Clinical Policy: Teclistamab-cqyv (Tecvayli)

Reference Number: CP.PHAR.611
Effective Date: 03.01.23
Last Review Date: 02.26
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Teclistamab-cqyv (Tecvayli®) is a humanized recombinant immunoglobulin G4-proline, alanine, alanine (IgG4-PAA) antibody, and a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager.

FDA Approved Indication(s)

Tecvayli is 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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Tecvayli is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Multiple Myeloma (must meet all)**:**

1. Diagnosis of relapsed or refractory multiple myeloma;
2. Prescribed by or in consultation with a hematologist or an oncologist;
3. Age ≥ 18 years;
4. Prescribed in one of the following ways (a, b, or c):
    a. As monotherapy, and member has received or has documented intolerance to ≥ 4 prior lines of therapy (*see Appendix B for examples*) that include all of the following (i, ii, and iii):
        i. One proteasome inhibitor (e.g., bortezomib, Kyprolis®, Ninlaro®);
        ii. One immunomodulatory agent (e.g., Revlimid®, pomalidomide, Thalomid®);
        iii. One anti-CD38 antibody (e.g., Darzalex®/Darzalex Faspro™, Sarclisa®);
    b. In combination with a daratumumab-containing product (i.e., Darzalex or Darzalex Faspro), and member has received or has documented intolerance to ≥ 1

prior line of therapy (*see Appendix B for examples*) that include both of the following (i and ii):
    i. One proteasome inhibitor (e.g., bortezomib, Kyprolis, Ninlaro);
    ii. One immunomodulatory agent (e.g., Revlimid, pomalidomide, Thalomid);
  c. In combination with Talvey®, and member has received ≥ 3 prior lines of therapy (*see Appendix B for examples*);

**Prior authorization may be required*

5. One of the following (a or b):
   a. Member has measurable disease as evidenced by one of the following assessed within the last 28 days (i, ii, or iii):
      i. Serum M-protein ≥ 0.5 g/dL;
      ii. Urine M-protein ≥ 200 mg/24 h;
      iii. Serum free light chain (FLC) assay: involved FLC level ≥ 10 mg/dL (100 mg/L) provided serum kappa lambda FLC ratio is abnormal;
   b. Member has progressive disease, as defined by the IMWG response criteria (see *Appendix D*), assessed within 60 days following the last dose of the last anti-myeloma drug regimen received;
6. Member does not have a known active central nervous system (CNS) involvement (e.g., seizure, cerebrovascular ischemia) or exhibits clinical signs of meningeal involvement of multiple myeloma;
7. Request meets one of the following (a, b, or c):*
   a. If prescribed as monotherapy, dose does not exceed all of the following (i, ii, iii, and iv):
      i. Day 1: 0.06 mg/kg;
      ii. Day 4: 0.3 mg/kg;
      iii. Day 7: 1.5 mg/kg;
      iv. Day 8 and thereafter: 1.5 mg/kg per week;
   b. If prescribed in combination with daratumumab and hyaluronidase-fihj (Darzalex Faspro), dose does not exceed all of the following (i, ii, iii, and iv):
      i. Week 1: 0.06 mg/kg on day 1, 0.3 mg/kg on day 3, then 1.5 mg/kg on day 7;
      ii. Weeks 2 to 8: 1.5 mg/kg per week;
      iii. Weeks 9 to 24: 3 mg/kg every 2 weeks;
      iv. Week 25 and thereafter: 3 mg/kg every 4 weeks;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label dose use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Multiple Myeloma (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Tecvayli for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b, or c):*
   a. As monotherapy (i or ii):
      i. New dose does not exceed 1.5 mg/kg every 2 weeks;
      ii. New dose does not exceed 1.5 mg/kg per week, and documentation supports that member has not achieved and maintained a complete response or better for a minimum of 6 months;
   b. In combination with daratumumab: New dose does not exceed 3 mg/kg every 4 weeks;
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label dose use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents;

B. Active or prior history of CNS involvement with myeloma (e.g., seizures, cerebrovascular ischemia) or exhibit clinical signs of meningeal involvement of multiple myeloma.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BCMA: B-cell maturation antigen
CNS: central nervous system
CRS: cytokine release syndrome
FDA: Food and Drug Administration
ICANS: immune effector cell-associated neurotoxicity syndrome
IMWG: International Myeloma Working Group

