Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Tecvayli (teclistamab-cqyv)

Effective: August 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration - Approved Indications

Tecvayli (teclistamab-cqyv) 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:

- in combination with daratumumab and hyaluronidase-fihj in patients who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent
- 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.

Note: Providers and Members enrolled with Harvard Pilgrim Health Care may reference the HPHC/OncoHealth guideline located at https://oncohealth.us/medicalpolicies/harvardpilgrim/

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Tecvayli (teclistamab-cqyv) for Members when **ALL** the following criteria is met:

1. Documented diagnosis of relapsed or refractory multiple myeloma

AND

2. Patient is 18 years of age or older

AND

3. The prescribing physician is an oncologist or hematologist

AND

4. One of the following:
    a. All of the following:
        i. Documentation the patient has received at least **four (4)** prior lines of therapy, that include at least one drug from all of the following drug classes:
            1. Proteasome inhibitor (e.g., bortezomib, Kyprolis [carfilzomib], Ninlaro [ixazomib]).
            2. Immunomodulatory agent (e.g., thalidomide, lenalidomide, Pomalyst [pomalidomide])

3. Anti-CD38 monoclonal antibody (e.g., Darzalex [daratumumab], Darzalex Faspro [daratumumab and hyaluronidase fihj], Sarclisa [isatuximab])

ii. The patient has an Eastern Cooperative Oncology Group (ECOG) score of 0 to 2

b. All of the following:

i. Documentation the patient has received at least one (1) prior line of therapy, that includes at least one drug from all of the following drug classes:

1. Proteasome inhibitor (e.g., bortezomib, Kyprolis [carfilzomib], Ninlaro [ixazomib]).
2. Immunomodulatory agent (e.g., thalidomide, lenalidomide, Pomalyst [pomalidomide])

ii. Documentation of use in combination with Darzalex Faspro (daratumumab and hyaluronidase-fihj

Limitations

- The first three step-up titration doses of Tecvayli require inpatient hospitalization for up to 48 hours after administration. Tecvayli, even though given in an inpatient setting, still requires prior authorization from the plan.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9380	Injection, teclistamab-cqyv, 0.5 mg

References

1. Tecvayli (teclistamab-cqyv) [package insert]. Horsham, PA: Janssen Biotech Inc.; March 2026.
2. National Comprehensive Cancer Network (NCCN) Guidelines: Multiple Myeloma. Version: 5.2026.
3. Dose Escalation Study of Teclistamab, a Humanized BCMA*CD3 Bispecific Antibody, in Participants With Relapsed or Refractory Multiple Myeloma (MajesTEC-1). ClinicalTrials.gov Identifier: NCT03145181. Accessed online December 28, 2022 at https://clinicaltrials.gov/ct2/show/NCT03145181.
4. A Study of Teclistamab in Participants With Relapsed or Refractory Multiple Myeloma (MajesTEC-1). ClinicalTrials.gov Identifier: NCT04557098. Accessed online December 28, 2022 at https://clinicaltrials.gov/ct2/show/NCT04557098.
5. Moreau P, et al. Teclistamab in relapsed or refractory multiple myeloma. N Engl J Med. 2022;387(6):495–505. doi:10.1056/NEJMoa2203478.Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma V.3.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed November 6, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org.

Approval And Revision History

January 18, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)

February 14, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- Originally approved February 14, 2023 by P&T and January 18, 2023 by MPAC committees effective April 1, 2023
- Coding update per HCPCS level II quarterly release. Effective date July 1, 2023, the following HCPCS code has been added: J9380 replacing C9148
- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024
- February 13, 2024: Removed Harvard Pilgrim Health Care Commercial from Medical Necessity Guideline (eff April 1, 2024). Modified title of Medical Necessity Guideline from “Tecvayli™ (teclistamab-cqyv) injection, for subcutaneous administration” to “Tecvayli™ (teclistamab-cqyv)”. Added Tufts Health Together to the Medical Necessity Guideline. Removed the Limitation The Plan may authorize Tecvayli therapy for up to 12 months if Clinical Guideline Coverage Criteria is met. Added provider specialty requirements. Removed “The Member will only receive Tecvayli therapy as a single agent regimen.” Administrative update to the Limitation to be “The first three step-up titration doses of Tecvayli require inpatient hospitalization for up to 48 hours after administration. Tecvayli, even though given in an inpatient setting, still requires prior authorization from the plan.” Minor wording updates (effective May 1, 2024).
- January 14, 2025: No changes. Removed Tufts Health Together from the Medical Necessity Guideline. Coverage for Tufts Health Together will fall under the Unified Medical Policies Medical Necessity Guideline (eff 2/18/25).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- February 10, 2026: no changes. Administrative change: removed Carelink from template.
- July 14, 2026: Added coverage criteria for the supplemental indication in combination with daratumumab and hyaluronidase-fihj in patients who have received at least one prior line of therapy, including a proteasome inhibitor and an

immunomodulatory agent. Administrative updates: Template updated from “Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans” to “Tufts Health Together- MassHealth Accountable Care Partnership Plans.” Added clarifying language to overview section regarding Oncohealth. (eff 8/1/26)

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.