PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Talvey Prior Authorization Policy
- Talvey™ (talquetamab-tgvs subcutaneous injection – Janssen Biotech)

REVIEW DATE: 09/11/2024

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]

Guidelines
The National Comprehensive Cancer Network (NCCN) **multiple myeloma** (version 4.2024 – April 26, 2024) 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]

Safety
Talvey was approved with a Risk Evaluation and Mitigation Strategy (REMS) program due to the risk of cytokine release syndrome and neurotoxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS).[1]

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Talvey. 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

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 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.

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.; August 2023.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 4, 2024. Search term: talquetamab.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 4.2024 – April 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 4, 2024.