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: 09/30/2026

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**[1]:
- 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.

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]

Patients with light chain amyloidosis received Tecvayli according to the prescribing information.[4]

Guidelines

Tecvayli is discussed in guidelines from the National Comprehensive Cancer Network (NCCN)[2,3,5]:
- **Multiple Myeloma:** NCCN guidelines (version 2.2027 – September 24, 2026) recommend Tecvayli for relapsed or refractory disease with at least one prior line of therapy as monotherapy or in combination with other medications (category 1 or 2A).[2,3]
- **Systemic Light Chain Amyloidosis:** NCCN guidelines (version 1.2027 – August 19, 2026) recommend Tecvayli for the treatment of relapsed or refractory previously treated disease as a single agent as "Useful in Certain Circumstances" (category 2A).[2,5]

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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 indications. 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 one of 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 relapsed or refractory disease; AND
   - **C)** Patient has tried at least one systemic regimen; AND
     Note: Examples of a systemic regimen including one or more of the following drugs: Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), Sarclisa (isatuximab-irfc intravenous infusion), Sarclisa Escena (isatuximab-irfc subcutaneous injection), bortezomib, Kyprolis (carfilzomib intravenous infusion), Ninlaro (ixazomib capsules), lenalidomide, pomalidomide, or Thalomid (thalidomide capsules).
   - **D)** The medication will be prescribed by or in consultation with an oncologist or hematologist.

   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.

Other Uses With Supportive Evidence

2. **Systemic Light Chain Amyloidosis.** 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 has tried at least one systemic regimen; AND
     Note: Examples of systemic regimens include those containing one or more of the following products: Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), Darzalex (daratumumab intravenous infusion); bortezomib, lenalidomide, cyclophosphamide, and melphalan.
   - **C)** The medication will be prescribed by or in consultation with an oncologist or hematologist.

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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 September 21, 2026. Search term: teclistamab.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 2.2027 – September 24, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 25, 2026.
4. Stalker M, Garfall A, Cohen A, et al. Safety and efficacy of teclistamab in patients with relapsed or refractory AL amyloidosis. *Eur J Haematol*. 2024; 114(3):443-447.
5. The NCCN Systemic Light Chain Amyloidosis Clinical Practice Guidelines in Oncology (version 1.2027 – August 19, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 21, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
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

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HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Multiple Myeloma:** The following options for approval were removed: combination use with Darzalex (daratumumab intravenous infusion) or Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection) when the patient has tried lenalidomide and at least one proteasome inhibitor (along with the Note of examples of proteasome inhibitor); combination use with Talvey (talquetamab-tgvs subcutaneous injection) when the patient has tried at least three prior lines of therapy; when a patient has tried four systemic therapies, and has received at least one drug from each of the following classes: proteasome inhibitor, immunomodulatory drug, or anti-CD38 monoclonal antibody along with the Note of examples of each class. The requirements that the patient has relapsed or refractory disease and patient tried at least one systemic regimen were added. The specialist requirement was updated to include a hematologist. **Systemic Light Chain Amyloidosis:** Condition of approval and criteria were added to Other Uses with Supportive Evidence.	09/30/2026

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