CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines
Medical Benefit Drugs

Tecvayli™ (teclistamab-cqyv) injection, for subcutaneous administration

Effective: July 1, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, 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

Accelerated approval of Tecvayli was based on results from the Phase 1/2 MajesTEC-1 study. Patients were excluded if they had a ECOG performance score of two or higher. 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.

There are no guidelines for sequencing the options that can be used in the fifth line setting. Providers will consider patient comorbidities, ability to tolerate side effects, ECOG score, prior exposure to agents, and availability of therapies in the specific area.

Food and Drug Administration (FDA) Approved Indications:

TECVAYLI 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 who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. 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.

REMS Program Requirement:

The approved label for Tecvayli includes a Boxed Warning for life-threatening or fatal Cytokine Release Syndrome (CRS) and neurologic toxicity, including Immune effector cell-associated neurotoxicity syndrome (ICANS), and the drug will only be available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), called the TECVAYLI REMS program. Notable requirements of the TECVAYLI REMS program include the following:

- Prescribers must be certified with the program by enrolling and completing training.
- Prescribers must counsel patients receiving TECVAYLI about the risk of CRS and neurologic toxicity, including ICANS, and provide patients with Patient Wallet Card.
- Pharmacies and healthcare settings that dispense TECVAYLI must be certified with the TECVAYLI REMS program and must verify prescribers are certified through the TECVAYLI REMS program.
- Wholesalers and distributers must only distribute TECVAYLI to certified pharmacies or healthcare settings.

Further information about the TECVAYLI REMS program is available at www.TECVAYLIREMS.com or by telephone at 1-855-810-8064.

Note: Due to the risk of CRS and neurologic toxicity, including ICANS, hospitalization is required during administration of the first three (3) doses of Tecvayli. Tecvayli is given in a step-up titration regimen, which includes step-up dose 1 (Day 1), step-up dose 2 (Day 4), and then the first treatment dose (Day 7), all of which must be done in a hospital setting for 48 hours. Authorization for inpatient hospitalizations must be requested separately through Precert review. After the initial three (3) doses, Tecvayli may be administered in an outpatient setting by a healthcare provider.

Clinical Guideline Coverage Criteria

The Plan may cover Tecvayli (teclistamab-cqyv) when all the following clinical criteria is met:

1. The Member has a confirmed diagnosis of relapsed or refractory multiple myeloma (RRMM) and has already received at least four (4) prior lines of therapy, including:
    a. A proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib], or Ninlaro [ixazomib]).
    b. an immunomodulatory agent (e.g. Thalomid [thalidomide], Revlimid [lenalidomide] or Pomalyst [pomalidomide])
    c. an anti-CD38 monoclonal antibody (e.g., Darzalex, Darzalex Faspro [daratumumab], Sarclisa [isatuximab])

AND

2. The Member is 18 years of age or older

AND

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

AND

4. The Member will only receive Tecvayli therapy as a single agent regimen

Limitations

- The Plan may authorize Tecvayli therapy for up to 12 months if Clinical Guideline Coverage Criteria is met.
- The first three step-up titration doses of Tecvayli require inpatient hospitalization for up to 48 hours after administration. Inpatient hospital stays must be approved separately through Precert review.

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.; October 2022.
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.
- June 2023 updated CPCT logo
- Coding update per HCPCS level II quarterly release. Effective date July 1, 2023, the following HCPCS code has been added: J9380 replacing C9148.
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.

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.