Reference number(s)
5658-A

Standard Medicare Part B Management Tecvayli

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tecvayli	teclistamab-cqyv

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication[1]

Tecvayli 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, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

Compendial Use[2]

- Multiple myeloma
- POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome
- Monoclonal immunoglobulin deposition disease (MIDD)
- Plasma cell-related monoclonal gammopathy of renal significance (MGRS)

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

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Documentation

The following documentation must be available, upon request, for all submissions: chart notes or medical record documentation demonstrating failure of previous lines of therapy.

Coverage Criteria

Multiple Myeloma[1-2]

Authorization of 12 months may be granted for treatment of relapsed or refractory multiple myeloma when any of the following criteria is met:

- The requested medication will be used in combination with daratumumab (Darzalex) or daratumumab and hyaluronidase-fihj (Darzalex Faspro) and member is bortezomib- refractory or lenalidomide-refractory.
- The requested medication will be used as a single agent and member has received at least 4 prior therapies, including at least one drug from each of the following categories:
    - Proteasome inhibitor (e.g., bortezomib, ixazomib, carfilzomib)
    - Immunomodulatory agent (e.g., lenalidomide, pomalidomide, thalidomide)
    - Anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab)
- The requested medication will be used in combination with talquetamab-tgvs (Talvey) and member has received at least 3 prior therapies.

POEMS (Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal protein, Skin changes) Syndrome, Monoclonal Immunoglobulin Deposition Disease (MIDD), and Monoclonal Gammopathy of Renal Significance (MGRS)[2]

Authorization of 12 months may be granted for the treatment of POEMS syndrome, MIDD, and plasma cell-related MGRS as a single agent or in combination with daratumumab (Darzalex), daratumumab and hyaluronidase-fihj (Darzalex Faspro) or talquetamab-tgvs (Talvey).

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

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- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication listed in the coverage criteria
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen AND
    - No evidence of disease progression while on the current regimen

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Tecvayli.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Multiple Myeloma

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Tecvayli for treatment of multiple myeloma, POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome, monoclonal immunoglobulin deposition disease (MIDD), and monoclonal gammopathy of renal significance (MGRS) can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Tecvayli [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed February 3, 2026.

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