VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Talvey Utilization Management Medical Policy
- Talvey™ (talquetamab-tgvs subcutaneous injection – Janssen Biotech)

REVIEW DATE: 08/16/2023

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]

Dosing Information

The dosing schedule of Talvey includes weight-based step-up doses administered subcutaneously (SC), followed by the first treatment dose.[1] After the first treatment dose is given, Telvay is given once weekly or once every 2 weeks thereafter until disease progression or unacceptable toxicity.

Guidelines

Guidelines have not yet addressed Talvey. For late relapse or progressive multiple myeloma in patients who have received at least four previous therapies including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, the National Comprehensive Cancer Network (NCCN) **multiple myeloma** (version 3.2023 – December 8, 2022) clinical practice guidelines recommend Abecma® (idecabtagene vicleucel intravenous [IV] infusion), Carvykti™ [ciltacabtagene autoleucel IV infusion]), or Tecvayli™ (teclistamab-cqyv SC injection).[2] Blenrep™ (belantamab mafodotin-blmf IV infusion) is listed as "Useful in Certain Circumstances".

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 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

---

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.

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

A) Weekly Dosing Schedule: Approve 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

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 Multiple Myeloma Clinical Practice Guidelines in Oncology (version 2.2023 – December 8, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 10, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/16/2023