Tecvayli (teclistamab-cqyv)
PAM – 065

Iowa Medicaid Program	Prior Authorization	**Effective Date**	04/01/2023
Revision Number	4	**Last Reviewed**	10/16/2026
Reviewed By	Medicaid Medical Director	**Next Review**	07/16/2027
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):	Indicated for the treatment of adult patients with relapsed or refractory multiple myeloma: 1. in combination with daratumumab and hyaluronidase-fijh [Darzalex Faspro®] in patients who have received at least one prior line of therapy, including a proteosome inhibitor and an immunomodulatory agent. 2. 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. ➢ FDA approved conversion from accelerated approval to traditional approval (for the monotherapy regimen) on 3/5/26
Dosage and Administration:	• TECVAYLI is for subcutaneous injection only. • See dosage in following Tables 1 and 2. • Administer according to step-up dosing schedule in Tables 1 and 2 to reduce the incidence and severity of cytokine release syndrome (CRS). • Due to the risk of CRS and neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), patients should be hospitalized for 48 hours after administration of both step-up dose 1 and step-up dose 2. • Instruct patients to remain within proximity of a healthcare facility and monitor them daily for 48 hours after the first treatment dose within the step-up dosing schedule.
How Supplied:	Single-dose vial containing either: • 30 mg/3 mL (10 mg/mL) or • 153 mg/1.7 mL (90 mg/mL)
Benefit Category:	Medical

Dosing Table 1: IN COMBINATION with Daratumumab and Hyaluronidase-fihj

— Tecvayli® should be administered until disease progression or unacceptable toxicity
— Daratumumab and hyaluronidase-fihj listed as Darzalex Faspro® in Dosing table 1

Dosing Schedule	Week/ Day	TECVAYLI Dosage	Concomitant Therapy
	Day 0	N/A	Darzalex Faspro®
Step-up dosing schedule	Day 1	Step-up dose 1 (0.06 mg/kg)	N/A
	Day 3	Step-up dose 2 (0.3 mg/kg)	N/A
	Day 7	First treatment dose (1.5 mg/kg)	Darzalex Faspro®
Weekly dosing schedule	Weeks 2 to 8	1.5 mg/kg once weekly	Darzalex Faspro® once weekly
Biweekly (every 2 weeks) dosing schedule	Weeks 9 to 24	3 mg/kg every 2 weeks	Darzalex Faspro® every 2 weeks
Every 4 weeks dosing schedule	Week 25 onwards	3 mg/kg every 4 weeks	Darzalex Faspro® every 4 weeks

Dosing Table 2: AS MONOTHERAPY

— Tecvayli® should be administered until disease progression or unacceptable toxicity

Dosing Schedule	Day	Dosage	
All Patients			
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 once 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 2 weeks) dosing schedule	The dosing frequency may be decreased to 1.5 mg/kg every 2 weeks		

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, life-threatening, or fatal reactions, can occur in patients receiving 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) called the TEVAYLI and TALVEY 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: **c**alcium elevation; **r**enal insufficiency (kidney impairment); **a**nemia; and **b**one 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 36,000 new cases of MM and 10,850 deaths from MM in the United States in 2026 (representing 1.7 percent of all new cancer cases and 1.7 percent of all cancer deaths).[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) Clinical Practice Guidelines in Oncology document evidence-based, consensus-driven management to ensure that all patients receive preventive, diagnostic, treatment, and supportive services that are most likely to lead to optimal outcomes. The guidelines are developed and updated by 63 individual panels, comprising over 1,900 clinicians and oncology researchers from the 33 NCCN

Member Institutions. The categories for recommendations are based on both the level of clinical evidence available and the degree of consensus within the NCCN Guidelines Panel.

The library of NCCN Guidelines® currently apply to more than 97 percent of people living with cancer or anyone at risk for a diagnosis of cancer in the United States. The guidelines incorporate real-time updates in keeping with the rapid advancements in the field of cancer research and management and are intended to assist all individuals who impact decision-making in cancer care, including physicians, nurses, pharmacists, payers, patients and their families, and others.

The NCCN Guidelines® provide recommendations based on the best evidence available at the time they are derived. Because new data are published continuously, it is essential that the NCCN Guidelines also be continuously updated and revised* to reflect new data and clinical information that may add to or alter current clinical practice standards.[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.5.2026 – January 9, 2026)

* 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.

