Tecvayli™ (teclistamab-cqyv)
(Subcutaneous)

Document Number: IC-0682

Last Review Date: 03/05/2024
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Dates Reviewed: 12/2022, 03/2023, 03/2024

I. Length of Authorization

Following initial inpatient administration of three doses (step-up dose 1, step-up dose 2, and the first treatment dose), coverage will be provided for 6 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**
- 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]

- Prescribers are enrolled in and meet the conditions of the TECVAYLI and TALVEY REMS® program; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient will be administered prophylaxis for infection (e.g., herpes zoster reactivation) according to local guidelines; **AND**
- Patient immunoglobulin levels will be monitored throughout treatment; **AND**
- Patient does not have any of the following comorbidities:

  - Stroke
  - Seizure
  - Active CNS involvement or clinical signs of meningeal involvement of multiple myeloma; **AND**

- Patient 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**
- Used as single agent treatment; **AND**

Multiple Myeloma † ‡ Φ [1-3]

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

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

IV. Renewal Criteria [1]

Coverage may be renewed based upon the following criteria:

- Patient 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]

<table>
<tr><th>Indication</th><th>Dose</th></tr>
<tr><td>Multiple Myeloma</td><td>

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 table below)
In patients 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 table below)

<table>
<tr><th>Dosing schedule</th><th>Day</th><th>Dose</th></tr>
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	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
	Patients who have achieved and maintained a complete response or better for a minimum of 6 months			
	Biweekly (every two weeks) dosing schedule [a]	The dosing frequency may be decreased to 1.5 mg/kg every two weeks.		
	– [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.			
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.				

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.; February 2024. Accessed February 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for teclistamab. National Comprehensive Cancer Network, 2024. 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 January 2024.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma Version 2.2024. National Comprehensive

Cancer Network, 2024. 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 January 2024.

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)

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, 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