

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; selected revision 03/18/2026

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 combination with Darzalex Faspro® (daratumumab and hyaluronidase-fihj subcutaneous injection) in adults who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent;
- As monotherapy 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

Tecvayli is administered by subcutaneous injection.¹ Monotherapy 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.

Tecvayli in combination with Darzalex Faspro dosing includes step-up doses of 0.06 mg/kg on Day 1 and 0.3 mg/kg on Day 3, followed by the first treatment dose of 1.5 mg/kg on Day 7. From Week 2-8, the dosing is 1.5 mg/kg once weekly. From Weeks 9-24, the dosing is 3 mg/kg every 2 weeks. From Week 25 onwards, the dosing is 3 mg/kg every 4 weeks.

Tecvayli dosing ranged from 0.75 mg/kg to 3.0 mg/kg and were given either weekly (lower doses) or biweekly (higher doses) when used in combination with Talvey™ (talquetamab-tgvs subcutaneous injection).³

Guidelines

The National Comprehensive Cancer Network (NCCN) multiple myeloma (version 5.2026 – January 9, 2026) clinical practice guidelines recommend Tecvayli for relapsed or refractory disease in the following situations: in combination with Darzalex® (daratumumab intravenous infusion) if bortezomib- or lenalidomide-refractory after one prior line of therapy (including lenalidomide and a proteasome inhibitor) as a “Preferred” regimen (category 1); as a single-agent as a “Preferred Regimen” in patients who have received at least four previous therapies including an anti-CD38 monoclonal antibody, proteasome inhibitor, and an immunomodulatory agent (category 2A); and in combination with Talvey 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

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- 1. Multiple Myeloma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
- A)** Patient is ≥ 18 years of age; AND
 - B)** Patient meets ONE of the following (i, ii, or iii):
 - i.** Patient meets ALL of the following (a, b and c):
 - a)** Patient has tried lenalidomide; AND
 - b)** Patient has tried at least one proteasome inhibitor; AND
Note: Examples of a proteasome inhibitor include bortezomib, Kyprolis (carfilzomib intravenous infusion), Ninlaro (ixazomib capsules); AND
 - c)** The medication will be used in combination with Darzalex (daratumumab intravenous infusion) or Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection); OR
 - ii.** Patient meets BOTH of the following (a and b):
 - a)** Patient has tried at least four systemic regimens; AND
 - b)** Among the previous regimens tried, the patient has received at least one drug from each of the following classes [(1), (2), and (3)]:
 - (1)** Proteasome inhibitor; AND
Note: Examples include bortezomib, Kyprolis (carfilzomib intravenous infusion), Ninlaro (ixazomib capsules).
 - (2)** Immunomodulatory drug; AND
Note: Examples include lenalidomide, Pomalyst (pomalidomide capsules), Thalomid (thalidomide capsules).
 - (3)** Anti-CD38 monoclonal antibody; OR
Note: Examples include Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), or Sarclisa (isatuximab-irfc intravenous infusion).
 - iii.** Patient meets BOTH of the following (a and b):

- a) Patient has tried at least three prior lines of therapy; AND
- b) The medication will be used in combination with Talvey (talquetamab-tgvs subcutaneous injection); AND
- C) The medication will be prescribed by or in consultation with an oncologist.

Dosing. Approve the following dosing regimen (A, B and C):

- 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; AND
- C) Approve 3 mg/kg administered subcutaneously no more frequently than once every 2 weeks.

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.; March 2026.
2. The NCCN Drugs and Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 9, 2026. Search term: teclistamab.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 5.2026 – January 9, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 9, 2026.

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
Selected Revision	Multiple Myeloma: An option for approval was added for a patient who has tried lenalidomide, at least one proteasome inhibitor, and the medication will be used in combination with Darzalex (daratumumab intravenous infusion) or Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection). A note was added with examples of a proteasome inhibitor. An option for approval was added for a patient who has tried at least three prior lines of therapy and the medication will be used in combination with Talvey (talquetamab-tgvs subcutaneous injection). The dosing requirements were updated to include “approve 3 mg/kg administered subcutaneously no more frequently than once every 2 weeks.”	03/18/2026

09/10/2025

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