

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Bispecific – GPRC5D-Directed) – Talvey Utilization Management Medical Policy

- Talvey™ (talquetamab-tgvs subcutaneous injection – Janssen Biotech)

REVIEW DATE: 09/10/2025

OVERVIEW

Talvey, a bispecific GPRC5D-directed CD3 T-cell engager, is indicated for the treatment of relapsed or refractory **multiple myeloma** in adults who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.¹

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 of clinical benefit in a confirmatory trial(s).

Dosing Information

Talvey is administered by subcutaneous injection with recommendations for two types of dosing schedules (weekly or biweekly).¹ The dosing schedule of Talvey weekly includes two weight-based step-up doses of 0.01 mg/kg given on Day 1 and 0.06 mg/kg given on Day 4, followed by the first treatment dose of 0.4 mg/kg given on Day 7.¹ After the first treatment dose is given, Talvey is given once weekly thereafter until disease progression or unacceptable toxicity. The dosing schedule of Talvey biweekly includes three weight-based step-doses of 0.01 mg/kg given on Day 1, 0.06 mg/kg given on Day 4, 0.4 mg/kg on Day 7, followed by the first treatment dose of 0.8 mg/kg given on Day 10. After the first treatment dose is given, Talvey is given once every 2 weeks thereafter until disease progression or unacceptable toxicity.

Guidelines

The National Comprehensive Cancer Network (NCCN) **multiple myeloma** (version 2.2026 – July 16, 2025) clinical practice guidelines recommend Talvey as a “Preferred Regimen” for the treatment of relapsed or refractory multiple myeloma in patients have received at least four prior lines of therapy including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent (category 2A).^{2,3} Talvey is also recommended in combination with Tecvayli™ (teclistamab-cqyv subcutaneous injection) in those who have received at least 3 prior lines of therapy as “Useful in Certain Circumstances” (category 2A).

Safety

Talvey has a Boxed Warning for cytokine release syndrome (CRS) and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome (ICANS).¹ Talvey was approved with a Risk Evaluation and Mitigation Strategy (REMS) program due to the risk of CRS and neurotoxicity, including ICANS.¹

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Talvey. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing

documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Talvey as well as the monitoring required for adverse events and long-term efficacy, approval requires Talvey to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Talvey is recommended in those who meet the following criteria:

FDA-Approved Indication

- I. Multiple Myeloma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
- A) Patient is ≥ 18 years of age; AND
 - B) Patient has tried at least four systemic regimens; AND
 - C) Among the previous regimens tried, the patient has received at least one drug from each of the following classes (i, ii, and iii):
 - i. Proteasome inhibitor; AND
Note: Examples include bortezomib, Kyprolis (carfilzomib intravenous infusion), Ninlaro (ixazomib capsules).
 - ii. Immunomodulatory drug; AND
Note: Examples include lenalidomide, Pomalyst (pomalidomide capsules), Thalomid (thalidomide capsules).
 - iii. Anti-CD38 monoclonal antibody; AND
Note: Examples include Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), or Sarclisa (isatuximab-irfc intravenous infusion).
 - D) The medication will be prescribed by or in consultation with an oncologist.

Dosing. Approve ONE of the following dosing regimens (A or B):

- A) **Weekly Dosing Schedule:** Approve BOTH of the following (i and ii):
 - i. Step-up dosing (a, b, and c):
 - a) Dose 1: Approve 0.01 mg/kg administered subcutaneously on Day 1; AND
 - b) Dose 2: Approve 0.06 mg/kg administered subcutaneously, 2 to 7 days after Dose 1; AND
 - c) Dose 3: Approve 0.4 mg/kg administered subcutaneously, 2 to 7 days after Dose 2; AND
 - ii. Approve 0.4 mg/kg administered subcutaneously no more frequently than once weekly.
- B) **Every 2 Weeks Dosing Schedule:** Approve the following (i and ii):
 - i. Step-up dosing (a, b, c, and d):
 - a) Dose 1: Approve 0.01 mg/kg administered subcutaneously on Day 1; AND
 - b) Dose 2: Approve 0.06 mg/kg administered subcutaneously, 2 to 7 days after Dose 1; AND
 - c) Dose 3: Approve 0.4 mg/kg administered subcutaneously, 2 to 7 days after Dose 2; AND
 - d) Dose 4: Approve 0.8 mg/kg administered subcutaneously, 2 to 7 days after Dose 3; AND
 - ii. Approve 0.8 mg/kg administered subcutaneously no more frequently than once every 2 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

09/10/2025

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Coverage of Talvey is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Talvey™ subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech.; August 2023.
2. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on September 8, 2025. Search term: talquetamab.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 2.2026 – July 16, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on September 8, 2025.

HISTORY

| Type of Revision | Summary of Changes | Review Date |
|------------------|---|-------------|
| New Policy | -- | 08/16/2023 |
| Annual Revision | No criteria changes. | 09/11/2024 |
| Update | 04/08/2025: The policy name was changed from “Oncology (Injectable) – Talvey UM Medical Policy” to “Oncology (Injectable – Bispecific – GPRC5D-Directed) – Talvey UM Medical Policy”. | N/A |
| Annual Revision | No criteria changes. | 09/10/2025 |