Title: Tecvayli (teclistamab-cqyv)	**Division: Medical Management** **Department: Utilization Management**
Approval Date: 1/31/2023	**LOB: Medicaid, HIV SNP, HARP, CHP, Medicare, UltraCare, MetroPlus Gold, Goldcare, Essential Plan, QHP**
Effective Date: 1/31/2023	**Policy Number: UM-MP345**
Review Date: 1/28/2025	**Cross Reference Number:**
Retired Date:	**Page 1 of 12**

I. APOLICY DESCRIPTION:

Medical Oncology – Anti CD-3; Anti-BCMA; Bispecific T-Cell Engager; Mab, Tecvayli (teclistamab-cqyv)

II. RESPONSIBLE PARTIES:

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

III. DEFINITIONS:

Tecvayli (teclistamab-cqyv) is an anti-neoplastic therapy that binds to the CD3 receptor on T-cells and B-cell maturation antigen (BCMA) on the surface of multiple myeloma cells. This results in T-cell activation and the release of various inflammatory cytokines, which results in the lysis of BCMA-expressing multiple myeloma cells. Tecvayli is currently used for the treatment of adult patients with multiple myeloma that is refractory or has relapsed after using at least 4 lines of therapy including a proteasome inhibitor, immunomodulatory agent and an anti-CD38 monoclonal antibody.

IV. POLICY:

Tecvayli will be considered medically necessary once the following coverage criteria is met:

INITIAL REQUEST:

1. Multiple myeloma (MM) that is refractory or in relapse:

A. Member is 18 years of age or older;

AND

B. Member has a diagnosis confirmed by submitted documentation including clinical chart notes of relapsed or refractory Multiple Myeloma;

AND

C. Member has measurable disease defined as ONE of the following:

a. Serum monoclonal paraprotein (M-protein) ≥ 1 g/dL;

OR

b. Urine M-protein ≥ 200 mg/24 hours;

OR

c. Serum immunoglobulin free light chain ≥ 10 mg/dL and abnormal serum free light chain ratio;

AND

D. Member has received treatment with at least four prior lines of therapy, including at least ONE drug from each of the following categories:

a. Proteasome inhibitor [e.g., Velcade (bortezomib), Kyprolis (carfilzomib)];
AND
b. Immunomodulatory agent [e.g., Revlimid (lenalidomide), Pomalyst (pomalidomide), Thalomid (thalidomide)];
AND
c. Anti-CD38 monoclonal antibody [e.g., Darzalex (daratumumab)];

AND

E. Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1;

AND

F. ONE of the following:
a. Member has a creatinine clearance ≥ 40 mL/min;
OR
b. ALL of the following:
i. Member has a creatinine clearance < 40 mL/min;
AND
ii. Member's Nephrologist or prescribing provider acknowledges that the safety of Tecvayli in renally-impaired members is unknown and will closely monitor member during treatment;

AND

G. If member is biologically female of childbearing age, member meets ALL of the following:
a. Member has a negative pregnancy test before initiation of Tecvayli,
AND
b. Member will use an effective method of contraception during the course of treatment and 5 months after the last dose of Tecvayli;

AND

H. Member does not have ANY of the following as per the discretion of the prescriber *(Note: If member has any of the following then attestation needs to be provided which states that member is being followed by a neurologist, pulmonologist or any other qualified physician per condition to monitor member if Tecvayli is still to be given per physician's discretion)*:
a. Active central nervous system (CNS) involvement as confirmed by prescriber including clinical signs of meningeal involvement of multiple myeloma;
OR
b. Pulmonary compromise requiring oxygen supplementation during therapy;
OR

c. Cardiac disease (i.e., myocardial infarction, stage III-IV congestive heart failure) that can adversely affect therapy;

OR

d. An active uncontrolled infection including human immunodeficiency virus (HIV), Hepatitis B or C and Cytomegalovirus (CMV);

OR

e. An active autoimmune disease including graft versus host disease requiring to be on immunosuppressive agents;

OR

f. Plasma cell leukemia, Waldenström's macroglobulinemia, POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes), or amyloidosis;

AND

I. Member has not used a prior therapy that targets B cell maturation antigen (BCMA) and/or is a CD3-redirecting therapy including Tecvayli;

AND

J. Tecvayli will be prescribed through the consultation of a Hematologist or Oncologist;

AND

K. Member is not currently enrolled in Multiple Myeloma clinical trial or is ineligible for clinical trial enrollment;

AND

L. Tecvayli will be given based on the FDA approved dosing (Refer to package insert for dosing guidance);

AND

M. Member will receive Tecvayli at a healthcare facility enrolled in the Tecvayli Risk Evaluation and Mitigation Strategy (REMS) and are aware of how to manage relevant toxicities of Tecvayli (See Appendices A through C)

