

Specialty Guideline 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 Indications¹

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 Use²

- 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 are considered experimental/investigational and not medically necessary.

Documentation

Reference number(s)
5657-A

Submission of the following information is necessary to initiate the prior authorization review: chart notes or medical record documentation demonstrating failure of previous lines of therapy.

Coverage Criteria

Multiple Myeloma¹⁻²

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

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

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