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
MM: regimens containing proteasome inhibitors, immunomodulatory agents and/or anti-CD38 monoclonal antibodies (examples – NCCN)		
bortezomib / lenalidomide (Revlimid®) or pomalidomide or Thalomid (thalidomide) / dexamethasone	Varies	Varies
Kyprolis (carfilzomib – weekly or twice weekly) / dexamethasone	Varies	Varies
Kyprolis (carfilzomib) / lenalidomide (Revlimid) / dexamethasone	Varies	Varies
Ninlaro (ixazomib) / lenalidomide (Revlimid) / dexamethasone	Varies	Varies
Darzalex (daratumumab) / bortezomib / dexamethasone ± Thalomid (thalidomide)	Varies	Varies
Darzalex (daratumumab) / lenalidomide (Revlimid) / dexamethasone	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): cytokine release syndrome (CRS) and neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS)

Appendix D: General Information

- Due to the risks of CRS, patients should be hospitalized for 48 hours after administration of all doses within the step-up dosing schedule including the first maintenance dose. Subsequent weekly maintenance doses are managed on outpatient basis according to the Tecvayli REMS program (*see Appendix E for more details on REMS Program*).
- In the MajesTEC-1 trial, 100% of enrolled patients reported having an adverse event, of which 94.5% were grade 3 or 4. The most common hematologic adverse events were neutropenia (70.9%), anemia (52.1%), and thrombocytopenia (44.0%). The most common non-hematologic adverse events were diarrhea (28.5%), fatigue (27.9%), and nausea (27.3%).
- In the MajesTEC-1 trial, 72.1% of participants experienced any grade CRS, and 14.5% of participants experienced any grade ICANS. Both toxicities were managed with supportive measures that included administration of tocilizumab (in 60/119 patients with CRS, and 3/24 patients with ICANS), low-flow oxygen by nasal cannula, glucocorticoids, levetiracetam, and gabapentin.
- In the MajesTEC-1 trial, five deaths were considered to have been related to Tecvayli treatment including one death resulting from progressive multifocal leukoencephalopathy, two deaths related to Covid-19, one death related to hepatic failure, and one death related to streptococcal pneumonia. Subjects positive for hepatitis B, hepatitis C, and/or HIV were excluded from the trial. Prior to treatment with Tecvayli, initiation of antiviral prophylaxis to prevent herpes zoster reactivation is recommended.
- The IMWG response criteria for multiple myeloma definition of progressive disease requires only one of the following:
  - Increase of 25% from lowest response value in any of the following:
    - Serum M-component (absolute increase must be ≥ 0.5 g/dL), and/or
    - Urine M-component (absolute increase must be ≥ 200 mg/24 h), and/or
    - Only in patients without measurable serum and urine M-protein levels: the difference between involved and uninvolved FLC levels (absolute increase must be > 10 mg/dL)
    - Only in patients without measurable serum and urine M protein levels and without measurable disease by FLC levels, bone marrow plasma cell percentage irrespective of baseline status (absolute increase must be ≥ 10%)
  - Appearance of a new lesion(s), ≥ 50% increase from nadir in SPD (sum of the products of the maximal perpendicular diameters of measured lesions) of > 1 lesion, or ≥ 50% increase in the longest diameter of a previous lesion > 1 cm in short axis
  - ≥ 50% increase in circulating plasma cells (minimum of 200 cells per µL) if this is the only measure of disease
- The Standard IMWG response criteria (per NCCN) define complete response as the negative immunofixation on the serum and urine and disappearance of any soft tissue plasmacytomas and < 5% plasma cells in bone marrow aspirates.

Appendix E: Tecvayli REMS Program Information

- Tecvayli is available only through a restricted REMS program due to the risk of cytokine release syndrome and neurologic toxicity, including ICANS.
- Prescribers are required to:
  1) obtain certification with the program by enrolling and completing training;
  2) counsel patients about the risks associated with Tecvayli therapy;
  3) provide patients with patient wallet card.
- Dispensers are required to:
  1) obtain certification with the program;
  2) verify prescriber certification status with the program prior to dispensing the product.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Multiple myeloma	Monotherapy: Step-up dosing schedule[a]: • Day 1: 0.06 mg/kg subcutaneously (step-up dose 1) • Day 4[b]: 0.3 mg/kg subcutaneously (step-up dose 2) • Day 7[c]: 1.5 mg/kg subcutaneously (first treatment dose) Weekly dosing schedule[a]: • 1.5 mg/kg subcutaneously once weekly (one week after first treatment dose and weekly thereafter) Biweekly dosing schedule[a]: • 1.5 mg/kg subcutaneously every two weeks for patients who have achieved and maintained a complete response or better for a minimum of 6 months In combination with daratumumab and hyaluronidase-fihj[a]: • Week 1: 0.06 mg/kg subcutaneously on day 1, 0.3 mg/kg subcutaneously on day 3[b], then 1.5 mg/kg subcutaneously on day 7[c] • Weeks 2 to 8: 1.5 mg/kg subcutaneously once weekly • Weeks 9 to 24: 3 mg/kg subcutaneously every 2 weeks • Week 25 and thereafter: 3 mg/kg subcutaneously every 4 weeks	See regimen

