IOWA Health and Human Services

Tecvayli (teclistamab-cqyv)
PAM – 065

Iowa Medicaid Program	Prior Authorization	**Effective Date**	04/01/2023
Revision Number	3	**Last Reviewed**	07/18/2025
Reviewed By	Medicaid Medical Director	**Next Review**	07/17/2026
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	10/20/2023

Overview

Medication: [1]	teclistamab-cqyv
Brand Name:	Tecvayli®
Pharmacologic Category:	Antineoplastic; bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager
FDA-Approved Indication(s):	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. ➢ Accelerated Approval: 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(s).
How Supplied:	Single-dose vial containing either 30 mg/3 mL (10 mg/mL) or 153 mg/1.7 mL (90 mg/mL)

Dosage and Administration:

Schedule	Day	Dose	
Step-up Dosing Schedule	Day 1	Step-up dose 1 *	0.06 mg/kg
	Day 4	Step-up dose 2 *	0.3 mg/kg
	Day 7	First treatment dose *	1.5 mg/kg
Weekly Dosing Schedule	One week after first treatment dose and weekly thereafter	Subsequent treatment doses	1.5 mg/kg once weekly
Patients who achieve and maintain a complete response or better for at least 6 months			
Biweekly (every 2 weeks) dosing schedule	The dosing frequency may be decreased to 1.5 mg/kg every 2 weeks		

* 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 step-up dosing schedule. See boxed warning.

Benefit Category:	Medical

BOXED WARNING: CYTOKINE RELEASE SYNDROME (CRS) and NEUROLOGIC TOXICITY INCLUDING IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME (ICANS)

Cytokine release syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving Tecvayli®. Initiate treatment with Tecvayli® step-up dosing schedule to reduce risk of CRS. Withhold Tecvayli® until CRS resolves or permanently discontinue based on severity.

Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious and life-threatening reactions, can occur with Tecvayli®. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withhold Tecvayli® until neurologic toxicity resolves or permanently discontinue based on severity.

Tecvayli® and Talvey® REMS: Because of the risk of CRS and neurologic toxicity, including ICANS, Tecvayli® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS).

Descriptive Narrative

Multiple myeloma (MM) is a malignant hematological disorder characterized by the clonal proliferation of plasma cells 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. Most patients with MM present with signs or symptoms related to the infiltration of plasma cells into the bone or other organs or to kidney damage from immunoglobulin deposition. While the clinical presentation is usually subacute, a small percentage of patients present acutely with findings that require rapid attention and intervention (e.g., spinal cord compression, kidney failure, hyperviscosity).

The acronym "CRAB" is sometimes used to remember myeloma-defining events that are used in the diagnosis of MM: calcium elevation; renal insufficiency (kidney impairment); anemia; and bone disease. It is important to distinguish MM both from other causes of the clinical presentations above and from other plasma cell dyscrasias for the purposes of prognosis and treatment.

MM primarily affects older individuals, the median age at diagnosis is 65 to 74 years. It is slightly more frequent in men than in women (approximately 1.4:1), and while MM occurs in all races and all geographic locations, the incidence varies by ethnicity. The incidence in African Americans and Black populations is two to three times that in White populations in studies from the United States and United Kingdom. In contrast, the risk is lower in the Japanese and Mexican populations.[2]

Data from the US Surveillance, Epidemiology, and End Results (SEER) registry estimates 36,110 new cases of MM and 12,030 deaths from MM in the United States in 2025 (representing 1.8 percent of all new cancer cases and 1.9 percent of all cancer deaths). This correlates with an annual incidence of 7.3 per 100,000 men and women per year, and an annual death rate of 2.9 per 100,000 men and women per year.[3]

Treatment alleviates symptoms, reverses cytopenias, and decreases end-organ damage, and it aims to achieve a sustained response, improve quality of life, and prolong overall survival (OS). While most patients with multiple myeloma will have an initial response to treatment, conventional therapy is not curative, and MM will ultimately relapse. In addition, a minority will have primary refractory disease that does not respond to initial treatment.[4]

Guidelines

The National Comprehensive Cancer Network (NCCN) publishes guidelines for the prevention, diagnosis, and management of malignancies across the continuum of care. The NCCN Guidelines® are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to 97 percent of cancers affecting patients in the United States. The guidelines are developed and updated by 61 individual panels, comprising over 1,700 clinicians and oncology researchers from the 33 NCCN Member Institutions.

Guidelines are reviewed and updated on a continual basis to ensure that the recommendations take into account the most current evidence. To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.[5,6]

The information referenced at the time of this policy writing/revision is from the NCCN Guidelines® for (note version number and effective date):[7]

- Multiple Myeloma (v.2.2025 – April 11, 2025)

NCCN Guidelines® Recommendation(s) – Multiple Myeloma – PREVIOUSLY TREATED

(1) Relapsed/refractory disease after 3 prior therapies [a, b]
  a. After at least four prior therapies, including an anti-CD38 monoclonal antibody, a proteosome inhibitor (PI), and an immunomodulatory agent (IMiD) [c]
    i. Teclistamab: Category 2A, Preferred Regimen

[a] Regimens included under 1–3 prior therapies can also be used later in the disease course. Attempt should be made to use drugs/drug classes the patients have not been exposed to or exposed to >1 line prior.

