Medical Policy

Tecvayli® (teclistamab-cqyv)	
MEDICAL POLICY NUMBER	Med_Clin_Ops-136
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Tecvayli (teclistamab-cqyv) therapy.

POLICY

Prior Authorization and Medical Review is required.

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.

- Max Units (per dose and over time):
  - 234mg every 7 days

Initial

A. Patient is 18 years of age or older, unless otherwise specified; **AND**

B. Patient has not received prior treatment with any B-cell maturation antigen (BCMA) targeted therapy; **AND**
C. Prescribers are enrolled in the TECVAYLI REMS® program; **AND**
D. Used as continuation therapy following inpatient administration of the step-up dose 1, step-up dose 2, and the first treatment dose; **AND**
    a. Patient had an absence of unacceptable toxicity while on therapy; **AND**
E. Patient does not have an active infection, including clinically important localized infections; **AND**
F. Prophylaxis for infection (e.g., herpes zoster reactivation) will be followed according to guidelines; AND
G. Patient immunoglobulin levels will be monitored throughout treatment; **AND**
H. Patient does not have any of the following comorbidities:
    a. Stroke
    b. Seizure
    c. CNS involvement or clinical signs of meningeal involvement of multiple myeloma
    d. ECOG performance score of 2 or Higher
I. 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**
J. Used as a single-agent therapy; **AND**

Multiple Myeloma

A. Patient has relapsed or refractory disease; **AND**
B. 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.)

Renewal

Coverage may be renewed based upon the following criteria:

A. 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**
B. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
C. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), severe infusion-related reactions, cytokine release syndrome (CRS), hepatotoxicity, neutropenia and infection, etc.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

A. TECVAYLI (teclistamab) injection, for subcutaneous use. Initial U.S. Approval: 2022.

a. TECVAYLI (teclistamab) injection for subcutaneous use is a clear to slightly opalescent, colorless to light yellow solution in a single dose vial. Vias are supplied as ready-to-use solution that do not need dilution prior to administration.

CODING

Applicable NDC Codes	
57894-0449-01	Tecvayli 30mg/3mL solution for injection in a single-dose vial
57894-0450-01	Tecvayli 153mg/1.7mL solution for injection in a single-dose vial

Applicable Procedure Code	
J9999	Not otherwise classified, antineoplastic drug

Applicable ICD-10 Codes	
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

EVIDENCE BASED REFERENCES

1. Tecvayli [package insert]. Horsham, PA; Janssen Biotech, Inc.; October 2022. Accessed October 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for teclistamab. National Comprehensive Cancer Network, 2022. 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 October 2022.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma Version 1.2023. National Comprehensive Cancer Network, 2022. 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 2022.
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.

POLICY HISTORY

Original Effective Date	2/28/2023
Revised Date	
P&T Committee Endorsement	02/28/2023
Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan	01/01/2024