

<u>T-Cell Immunotherapy</u> Tecvayli (teclistamab-cqyv) Effective 06/01/2025

Plan	 ☑ MassHealth UPPL □Commercial/Exchange 		☑ Prior AuthorizationProgram Type□ Quantity Limit□ Step Therapy
Benefit	 Pharmacy Benefit Medical Benefit 	Program Type	
Specialty	N/A		
Limitations			
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

Tecvayli (teclistamab-cqyv), is a subcutaneous "off-the-shelf" T-cell-redirecting, bispecific antibody that targets both B-cell maturation antigen (BCMA) and cluster of differentiation3 (CD3). It is 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 (PI), an immunomodulatory (IMiD) agent and an anti-CD38 monoclonal antibody.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

- 1. Diagnosis of relapsed/refractory multiple myeloma
- 2. Prescriber is a hematologist or oncologist
- 3. Appropriate dosing (member's weight must be provided)
- 4. Member is ≥ 18 years of age on treatment date (include anticipated leukapheresis date (for CAR-T therapies), initial administration date, anticipated admission, and discharge dates as applicable)
- 5. Member has failed \geq 4 lines of systemic therapies
- 6. Member's disease is refractory to at least ONE proteasome inhibitor or the member has a contraindication to ALL proteasome inhibitors §
- 7. Member's disease is refractory to at least ONE immunomodulatory agent or the member has a contraindication to ALL immunomodulatory agents §
- 8. Member's disease is refractory to at least ONE anti-CD38 monoclonal antibody or the member has a contraindication to ALL an anti-CD38 monoclonal antibodies §

9. Administration will take place in a healthcare facility that has been certified pursuant to the REMS program specific to the treatment being provided ‡

[‡] Please see Appendix for a list of healthcare facilities that are certified to administer this drug §Please refer to the Appendix for additional information on treatments for multiple myeloma.

Limitations

1. Approvals will be granted for 3 months. There is currently no data to support repeat dosing of CAR-T therapies

Appendix

Healthcare Facilities Certified through Risk Evaluation and Mitigation Strategy (REMS) program

Per manufacturer websites, the following healthcare facilities have been certified pursuant to the REMS program to administer the specific treatments defined in the table below. Please check manufacturer websites for the most updated information.

Treatment	Healthcare Facilities	
Tecvayli (teclistamab-cqyv)	Attestation on PA form that prescriber/treatment site	
	is REMS certified is sufficient.	

Treatments for Multiple Myeloma

According to the NCCN guidelines, the following drugs are part of treatment regimens that may be used for the treatment of multiple myeloma:

- Proteasome inhibitor: bortezomib, Velcade (bortezomib), Kyprolis (carfilzomib), and Ninlaro (ixazomib)
- Immunomodulatory agent: Pomalyst (pomalidomide), Revlimid (lenalidomide) and Thalomid (thalidomide)

• Anti-CD38 monoclonal antibody: Darzalex (daratumumab), Darzalex Faspro (daratumumab-hyaluronidase-fihj), and Sarclisa (isatuximab-irfc).

References

- 1. Tecvayli [package insert]. Horsham (PA): Janssen Biotech, Inc.; 2024 Nov
- National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Multiple Myeloma Version 2.2023 [guideline on the internet]. Fort Washington, Pennsylvania: National Comprehensive Cancer Network; 2022 Oct 31 [cited 2022 Nov 4]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf.

Review History

05/10/2023 - Created for P&T. Tecvayli (teclistamab-cqyv) will now require a PA through MB. Effective 6/5/23. 05/15/25 – Reviewed and updated for P&T. Updated formatting and references. Clinical criteria remains the same. Effective 6/1/25