[b] Autologous HCT should be considered in eligible patients who have not previously received HCT or had a prolonged response to initial HCT.

[c] Patients can receive more than one B-cell maturation antigen (BCMA) targeted therapy. Optimal sequencing of sequential BCMA targeted therapies is not known; however accumulated data suggests immediate follow on with second BCMA directed therapy after relapse may be associated with lower response rates.

NCCN Categories of Evidence and Consensus (all recommendations are category 2A unless otherwise indicated)	
Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

NCCN Categories of Preference (all recommendations are considered appropriate)	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for select patient populations (defined with recommendation).

Eastern Cooperative Oncology Group (ECOG) Performance Status Scale [8]

Developed by the Eastern Cooperative Oncology Group (ECOG), now part of the ECOG-ACRIN Cancer Research Group, and published in 1982, the ECOG Performance Status Scale describes a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). It is used by doctors and researchers to assess how a patient's disease is progressing, how the disease affects the daily living abilities of the patient, and to determine appropriate treatment and prognosis.

Grade	ECOG Performance Status [Synonyms: WHO/Zubrod score]
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, e.g., light housework, 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.

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Criteria

Prior authorization is required.

Tecvayli® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of multiple myeloma; **AND**
2. Member has relapsed or refractory disease after four or more prior therapies, which include at least **ONE OF EACH** from the following categories:
    a. An anti-CD38 monoclonal antibody; **AND**
    b. An immunomodulatory agent; **AND**
    c. A proteasome inhibitor; **AND**
3. Member is 18 years of age or older; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; **AND**
5. Member does not have active central nervous system (CNS) involvement or exhibit clinical signs of meningeal involvement of multiple myeloma; **AND**
6. Prescribed by, or in consultation with, a hematologist or oncologist; **AND**
7. Member will receive Tecvayli® at a facility that is certified under the TECVAYLI and TALVEY Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
8. Request meets one of the following (a or b):
    a. Tecvayli® is prescribed as monotherapy and dose does not exceed 1.5 mg/kg once weekly (after initial step-up dosing schedule); or,
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Tecvayli® is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy, as demonstrated by tumor response or lack of disease progression, and an acceptable toxicity profile; **AND**
3. Prescribed by, or in consultation with, a hematologist or oncologist; **AND**
4. Member will receive Tecvayli® at a facility that is certified under the TECVAYLI and TALVEY Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
5. Request meets one of the following (a or b):
    a. Tecvayli is prescribed as monotherapy and (i or ii):
        i. Dose does not exceed 1.5 mg/kg once weekly; or,
        ii. Dose does not exceed 1.5 mg/kg once every 2 weeks **AND** member has achieved and maintained a complete response or better for at least 6 months; or
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	6 months	12 months
Quantity Limits	1.5 mg/kg once weekly (after completion of step-up dosing schedule)	1.5 mg/kg once weekly OR 1.5 mg/kg once every 2 weeks in member who has achieved and maintained a complete response for 6 months or better.

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
~~C9148~~	~~Injection, teclistamab-cqyv, 0.5 mg~~ *(effective 4-1-2023 to 6-30-2023)*
J9380	Injection, teclistamab-cqyv, 0.5 mg

ICD-10	Description
C90.0	Multiple myeloma
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse

NDC (Strength)	Labeler	Dosage	Pkg Size	Pkg Qty	Units/ Pkg
57894-0449-01 (30 mg/3 mL)	Janssen Biotech, Inc. (57894)	0.5 mg	1	EA	60
57894-0450-01 (153 mg/1.7 mL)	Janssen Biotech, Inc. (57894)	0.5 mg	1	EA	306

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current

literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Tecvayli® prescribing information (11/2024). Janssen Biotech, Inc.: Horsham, PA. Available online: www.tecvaylihcp.com. Accessed June 9, 2025.

[2] Laubach JP. Multiple myeloma: Clinical features, laboratory manifestations, and diagnosis. Connor RF, ed., ed. UpToDate. Waltham, MA: UpToDate, Inc. www.uptodate.com. Accessed June 9, 2025.

[3] SEER Cancer Stat Facts: Myeloma. National Cancer Institute. Bethesda, MD. Available online at seer.cancer.gov/statfacts/html/mulmy.html. Accessed June 9, 2025.

[4] Laubach JP. Multiple myeloma: Overview of management. Connor RF, ed., ed. UpToDate. Waltham, MA: UpToDate, Inc. www.uptodate.com. Accessed June 9, 2025.

[5] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[6] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[7] NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version, go online to NCCN.org. NCCN Guidelines® referenced (note version number and effective date):

- Multiple Myeloma (v.2.2025 – April 11, 2025)

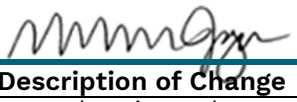
[8] Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655. PMID 7165009.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
07/18/2025	CAC	Annual review. Updated SEER data with 2025 information. Updated footnote in NCCN Guidelines and updated references.	3
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
07/19/2024	CAC	Annual review. Changed to July review cycle to align with similar therapies. Updated Overview table and criteria to include new dosing option for bi-weekly (every 2 week) dosing in patients who achieve and maintain a complete response or better for at least 6 months (FDA-approved 2/20/2024). Reviewed NCCN Guidelines; no changes. Updated references.	2
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
10/20/2023	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee