POLICY: Oncology (Injectable) – Tecvayli

- Tecvayli™ (teclistamab-cqyv subcutaneous injection – Janssen Biotech)

EFFECTIVE DATE: 3/15/2023
LAST REVISION DATE: 11/13/2024

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Tecvayli, a bispecific B-cell maturation antigen (BCMA)-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 Tecvayli includes two step-up doses of 0.06 mg/kg administered subcutaneously (SC) on day 1 and 0.3 mg/kg SC on day 4, followed by the first treatment dose of 1.5 mg/kg SC on day 7.[1] One week after first treatment dose is given, Tecvayli 1.5 mg/kg SC is given once weekly thereafter until disease progression or unacceptable toxicity.

Guidelines

The National Comprehensive Cancer Network (NCCN) multiple myeloma (version 1.2025 – September 17, 2024) clinical practice guidelines recommend Tecvayli for relapsed or refractory disease in patients who have received at least four previous therapies including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.[2,3]

Safety

Tecvayli 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 Tecvayli. 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 Tecvayli as well as the monitoring required for adverse events and long-term efficacy, approval requires Tecvayli to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tecvayli 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
  - **1.** Note: Examples include bortezomib, Kyprolis (carfilzomib intravenous infusion), Ninlaro (ixazomib capsules).
- **ii.** Immunomodulatory drug; AND
  - **2.** Note: Examples include lenalidomide, Pomalyst (pomalidomide capsules), Thalomid (thalidomide capsules).
- **iii.** Anti-CD38 monoclonal antibody; AND
  - **3.** 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 the following dosing regimen (A and B):

A) Step-up dosing (i, ii, and iii):

- **i.** Dose 1: Approve 0.06 mg/kg administered subcutaneously on Day 1; AND
- **ii.** Dose 2: Approve 0.3 mg/kg administered subcutaneously, 2 to 7 days after Dose 1; AND
- **iii.** Dose 3: Approve 1.5 mg/kg administered subcutaneously, 2 to 7 days after Dose 2; AND

B) Approve 1.5 mg/kg administered subcutaneously no more frequently than once weekly.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tecvayli 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. Tecvayli™ subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech.; May 2024.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 1, 2024. Search term: teclistamab.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 1.2025 – September 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 1, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	-	11/09/2022
Annual Revision	No criteria changes.	11/08/2023
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024
Annual Revision	No criteria changes.	11/13/2024