Initial Duration of Approval: *12 months*

RENEWAL REQUEST:

1. Multiple myeloma (MM) that is refractory or in relapse:

A. Initial conditions of coverage have been met;

AND

B. Member has experienced a positive clinical response to Tecvayli and continuation of therapy is deemed clinically appropriate by the prescriber;

AND

C. Member has not experienced any adverse reactions from therapy (i.e, recurrent grade 3 Cytokine Release Syndrome (CRS) or grade 3 CRS with duration ≥ 48 hours, grade 4 CRS, recurrent grade 3 or grade 4 neurological toxicity, grade 4 infection, grade 4 non-hematological adverse reaction, serious hypersensitivity reaction

Renewal Duration of Approval: *12 months*

V. LIMITATIONS/ EXCLUSIONS:

Tecvayli is considered to be experimental and investigational if prescribed for indications other than for the treatment of multiple myeloma that is refractory or in relapse.

Tecvayli is only available at Qualified Treatment Centers.

VI. APPLICABLE PROCEDURE CODES:

CPT	Description
J9380	Injection, teclistamab-cqyv, 0.5 mg

VII. APPLICABLE DIAGNOSIS CODES:

CODE	Description
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse

VIII. REFERENCES:

1. Tecvayli (teclistamab-cqyv) [prescribing information]. Horsham, PA: Janssen Biotech, Inc; November 2024.
2. 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. doi:10.1056/NEJMoa2203478
3. Tecvayli. IPD Analytics Database CodeSource. Available at: http://codesource.ipdanalytics.com/search-results/apc/all/tecvayli
4. Girgis S, et al. Translational modeling predicts efficacious therapeutic dosing range of teclistamab for multiple myeloma [published correction appears in Target Oncol. Target Oncol. 2022;17(4):433–439. doi:10.1007/s11523-022-00893-y
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. Pillarisetti K, 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. doi:10.1182/bloodadvances.2020002393
7. Usmani SZ, 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.
8. Tecvayli Qualified Treatment Center. Available at: https://www.tecvaylihcp.com/treatment-locator/

IX. Appendix A: CRS Grading and Management Guidance

CRS Grade & Symptoms	Actions
Grade 1 Temperature ≥38°C (100.4°F)* attributed to CRS.	Withhold teclistamab until CRS resolves. Administer premedication prior to the next teclistamab dose.
Grade 2 Temperature ≥38°C (100.4°F)* attributed to CRS, with hypotension responsive to fluids and not requiring vasopressors and/or oxygen requirement of low-flow nasal cannula (≤6 L/minute) or blow-by.	Withhold teclistamab until CRS resolves. Administer premedication prior to the next teclistamab dose. Patients should be hospitalized for 48 hours following the next teclistamab dose.

Grade 3 Temperature ≥38°C (100.4°F)* attributed to CRS, with hypotension requiring one vasopressor with or without vasopressin and/or oxygen requirement of high-flow nasal cannula (>6 L/minute), face mask, nonrebreather mask, or Venturi mask.	First occurrence of grade 3 CRS with duration <48 hours: Withhold teclistamab until CRS resolves. Provide supportive therapy as clinically necessary (may include intensive care). Administer premedication prior to the next teclistamab dose. Patients should be hospitalized for 48 hours following the next teclistamab dose.
	Recurrent grade 3 CRS or grade 3 CRS with duration ≥48 hours: Permanently discontinue teclistamab and provide supportive care as clinically necessary (may include intensive care).
Grade 4 Temperature ≥38°C (100.4°F)* attributed to CRS, with hypotension requiring multiple vasopressors (excluding vasopressin) and/or oxygen requirement of positive pressure (eg, CPAP, BiPAP, intubation, and mechanical ventilation)**.	Permanently discontinue teclistamab and provide supportive care as clinically necessary (may include intensive care).
*Fever may be masked by antipyretics or anticytokine therapy. **CPAP = continuous positive airway pressure; BiPAP = bilevel positive airway pressure.	

X. Appendix B: Tecvayli-Related Neurologic Toxicity Management

Severity Grade (Excluding ICANS)	Actions
Grade 1	Withhold teclistamab until neurologic toxicities/symptoms resolve or stabilize.
Grade 2 or grade 3 (first occurrence)	Withhold teclistamab until neurologic toxicities/symptoms improve to ≤ grade 1. Provide supportive therapy as clinically appropriate.
Recurrent grade 3 or grade 4	Permanently discontinue teclistamab. Provide supportive care as clinically appropriate (may include intensive care).

