CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

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

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

REVIEW DATE: 09/30/2026

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 2.2027 – September 24, 2026) clinical practice guidelines recommend Talvey for relapsed/refractory multiple myeloma in combination with other medications, and as "Preferred" monotherapy in patients who 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]

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. 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.

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RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **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 relapsed or refractory disease; AND
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** Patient meets BOTH of the following (a and b):
       - **a)** Patient has tried at least one systemic regimen; AND
         Note: Examples of agents used in a systemic regimen include one or more of the following: Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), Sarclisa (isatuximab-irfc intravenous infusion), Sarclisa Escena (isatuximab-irfc subcutaneous injection), bortezomib, Kyprolis (carfilzomib intravenous infusion), Ninlaro (ixazomib capsules), lenalidomide, pomalidomide, or Thalomid (thalidomide capsules).
       - **b)** The medication will be used in combination with at least one of the following: Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), Tecvayli (teclistamab-cqyv subcutaneous injection), or pomalidomide; OR
     - **ii.** Patient meets BOTH of the following (a and b):
       - **a)** Patient has tried at least four systemic regimens; AND
         Note: Examples of agents used in a systemic regimen include one or more of the following: Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), Sarclisa (isatuximab-irfc intravenous infusion), Sarclisa Escena (isatuximab-irfc subcutaneous injection), bortezomib, Kyprolis (carfilzomib intravenous infusion), Ninlaro (ixazomib capsules), lenalidomide, pomalidomide, or Thalomid (thalidomide capsules).
       - **b)** The medication will be used as monotherapy; AND
   - **D)** The medication will be prescribed by or in consultation with an oncologist or hematologist.

   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; OR
   - **B)** Every 2 Weeks Dosing Schedule: Approve BOTH of 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.

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CONDITIONS NOT RECOMMENDED FOR APPROVAL

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.; October 2025.
2. The NCCN Drugs and Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 24, 2026. Search term: talquetamab.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 2.2027 – September 24, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 25, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
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
Annual Revision	**Multiple Myeloma:** The requirement that the patient has relapsed or refractory disease was added. An option for approval was added when the patient has tried at least one systemic regimen (with a Note of examples of a systemic regimen), and when Talvey is used in combination with at least one of the following: Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), Tecvayli (teclistamab-cqyv subcutaneous injection), or pomalidomide. For a patient that has tried four systemic therapies, the requirement that the patient has received at least one drug from each of the following classes: proteasome inhibitor, immunomodulatory drug, or anti-CD38 monoclonal antibody was removed, a Note was added with examples of a systemic regimen, and the requirement that the medication will be used as monotherapy was added. The specialist requirement was updated to include a hematologist.	09/30/2026

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