Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Teclistamab-cqyv (Tecvayli®)	**MP-RX-FP-144-24**	☒ **MMM MA** ☒ **MMM MultiHealth**	**6/28/2024** **Last Review Date:** **5/6/2026**	**5/6/2026** **Frequently Revision:** **Annual**

Service Category:

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Other: Part B Drugs

Service Description:

This document addresses the use of *Teclistamab-cqyv (Tecvayli®),* a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager approved by the Food and Drug Administration (FDA) for the treatment of adult patients with relapsed or refractory multiple myeloma in combination with daratumumab and hyaluronidase-fihj in patients who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, or as monotherapy, in patients who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

Background Information:

Teclistamab is a bispecific T-cell engaging antibody that binds to the CD3 receptor expressed on the surface of T-cells and B-cell maturation antigen (BCMA) expressed on the surface of multiple myeloma cells and some healthy B-lineage cells. In vitro, teclistamab activated T-cells, caused the release of various proinflammatory cytokines, and resulted in the lysis of multiple myeloma cells.

The FDA approved indication for Tecvayli is for the treatment of adult patients with relapsed or refractory multiple myeloma in combination with daratumumab and hyaluronidase-fihj in those who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, or as monotherapy after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

Tecvayli has a black box warning for cytokine release syndrome (CRS), including life-threatening or fatal reactions. Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious and life- threatening reactions can also occur. Due to these black box warnings, Tecvayli is only available through a Risk Evaluation and Mitigation Strategy (REMS) program.

Tecvayli is a subcutaneous injection. The prescribing information includes recommended dosing schedules for both monotherapy and combination therapy. For monotherapy, Tecvayli is administered as step-up doses of 0.06 mg/kg and 0.3 mg/kg followed by 1.5 mg/kg once weekly until disease progression or unacceptable toxicity. In individuals who achieve and maintain a complete response or better for a minimum of 6 months, the dosing frequency may be decreased to 1.5 mg/kg every 2 weeks.

The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 1 and 2A level of evidence for the following uses:

- Relapsed or refractory Multiple Myeloma:
    - in combination with daratumumab if bortezomib- or lenalidomide-refractory (preferred)

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- as a single agent in those who have received at least four prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent (preferred)
- in combination with talquetamab-tgvs in those who have received at least 3 prior lines of therapy (useful in certain circumstances)

**The above regimens may also be used for the treatment of Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal protein, Skin changes (POEMS) (useful in certain circumstances), Monoclonal Immunoglobulin Deposition Disease (MIDD), and plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS).*

Definitions and Measures

- ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:
  - 0 = Fully active, able to carry on all pre-disease performance without restriction
  - 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
  - 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
  - 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
  - 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
  - 5 = Dead
- Multiple Myeloma: Is an infiltration of plasma cells into the bone or other organs producing a monoclonal immunoglobulin. The plasma cells proliferate in the bone marrow and can result in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures.
- Refractory Disease: Illness or disease that does not respond to treatment.
- Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Approved Indications

A. Treatment of adult patients with relapsed or refractory multiple myeloma:
   a. in combination with daratumumab and hyaluronidase-fihj in patients who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent.
   b. as monotherapy, in patients who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

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Other Uses

A. See Background Information above.

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Medical Necessity Guidelines:

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Teclistamab-cqyv (Tecvayli®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual has a diagnosis of relapsed or refractory multiple myeloma (Label, NCCN 1, 2A); **AND**

ii. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-1; **AND**

iii. Individual is using in *one* of the following ways:

A. Individual is using as monotherapy; **AND**

B. Individual has had at least FOUR prior therapies, including an anti-CD38 monoclonal antibody (e.g. daratumumab), a proteasome inhibitor (e.g. bortezomib, ixazomib, or carfilzomib), and an immunomodulatory agent (e.g. lenalidomide or pomalidomide);

OR

C. Individual is using Tecvayli in combination with daratumumab and hyaluronidase-fihj; **AND**

D. Individual has had at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent; **AND**

E. Individual is bortezomib-refractory or lenalidomide-refractory;

OR

F. Individual has had at least THREE prior therapies, including an anti-CD38 monoclonal antibody (e.g. daratumumab), a proteasome inhibitor (e.g. bortezomib, ixazomib, or carfilzomib), and an immunomodulatory agent (e.g. lenalidomide or pomalidomide); **AND**

