

Tecvayli™ (teclistamab-cqyv) (Subcutaneous)

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I. Length of Authorization

After the initial hospital administration of three doses (step-up dose 1, step-up dose 2, and the first treatment dose), coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Tecvayli 30 mg/3 mL solution for injection in a single-dose vial: 2 vials every 7 days
- Tecvayli 153 mg/1.7 mL solution for injection in a single-dose vial: 2 vials every 7 days

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

- 468 billable units (234 mg) every 7 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient has not received prior treatment with any B-cell maturation antigen (BCMA) targeted therapy; **AND**
- Prescribers are enrolled in the TECVAYLI REMS® program; **AND**
- Used as continuation therapy following inpatient administration of the step-up dose 1, step-up dose 2, and the first treatment dose; **AND**
- Patient had an absence of unacceptable toxicity while on inpatient administration; **AND**

Universal Criteria ¹

- Patient does not have an active infection, including clinically important localized infections; **AND**
- Prophylaxis for infection (e.g., herpes zoster reactivation) will be followed according to guidelines; **AND**
- Patient immunoglobulin levels will be monitored throughout treatment; **AND**

- Patient does not have any of the following comorbidities:
 - Stroke
 - Seizure
 - CNS involvement or clinical signs of meningeal involvement of multiple myeloma; **AND**
- Patient has not had an allogenic stem cell transplant within the previous six months or an autologous stem cell transplant within the previous 12 weeks; **AND**
- Used as a single-agent; **AND**

Multiple Myeloma † ‡ ◻¹⁻⁵

- Patient has relapsed or refractory disease; **AND**
- Patient has received at least four (4) prior therapies, including a proteasome inhibitor (e.g., bortezomib, etc.), an immunomodulatory agent (e.g., lenalidomide, thalidomide, etc.) and an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab, etc.)

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

IV. Renewal Criteria¹

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the 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 reactions, cytokine release syndrome (CRS), hepatotoxicity, neutropenia/febrile neutropenia, severe infections, etc.

V. Dosage/Administration¹

Indication	Dose				
Multiple Myeloma	The recommended dosage is step-up doses of 0.06 mg/kg and 0.3 mg/kg followed by 1.5 mg/kg, administered subcutaneously by a healthcare provider, once weekly until disease progression or unacceptable toxicity.				
	Dosing schedule	Day	Dose		
	Step-up dosing schedule ^a	Day 1	Step-up dose 1	0.06 mg/kg	
		Day 4 ^b	Step-up dose 2	0.3 mg/kg	
		Day 7 ^c	First treatment dose	1.5 mg/kg	
Weekly dosing schedule ^a	One week after first treatment dose and weekly thereafter	Subsequent treatment doses	1.5 mg/kg once weekly		
<ul style="list-style-type: none"> – ^a See package insert for recommendations on restarting Tecvayli after dose delay. – ^b 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. – ^c 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. 					
<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, patients 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:

- J9999 – Not otherwise classified, antineoplastic drugs (*Discontinue on 07/01/2023*)
- C9148 – Injection, teclistamab-cqyv, 0.5 mg; 1 billable unit = 0.5 mg (*Discontinue on 07/01/2023*)
- J9380 – Injection, teclistamab-cqyv, 0.5 mg; 1 billable unit = 0.5 mg (*Effective 07/01/2023*)

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.; October 2022. Accessed February 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for teclistamab. National Comprehensive Cancer Network, 2023. 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 February 2023.

3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma Version 3.2023. National Comprehensive Cancer Network, 2023. 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 February 2023.
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.

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)

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered 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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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