Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Tecvayli™ (teclistamab-cqyv)

Effective: April 1, 2025

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

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

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

☐ Tufts Health Together – MassHealth MCO Plan and 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

Multiple myeloma (MM) is a progressive, incurable blood cancer that affects plasma cells. Plasma cells are a type of matured B cells found in bone marrow that produce antibodies. When damaged, they rapidly displace normal cells and create tumors in the bone marrow. MM is typically characterized by the neoplastic proliferation of plasma cells producing a monoclonal immunoglobulin. The plasma cells proliferate in the bone marrow and can result in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures. Additional disease-related complications include hypercalcemia, kidney impairment, anemia, and infections.

While overall outcomes for patients with MM have improved substantially in recent decades, MM is a heterogeneous disease with some patients progressing rapidly despite treatment and others responding to treatment for many years. There are many approved treatment combinations for patients with relapsed or refractory multiple myeloma (RRMM). Most patients experience serial relapses over time and will ultimately receive most if not all available agents at some point during their disease course. There are no guidelines for sequencing treatment options that can be used in the fifth line setting for RRMM. Providers will consider patient comorbidities, ability to tolerate side effects, ECOG score, prior exposure to agents, and availability of therapies in the specific area.

Accelerated approval of Tecvayli (teclistamab-cqyv) was based on results from the Phase 1/2 MajesTEC-1 study. Treatment with Tecvayli demonstrated an overall response rate of 61.8%. The estimated duration of response rate among responders was 90.6% at six months and 66.5% at nine months. The median duration of response was not estimable.

Tecvayli is available as an “off-the-shelf” T cell–redirecting, bispecific antibody targeting both B-cell maturation antigen (BCMA) and cluster of differentiation 3 (CD3), and it is administered subcutaneously as a weekly treatment until disease progression.

Food and Drug Administration - Approved Indications

Tecvayli (teclistamab-cqyv) is a bispecific BCMA-directed CD3 T-cell engager indicated for the treatment of adult patients with RRMM who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and

an anti-CD38 monoclonal antibody.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Clinical Guideline Coverage Criteria

The plan may authorize Tecvayli for Members when **ALL** the following criteria is met:

1. Documented diagnosis of relapsed or refractory multiple myeloma

AND

2. 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:
    a. Proteasome inhibitor (e.g., bortezomib, Kyprolis [carfilzomib], Ninlaro [ixazomib]).
    b. Immunomodulatory agent (e.g. thalidomide, lenalidomide or Pomalyst [pomalidomide])
    c. Anti-CD38 monoclonal antibody (e.g., Darzalex [daratumumab], Darzalex Faspro [daratumumab and hyaluronidase fjhi], Sarclisa [isatuximab])

AND

3. Patient is 18 years of age or older

AND

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

AND

5. The prescribing physician is an oncologist or hematologist

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.; May 2024.
2. National Comprehensive Cancer Network (NCCN) Guidelines: Multiple Myeloma. Version 3.2023.
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.
6. 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.

- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- February 13, 2024: Removed Harvard Pilgrim Health Care Stride Medicare Advantage 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)”. 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.” Updated the Limitation to 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).
- February 11, 2025: No changes. Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template (eff 4/1/25).
- March 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 4/1/25).

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines 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.