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.

Criteria

Prior authorization is required.

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

1. Diagnosis of multiple myeloma; **AND**
2. Disease is relapsed or refractory, and one of the following applies:
    a. Member has received at least one prior line of therapy, including a proteosome inhibitor and an immunomodulatory agent; or,
    b. Member has received at least four prior lines of therapy, including a proteosome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody; **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, b, or c):
    a. Member has received at least one prior line of therapy and:
        i. Tecvayli® is prescribed in combination with Darzalex Faspro® (daratumumab and hyaluronidase-fihj); and,
        ii. Dose does not exceed 1.5 mg/kg once weekly (after initial step-up dosing schedule); **OR**
    b. Member has received at least four prior lines of therapy and:
        i. Tecvayli® is prescribed as monotherapy; and,
        ii. Dose does not exceed 1.5 mg/kg once weekly (after initial step-up dosing schedule) through week 8; or 3 mg/kg once every 2 weeks beginning at week 9; **OR**
    c. 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, b, or c):
    a. Tecvayli is prescribed in combination with Darzalex Faspro® (daratumumab and hyaluronidase-fihj) and (i or ii):
        i. Dose does not exceed 3 mg/kg once every 2 weeks (weeks 9 to 24); or,
        ii. Dose does not exceed 3 mg/kg once every 4 weeks (week 25 onwards); **OR**
    b. Tecvayli is prescribed as monotherapy and (i or ii):
        i. Dose does not exceed 1.5 mg/kg once weekly; or,
        ii. Member has achieved and maintained a complete response or better for at least 6 months and dose does not exceed 1.5 mg/kg once every 2 weeks; **OR**
    c. 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

Authorization		Quantity Limits	Approval Duration
IN COMBINATION with Darzalex Faspro®			
	Initial	• 1.5 mg/kg once weekly through week 8 • 3 mg/kg every 2 weeks (weeks 9 to 24)	6 months
	Subsequent	• 3 mg/kg every 2 weeks (weeks 9 to 24) • 3 mg/kg every 4 weeks (week 25 onwards)	12 months
AS MONOTHERAPY			
	Initial	• 1.5 mg/kg once weekly	6 months
	Subsequent	• 1.5 mg/kg once weekly, or • 1.5 mg/kg every 2 weeks if patient has achieved and maintained a complete response or better for a minimum of 6 months	12 months

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 (03/2026). Janssen Biotech, Inc.: Horsham, PA. Available online: www.tecvaylihcp.com. Accessed July 31, 2026.

[2] Laubach JP. Multiple myeloma: Clinical features, laboratory manifestations, and diagnosis. Connor RF, ed., ed. UpToDate. Waltham, MA: UpToDate, Inc. www.uptodate.com. Accessed July 31, 2026.

[3] SEER Cancer Stat Facts: Myeloma. National Cancer Institute. Bethesda, MD. Available online at seer.cancer.gov/statfacts/html/mulmy.html. Accessed July 31, 2026.

[4] Laubach JP. Multiple myeloma: Overview of management. Connor RF, ed., ed. UpToDate. Waltham, MA: UpToDate, Inc. www.uptodate.com. Accessed July 31, 2026.

[5] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

[6] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

[7] NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are continuously updated and revised to reflect new data and clinical information that may add to or alter current clinical practice standards. To view the most recent and complete version, go online to NCCN.org. NCCN Guidelines® referenced at the time of this revision (note version number and effective date):

- Multiple Myeloma (v.5.2026 – January 9, 2026)

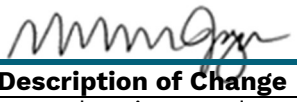
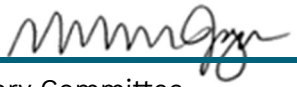
[8] Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655. PMID 7165009.

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
10/16/2026	CAC	Annual review. Updated references. Updated SEER statistics with 2026 data. FDA-approved 3/5/26: New indication for relapsed or refractory multiple myeloma (in combination with Darzalex Faspro). Updated Overview, Criteria, and Approval Duration & Quantity Limits. Policy format update: Removed current NCCN Guidelines recommendations, as guidelines may change more frequently than the review cadence of this document. Will continue to reference NCCN when writing criteria, and include the specific version referenced at the time of the policy writing/revision.	4
Signature William (Bill) Jagiello, DO			
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