

Tecvayli® (teclistamab-cqyv) (Subcutaneous)

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Dates Reviewed: 12/2022, 03/2023, 03/2024, 05/2024, 05/2025, 05/2026

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days), following initial inpatient administration of 2 doses (step-up dose 1, step-up dose 2).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 2448 billable units every 28 days

III. Initial Approval Criteria ¹

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**
- Used as continuation therapy following inpatient administration of all step-up doses; **AND**
 - Member had an absence of unacceptable toxicity while on inpatient administration of step-up doses; **OR**
 - Provider has confirmed that the first three doses are planned for inpatient administration **AND** will only proceed with continued treatment if the member had an absence of unacceptable toxicity to the inpatient administration of step-up doses

Universal Criteria ¹

- Member does not have an active infection, including clinically important localized infections; **AND**
- Member will be administered prophylaxis for infection (e.g., herpes zoster reactivation) according to local guidelines; **AND**
- Member immunoglobulin levels will be monitored throughout treatment; **AND**
- Member does not have any of the following comorbidities:
 - Stroke
 - Seizure
 - Active CNS involvement or clinical signs of meningeal involvement of multiple myeloma; **AND**

- Member has not had an allogenic stem cell transplant within the previous 6 months or an autologous stem cell transplant within the previous 12 weeks; **AND**

Multiple Myeloma* † ‡ Φ¹⁻³

- Member has relapsed or refractory disease; **AND**
 - Used as a single agent; **AND**
 - Member has received at least four (4) prior lines of therapy, including a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib, etc.), an immunomodulatory agent (e.g., lenalidomide, thalidomide, pomalidomide, etc.) and an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab, etc.) †; **OR**
 - Used in combination with talquetamab; **AND**
 - Member has received at least three (3) prior lines of therapy; **OR**
 - Used in combination with daratumumab and hyaluronidase-fihj; **AND**
 - Member has received at least one (1) prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent †.

**The regimens listed for the treatment of Multiple Myeloma may also be used for the treatment of Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal protein, Skin changes (POEMS), Monoclonal Immunoglobulin Deposition Disease (MIDD), and plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS)*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria¹

Prior authorization validity may be renewed based upon the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), severe administration-related/local injection-site reactions, cytokine release syndrome (CRS), hepatotoxicity, neutropenia/febrile neutropenia, severe infections, etc.

