenalidomide (Revlimid [®]) / dexamethasone	Varies	Varies
Ninlaro [®] (ixazomib) / lenalidomide (Revlimid [®]) / dexamethasone	Varies	Varies
Darzalex [®] (daratumumab) / bortezomib / dexamethasone ± Thalomid [®] (thalidomide)	Varies	Varies
Darzalex [®] (daratumumab) / lenalidomide (Revlimid [®]) / dexamethasone	Varies	Varies

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): None
- Boxed warning(s): cytokine release syndrome, neurologic toxicity

Appendix D: General Information

- The IMWG response criteria for multiple myeloma definition of progressive disease requires only one of the following:
 - Increase of 25% from lowest response value in any of the following:
 - Serum M-component (absolute increase must be ≥ 0.5 g/dL), and/or
 - Urine M-component (absolute increase must be ≥ 200 mg/24 h), and/or
 - Only in patients without measurable serum and urine M-protein levels: the difference between involved and uninvolved FLC levels (absolute increase must be > 10 mg/dL)
 - Only in patients without measurable serum and urine M protein levels and without measurable disease by FLC levels, bone marrow plasma cell percentage irrespective of baseline status (absolute increase must be $\geq 10\%$)
 - Appearance of a new lesion(s), $\geq 50\%$ increase from nadir in SPD (sum of the products of the maximal perpendicular diameters of measured lesions) of > 1 lesion, or $\geq 50\%$ increase in the longest diameter of a previous lesion >1 cm in short axis;

- $\geq 50\%$ increase in circulating plasma cells (minimum of 200 cells per μL) if this is the only measure of disease

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Relapsed or refractory MM	<p>Weekly dosing schedule:</p> <ul style="list-style-type: none"> • Day 1: 0.01 mg/kg • Day 4: 0.06 mg/kg • Day 7 (first treatment dose): 0.4 mg/kg • One week after first treatment dose (subsequent treatment doses): 0.4 mg/kg weekly <p>Biweekly (every 2 weeks) dosing schedule:</p> <ul style="list-style-type: none"> • Day 1: 0.01 mg/kg • Day 4: 0.06 mg/kg • Day 7: 0.4 mg/kg • Day 10 (first treatment dose): 0.8 mg/kg • Two week after first treatment dose (subsequent treatment doses): 0.8 mg/kg every 2 weeks <p>Dose calculation is based on actual body weight.</p>	0.4 mg/kg once weekly or 0.8 mg/kg every 2 weeks

VI. Product Availability

Single-dose vials for injection: 3 mg/1.5 mL (2 mg/mL); 40 mg/mL

VII. References

1. Talvey Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; August 2023. Available at: www.talvey.com. Accessed July 9, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 25, 2025.
3. National Comprehensive Cancer Network. Multiple Myeloma Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed August 25, 2025.
4. Chari A, Minnema MC, Berdeja JG, et al. Talquetamab, a t-cell–redirecting gprc5d bispecific antibody for multiple myeloma. *New England Journal of Medicine*. 2022;387(24):2232-2244.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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

Reviews, Revisions, and Approvals	Date
Policy created	10/2023
4Q 2024 annual review: added IMWG criterion defining progressive MM disease as MM class alignment; added Appendix D; references reviewed and updated.	10/2024
4Q 2025 annual review: added option to be prescribed in combination with Tecvayli with ≥ 3 prior lines of therapy per NCCN; initial approval duration changed from 6 to 12 months; references reviewed and updated.	10/2025