Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Teclistamab-cqyv (Tecvayli®)	MP-RX-FP-144-24	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ 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 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 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 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.

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

- Multiple Myeloma

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

Tecvayli is approved by the FDA for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial.

Other Uses

None.

Policy Name	Policy Number	Scope
Teclistamab-cqyv (Tecvayli®)	MP-RX-FP-144-24	☒ MMM MA ☒ MMM Multihealth

Applicable Codes

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.

HCPCS	Description
J9380	Injection, teclistamab-cqyv, 0.5 mg TECVAYLI

ICD-10	Description
C90.0	Multiple myeloma
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse

Policy Name	Policy Number	Scope
Teclistamab-cqyv (Tecvayli®)	MP-RX-FP-144-24	☒ MMM MA ☒ MMM Multihealth

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 2A); **AND**
ii. 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); **AND**
iii. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-1; **AND**
iv. No prior treatment with any B cell maturation antigen (BCMA) targeted therapy.

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 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):

Policy Name	Policy Number	Scope
Teclistamab-cqyv (Tecvayli®)	MP-RX-FP-144-24	☒ MMM MA ☒ MMM Multihealth

Requests for Teclistamab-cqyv (Tecvayli®) may not be approved when the above criteria (Section A: Criteria for Initial Approval) are not met and for all other indications.

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 weekly dosing schedule			
Dosing Schedule	**Day**	**Dose**	
Step-up dosing schedule	Day 1	Step-up dose 1	0.01 mg/kg
	Day 4[b]	Step-up dose 2	0.3 mg/kg
	Day 7[b]	First treatment dose	1.5 mg/kg
Weekly dosing schedule	One week after first treatment dose and weekly thereafter[c]	Subsequent treatment doses	1.5 mg/kg once weekly
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.

Policy Name	Policy Number	Scope
Teclistamab-cqyv (Tecvayli®)	MP-RX-FP-144-24	☒ MMM MA ☒ MMM Multihealth

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: December 8, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on December 8, 2023.
    a. Multiple Myeloma. V2.2024. Revised November 1, 2023.
5. NCT03145181. ClinicalTrials.gov. U.S. National Library of Medicine. Available https://clinicaltrials.gov/ct2/show/NCT03145181?term=NCT03145181&draw=2&rank=1.
6. NCT04557098. ClinicalTrials.gov. U.S. National Library of Medicine. Available https://clinicaltrials.gov/study/NCT04557098.
7. 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.
8. 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.

Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Policy Inception	New Medical Policy creation	4/18/2024	6/28/2024

Revised: 01/30/2024