V. Dosage/Administration^{1,8}

Indication	Dose					
Multiple Myeloma	In combination with daratumumab and hyaluronidase-fihj					
	<ul style="list-style-type: none"> • The recommended dosage is administered subcutaneously by a healthcare provider, until disease progression or unacceptable toxicity. (See table below) <table border="1" style="margin-left: 20px;"> <thead> <tr> <th>Dosing schedule</th> <th>Week/Day</th> <th>Dose^a</th> </tr> </thead> <tbody> <tr> <td style="height: 20px;"></td> <td></td> <td></td> </tr> </tbody> </table>	Dosing schedule	Week/Day	Dose ^a		
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	Step-up dosing schedule ^b	Day 1	Step-up dose 1 ^c	0.06 mg/kg																										
		Day 3	Step-up dose 2 ^d	0.3 mg/kg																										
		Day 7	First treatment dose ^{e,f}	1.5 mg/kg																										
	Weekly dosing schedule	Weeks 2 to 8	1.5 mg/kg once weekly ^f																											
	Biweekly (every two weeks) dosing schedule	Weeks 9 to 24	3 mg/kg every two weeks ^f																											
	Every four weeks dosing schedule	Week 25 onwards	3 mg/kg every four weeks ^f																											
<ul style="list-style-type: none"> – ^a See package insert for recommendations on restarting Tecvayli after dose delay. – ^b The Step-up dosing schedule is a component of the recommended Tecvayli dosage but is not applicable for the daratumumab and hyaluronidase-fihj dosing. – ^c Step-up dose 1 must be administered 20 hours or more after the daratumumab and hyaluronidase-fihj dose. – ^d Step-up dose 2 may be given between 2 to 4 days after step-up dose 1 and may be given up to 7 days after step-up dose 1 to allow for resolution of adverse reactions. – ^e First treatment dose may be given between 2 to 4 days after step-up dose 2 and may be given up to 7 days after step-up dose 2 to allow for resolution of adverse reactions. – ^f Administer TECVAYLI at least 3 hours after the daratumumab and hyaluronidase-fihj dose for the first treatment dose. For subsequent doses, administer TECVAYLI at least 15 minutes after the daratumumab and hyaluronidase-fihj dose. 																														
Monotherapy																														
<ul style="list-style-type: none"> • The recommended dosage is step-up doses of 0.06 mg/kg and 0.3 mg/kg followed by 1.5 mg/kg once weekly, administered subcutaneously by a healthcare provider, until disease progression or unacceptable toxicity. (See <i>table below</i>) • In members who have achieved and maintained a complete response or better for a minimum of 6 months, the dosing frequency may be decreased to 1.5 mg/kg every two weeks until disease progression or unacceptable toxicity. (See <i>table below</i>) 																														
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<p><i>Note: Administer Tecvayli subcutaneously according to the step-up dosing schedule noted above to reduce the incidence and severity of cytokine release syndrome (CRS). Due to the risk of CRS and neurologic toxicity, including ICANS, members should be hospitalized for 48 hours after administration of all doses within the Tecvayli step-up dosing schedule.</i></p>		

VI. Billing Code/Availability Information

HCPCS Code:

- J9380 – Injection, teclistamab-cqyv, 0.5 mg; 1 billable unit = 0.5 mg

NDC:

- Tecvayli 30 mg/3 mL solution for injection in a single-dose vial: 57894-0449-xx
- Tecvayli 153 mg/1.7 mL solution for injection in a single-dose vial: 57894-0450-xx

VII. References

1. Tecvayli [package insert]. Horsham, PA; Janssen Biotech, Inc.; March 2026. Accessed March 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for teclistamab. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2026.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma Version 5.2026. National Comprehensive Cancer Network, 2026. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed March 2026.
4. BGM Durie, J-L Harousseau, J S Miguel, et al on behalf of the International Myeloma Working Group. International uniform response criteria for multiple myeloma. *Leukemia*. Sep; 20(9):1467-73.
5. Moreau P, Garfall AL, van de Donk NWCJ, et al. Teclistamab in Relapsed or Refractory Multiple Myeloma. *N Engl J Med*. 2022 Aug 11;387(6):495-505. Doi: 10.1056/NEJMoa2203478. Epub 2022 Jun 5.
6. Usmani SZ, Garfall AL, van de Donk NWCJ, et al. Teclistamab, a B-cell maturation antigen × CD3 bispecific antibody, in patients with relapsed or refractory multiple myeloma (MajesTEC-1): a multicentre, open-label, single-arm, phase 1 study. *Lancet*. 2021 Aug 21;398(10301):665-674. Doi: 10.1016/S0140-6736(21)01338-6. Epub 2021 Aug 10. PMID: 34388396.

7. Pillarisetti K, Powers G, Luistro L, et al. Teclistamab is an active T cell-redirecting bispecific antibody against B-cell maturation antigen for multiple myeloma. Blood Adv. 2020 Sep 22;4(18):4538-4549. Doi: 10.1182/bloodadvances.2020002393. PMID: 32956453; PMCID: PMC7509877.
8. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Teclistamab-cqyv: Multiple Myeloma, MUM111. National Comprehensive Cancer Network, 2026. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed April 2026.

Appendix A – Non-Quantitative Treatment Limitations (NQL) Factor Checklist

Non-quantitative treatment limitations (NQLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime’s assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.32	Solitary plasmacytoma in relapse
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents:

<https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC