Clinical Policy: Talquetamab-tgvs (Talvey)

Reference Number: PA.CP.PHAR.649
Effective Date: 12/2023
Last Review Date: 10/2023

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 ≥ 18 years;
4. Disease is relapsed or refractory;
5. Member has received or has documented intolerance to ≥ 4 prior lines of therapies* (*see Appendix B*) that include all of the following (a, b, and c):
   a. One proteasome inhibitors (e.g., bortezomib, Kyprolis®, Ninlaro®)
   b. One immunomodulatory drugs (e.g., Thalomid®, lenalidomide, pomalidomide)
   c. One anti-CD38 monoclonal antibodies (e.g., Darzalex®, Sarclisa®)

   **Prior authorization may be required*
6. 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: 6 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.LTSS.PHAR.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.LTSS.PHAR.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
MM: multiple myeloma
NCCN: National Comprehensive Cancer Network

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 for all relevant lines of business 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)		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Relapsed or refractory MM	Weekly dosing schedule: • 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 Biweekly (every 2 weeks) dosing schedule: • 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 Dose calculation is based on actual body weight.	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.; Aug 2023. Available at: www.talvey.com. Accessed August 23, 2023.
2. National Comprehensive Cancer Network. Multiple Myeloma Version 3.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed August 23, 2023.
3. 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
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10/2023	