CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Bispecific – BCMA-Directed) – Tecvayli Utilization Management Medical Policy
- Tecvayli® (teclistamab-cqyv subcutaneous injection – Janssen Biotech)

REVIEW DATE: 09/10/2025

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]

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

Tecvayli is administered by subcutaneous injection.[1] Dosing includes two step-up doses of 0.06 mg/kg administered on Day 1 and 0.3 mg/kg on Day 4, followed by the first treatment dose of 1.5 mg/kg on Day 7. One week after the first treatment dose is given, Tecvayli 1.5 mg/kg is given once weekly thereafter. For patients who have achieved and maintained a complete response or better for a minimum of 6 months, the dosing interval may be extended to every two weeks 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 single-agent Tecvayli as a "Preferred Regimen" for the treatment of relapsed or refractory multiple myeloma in patients who have received at least four previous therapies including an anti-CD38 monoclonal antibody, proteasome inhibitor, and an immunomodulatory agent(category 2A).[2,3] Tecvayli is also recommended in combination with Talvey™ (talquetamab-tgvs subcutaneous injection) in those who have received at least 3 prior lines of therapy as "Useful in Certain Circumstances" (category 2A).

Safety

Tecvayli has a Boxed Warning for cytokine release syndrome (CRS) and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome (ICANS).[1] Tecvayli 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 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
       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 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.; August 2025.
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: teclistamab.

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
Annual Revision	No criteria changes.	11/08/2023
Annual Revision	No criteria changes.	11/13/2024
Update	04/08/2025: The policy name was changed from "Oncology (Injectable) – Tecvayli UM Medical Policy" to "Oncology (Injectable – Bispecific – BCMA-Directed) – Tecvayli UM Medical Policy".	N/A
Early Annual Revision	No criteria changes.	09/10/2025