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Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	November 25, 2022
Subject:	Tecvayli	**Page:**	1 of 5

Last Review Date: June 13, 2024

Tecvayli

Description

Tecvayli (teclistamab-cqyv)

Background
Tecvayli (teclistamab-cqyv) 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, Tecvayli activated T-cells, caused the release of various proinflammatory cytokines, and resulted in the lysis of multiple myeloma cells
(1).

Regulatory Status
FDA-approved indication: Tecvayli is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated 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 (1).

Tecvayli has a boxed warning regarding cytokine release syndrome (CRS) and neurotoxicity. Initiate treatment with Tecvayli step-up dosing schedule to reduce risk of CRS. Withold dose until CRS resolves or permanently discontinue based on severity. Neurotoxicity, including immune effector cell-associated neurotoxcitiy syndrome (ICANS) and serious and life-threatening reactions, can occur. Monitor patients for signs and symptoms of neurologic toxicity, including ICANS, during treatment. Withold dose until neurologic toxicity resolves or permanently discontinue based on severity. Tecvayli is only available through a restricted

program under a Risk Evaluation and Mitigation Strategy (REMS), called the Tecvayli REMS (1).

Tecvayli may cause hepatotoxicity, neutropenia and infections. Monitor liver enzymes, bilirubin and complete bloodcount at baseline and during treatment as clinically indicated. Signs and symptoms of infection should be monitored and treated appropriately. Withold in patients with active infection during the step-up dosing schedule (1).

Tecvayli can cause fetal harm when administerd to a pregnant woman because it contains a genotoxic compound and it targets actively dividing cells. Pregnant women should be advised of the potential risk to a fetus. Females of reproductive potential should be advised to use effective contraception during treatment with Tecvayli and for 5 months after the last dose (1).

The safety and effectiveness of Tecvayli in pediatric patients have not been established (1).

Related Policies
Blenrep, Elrexfio, Talvey

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tecvayli may be considered **medically necessary** if the conditions indicated below are met.

Tecvayli may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsed or refractory multiple myeloma (MM)

AND ALL of the following:

a. Patient has received at least 4 prior therapies, including **ALL** of the following:
   i. Anti-CD38 monoclonal antibody
   ii. Proteasome inhibitor
   iii. Immunomodulatory agent
b. Prescriber is certified with the Tecvayli REMS program
c. Prescriber agrees to monitor for signs and symptoms of cytokine release syndrome (CRS) and neurologic toxicity
d. Prescriber agrees to monitor liver enzymes, bilirubin and complete blood cell counts (CBC) at baseline and during treatment as clinically indicated
e. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Tecvayli and for 5 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsed or refractory multiple myeloma (MM)

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber is certified with the Tecvayli REMS program
c. Prescriber agrees to monitor for signs and symptoms of cytokine release syndrome (CRS) and neurologic toxicity
d. Prescriber agrees to monitor liver enzymes, bilirubin and complete blood cell counts (CBC) during treatment as clinically indicated
e. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Tecvayli and for 5 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Tecvayli (teclistamab-cqyv) is indicated for the treatment of relapsed or refractory multiple myeloma who have received at least four prior lines of therapy. Tecvayli has a boxed warning for cytokine release syndrome and neurologic toxicity. Hepatotoxicity, neutropenia and infections can occur in patients treated with Tecvayli; therefore liver enzymes, bilirubin, complete blood cell counts, and signs and symptoms of infections must be monitored. The safety and effectiveness of Tecvayli in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Tecvayli while maintaining optimal therapeutic outcomes.

References

1. Tecvayli [package insert]. Horsham, PA: Janssen Biotech, Inc; February 2024.
2. NCCN Drugs & Biologics Compendium® Teclistamab-cqyv 2024. National Comprehensive Cancer Network, Inc. Accessed on April 24, 2024.

Policy History

Date	Action
November 2022	Addition to PA
March 2023	Annual review and reference update
December 2023	Annual review and reference update
June 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.