Recommendations for management of Tecvayli-related ICANS	
ICANS Grade[a] & Symptoms[b]	**Actions**
Grade 1 ICE score 7 to 9[c], or depressed level of consciousness[d] (awakens spontaneously)	Withhold teclistamab until ICANS resolves. Monitor neurologic symptoms and consider consultation with neurologist/other specialists for further evaluation and management (eg, consideration for initiating seizure prophylaxis with nonsedating, antiseizure medication).
Grade 2 ICE score 3 to 6[c], or depressed level of consciousness[d] (awakens to voice)	Withhold teclistamab until ICANS resolves. Administer dexamethasone 10 mg IV every 6 hours (or equivalent); continue dexamethasone until resolution to ≤ grade 1, then taper. Monitor neurologic symptoms and consider consultation with neurologist/other specialists for further evaluation and management (eg, consideration for initiating seizure prophylaxis with nonsedating, antiseizure medication). Patients should be hospitalized for 48 hours following the next teclistamab dose.
Grade 3 ICE score 0 to 2[c], or depressed level of consciousness[d] (awakens only to tactile stimulus), or seizures[d] (either any clinical seizure, focal or generalized, that resolves rapidly, or nonconvulsive seizures on EEG that resolve with intervention), or Raised intracranial pressure (focal/local edema on neuroimaging[d])	First occurrence of grade 3 ICANS: Manage as per grade 2 ICANS. Provide supportive therapy as clinically appropriate (may include intensive care).
	Recurrent grade 3 ICANS: Permanently discontinue teclistamab. Manage as per grade 2 ICANS. Provide supportive therapy as clinically appropriate.

Grade 4 ICE score 0[c], or Depressed level of consciousness[d] (either unarousable or requires vigorous/repetitive tactile stimuli to arouse, or stupor or coma), or Seizures[d] (either life-threatening prolonged seizure >5 minutes, or repetitive clinical or electrical seizures without return to baseline in between), or Motor findings[d] (deep focal motor weakness such as hemiparesis or paraparesis), or Raised intracranial pressure/cerebral edema[d], with signs/symptoms including diffuse cerebral edema on neuroimaging, or decerebrate or decorticate posturing, or cranial nerve VI palsy, or papilledema, or Cushing triad	Permanently discontinue teclistamab. Manage with dexamethasone as per grade 2 ICANS. Alternatively, consider methylprednisolone 1,000 mg IV daily for ≥2 days. Monitor neurologic symptoms and consider consultation with neurologist/other specialists for further evaluation and management (eg, consideration for initiating seizure prophylaxis with nonsedating, antiseizure medication). Provide supportive therapy as clinically appropriate (may include intensive care).

[a]Based on American Society for Transplantation and Cellular Therapy (ASTCT) 2019 grading for ICANS.
[b]Management is determined by the most severe event (not attributable to any other cause).
[c]If patient is arousable and able to perform immune effector cell-associated encephalopathy (ICE) assessment: Orientation (oriented to year, month, city, hospital = 4 points), naming (name 3 objects, eg, point to clock, pen, button = 3 points), following commands (eg, “show me 2 fingers”

or "close your eyes and stick out your tongue" = 1 point), writing (ability to write a standard sentence = 1 point), attention (count backwards from 100 by 10 = 1 point). If unarousable and unable to perform ICE assessment (grade 4 ICANS = 0 points).
[d]Not attributable to any other cause.

XI. Appendix C: Tecvayli Dosage Guidance for Other Adverse Reactions

Adverse Reaction	Severity		Actions
Hematologic toxicity	ANC <500/mm3		Withhold teclistamab until ANC is ≥500/mm3.
	Febrile neutropenia		Withhold teclistamab until ANC is ≥1,000/mm3 and fever resolves.
	Hemoglobin <8 g/dL		Withhold teclistamab until hemoglobin is ≥8 g/dL.
	Platelets <25,000/mm3 or platelets 25,000 to 50,000/mm3 with bleeding		Withhold teclistamab until platelets are ≥25,000/mm3 and no evidence of bleeding.
Hypersensitivity reactions (systemic or local)	Withhold or consider permanently discontinuing teclistamab based on reaction severity.		
Infections	Monitor immunoglobulin levels during treatment; manage according to guidelines, including infection precautions and antibiotic/antiviral prophylaxis.		
	All grades	Withhold teclistamab for active infection during the step-up dosing schedule.	
	Grade 3	Withhold subsequent teclistamab treatment doses until infection improves to ≤ grade 1.	
	Grade 4	Consider permanent discontinuation of teclistamab. If not permanently discontinued, withhold subsequent treatment doses until infection improves to ≤ grade 1.	
Other nonhematologic adverse reactions	**Grade 3**	Withhold teclistamab until adverse reaction improves to ≤ grade 1.	
	Grade 4	Consider permanent discontinuation of teclistamab. If not permanently discontinued, withhold subsequent treatment doses until adverse reaction improves to ≤ grade 1.	

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Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and or paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.

All coding and website links are accurate at time of publication.

MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.