G. Individual is using in combination with talquetamab-tgvs; **AND**

H. Use is for previously treated relapsed/refractory multiple myeloma (NCCN 2A, useful in certain circumstances).

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Teclistamab-cqyv (Tecvayli®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for

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Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. The following information should be submitted for reauthorization:

A. A current oncology note documenting the patient's response to treatment showing no progression of disease.
B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

C. Authorization Duration

i. Initial Approval Duration: Up to 6 months
ii. Reauthorization Approval Duration: Up to 6 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

Requests for Teclistamab-cqyv (Tecvayli®) may not be approved for the following:

i. If the individual has plasma cell leukemia, Waldenström's macroglobulinemia, or primary amyloid light-chain amyloidosis; **OR**
ii. If the individual has any active central nervous system involvement or clinical signs of meningeal involvement of multiple myeloma; **OR**
iii. When the above criteria are not met and for all other indications.

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Tecvayli inj 30 mg/3 mL (10 mg/mL) SDV; 153 mg/1.7 mL (90 mg/mL) SDV			
Dosing Schedule	**Day**	**Dose**	
Step-up dosing schedule	Day 1	Step-up dose 1	0.06 mg/kg sc
	Day 4[b]	Step-up dose 2	0.3 mg/kg sc
	Day 7[c]	First treatment dose	1.5 mg/kg sc
Weekly dosing schedule	One week after first treatment dose and weekly thereafter[c]	Subsequent treatment doses	1.5 mg/kg sc 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		
Exceptions			
• 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.			

[a] See Table 2 of the PI for recommendations on restarting TECVAYLI after dose delays

[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.

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

ICD-10 Diagnostic Codes:

Codes	Description
C90.0	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

HCPCS Codes:

Codes	Description
J9380	Injection, teclistamab-cqyv, 0.5 mg [TECVAYLI]

CPT Codes:

Codes	Description

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Reference Information:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 7, 2025.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Janssen Biotech, Inc. (2026). TECVAYLI® (teclistamab-cqyv) injection, for subcutaneous use: Prescribing information. Revised March 2026. Retrieved April 16, 2026, from: https://www.jnjlabels.com/package-insert/product-monograph/prescribing-information/TECVAYLI-pi.pdf
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2026 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on April 16, 2025.
    a. Multiple Myeloma. V5.2026. Revised January 9, 2026.
6. NCT03145181. ClinicalTrials.gov. U.S. National Library of Medicine. Available at: https://clinicaltrials.gov/ct2/show/NCT03145181?term=NCT03145181&draw=2&rank=1.
7. NCT04557098. ClinicalTrials.gov. U.S. National Library of Medicine. Available at: https://clinicaltrials.gov/study/NCT04557098.
8. Moreau P, Garfall AL, van de Donk NWCJ, et.al. Teclistamab in Relapsed or Refractory Multiple Myeloma. N Engl J Med. 2022; 387(6):495-505. doi: 10.1056/NEJMoa2203478.
9. Usmani SZ, Garfall AL, van de Donk NWCJ, e.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; 398(10301):665-674. doi: 10.1016/S0140-6736(21)01338-6.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Focus Review	Updated medical policy to align with the most recent prescribing information by revising the Background Information to reflect the new FDA-labeled indication for use in combination with daratumumab and hyaluronidase-fihj for relapsed or refractory multiple myeloma after at least one prior line of therapy, while retaining the monotherapy pathway for individuals previously treated with at least four prior lines of therapy. Updated the Initial Approval criteria to add the new labeled daratumumab combination pathway, retain monotherapy criteria, and preserve the NCCN-supported talquetamab-tgvs combination pathway separately. Reviewed and refined the Conditions Not Covered section for consistency with the current label and NCCN recommendations. Coding reviewed: Added ICD-10-CM C90.10, C90.12, C90.20, C90.22, C90.30, C90.32, Z85.79. Updated references list. Administrative update to incorporate new template.	5/1/2026	5/6/2026
Annual Review	Addition of recommendation of NCCN clarify when four prior therapies is required versus three. Coding review: No changes.	12/3/2025	12/11/2025
Annual Review	Added conditions not covered. Update quantity limit table to add dosage forms and strengths for Tecvayli, specify sc route and include new FDA label updates to dosage and administration. Wording and formatting changes. Coding Reviewed: Updated description for HCPCS J9380; consolidated ICD10 codes for multiple myeloma.	3/20/2025	4/2/2025
Policy Inception	1/30/24: New Medical Policy creation	4/18/2024	6/28/2024