[a] *Refer to prescribing information Table 3 for recommendations on restarting therapy due to dose delays.*
[b] *Step-up dose 2 may be given between 2 to 4 days after step-up dose 1 and may be given up to 7 days after step-up dose 1 to allow for resolution of adverse reactions.*
[c] *First treatment dose may be given between 2 to 4 days after step-up dose 2 and may be given up to 7 days after step-up dose 2 to allow for resolution of adverse reactions.*

VI. Product Availability

Solution for subcutaneous injection in a single-dose vial:
- 30 mg/3 mL (10 mg/mL) used for step-up doses 1 and 2
- 153 mg/1.7 mL (90 mg/mL) used for treatment doses

VII. References

1. Tecvayli Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; March 2026. Available at: https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TECVAYLI-pi.pdf. Accessed March 12, 2026.
2. ClinicalTrials.gov. A phase 1, first-in-human, open-label, dose escalation study of teclistamab, a humanized BCMA x CD3 bispecific antibody in subjects with relapsed or refractory multiple myeloma. Available at: https://www.clinicaltrials.gov/ct2/show/NCT03145181. Accessed November 10, 2022.
3. ClinicalTrials.gov. A phase 1/2, first-in-human, open-label, dose escalation study of teclistamab, a humanized BCMA x CD3 bispecific antibody, in subjects with relapsed or refractory multiple myeloma. Available at: https://clinicaltrials.gov/ct2/show/NCT04557098. Accessed November 10, 2022.
4. Touzeau C, Krishnan AY, Moreau P, et al. Efficacy and safety of teclistamab in patients with relapsed/refractory multiple myeloma after BCMA-targeting therapies. Blood. Published online August 20, 2024.
5. Girgis S, Lin SXW, Pillarisetti K, et al. Translational modeling predicts efficacious therapeutic dosing range of teclistamab for multiple myeloma. Target Oncol. 2022;17(4):433-439.
6. Moreau P, Garfall AL, van de Donk NWCJ, et al. Teclistamab in relapsed or refractory multiple myeloma. N Engl J Med. 2022;387(6):495-505.
7. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed March 12, 2026.
8. National Comprehensive Cancer Network. Multiple Myeloma Version 5.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed March 12, 2026.
9. Pillarisetti K, Powers G, Luistro L, et al. Teclistamab is an active T cell-redirecting bispecific antibody against B-cell maturation antigen for multiple myeloma. Blood Adv. 2020;4(18):4538-4549.
10. Usmani SZ, Garfall AL, van de Donk NWCJ, et al. Teclistamab, a B-cell maturation antigen × CD3 bispecific antibody, in patients with relapsed or refractory multiple myeloma (MajesTEC-1): a multicentre, open-label, single-arm, phase 1 study. Lancet. 2021;398(10301):665-674.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	12.14.22	02.23
Added updated HCPCS code [J9380]	05.24.23	
1Q 2024 annual review: no significant changes; inactive HCPCS codes removed; references reviewed and updated.	10.18.23	02.24
1Q 2025 annual review: decreased serum M-protein criteria option from ≥ 1 g/dL to ≥ 0.5 g/dL for multiple myeloma criteria alignment; added additional option to currently required measurable disease requirement to allow for progressive disease as defined by IMWG; removed exclusion for previous treatment with anti-BCMA targeted therapy; revised all Commercial approval durations to "6 months or to the member's renewal date, whichever is longer" per template for this injectable agent; references reviewed and updated.	10.31.24	02.25
1Q 2026 annual review: revised initial Medicaid/HIM approval duration to 12 months; added combination therapy option with Talvey for ≥ 3 prior lines of therapy per NCCN; for continued therapy, added dosing option for not exceeding 1.5 mg/kg every two weeks and if dose requested is 1.5 mg/kg per week, added requirement for documentation supporting member has not achieved and maintained a complete response or better for a minimum of 6 months per PI; references reviewed and updated.	10.21.25	02.26
RT4: added new FDA-labeled indication of multiple myeloma in combination with daratumumab and hyaluronidase-fihj (Darzalex Faspro); updated existing indication of multiple myeloma as monotherapy from accelerated approval to full approval per prescribing information.	03.12.26	

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage

decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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