Medical Policy:

Tecvayli (teclistamab-cqyv) subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.369	February 12, 2025	December 15, 2022

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth 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). EmblemHealth 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 EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. 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 web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Tecvayli, a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager, is indicated for the treatment of adults 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 a bispecific T-cell engaging antibody that binds to the CD3 receptor expressed on the surface of T-cells and BCMA expressed on the surface of multiple myeloma cells and some healthy B-lineage cells. Tecvayli redirects CD3 positive T-cells to BCMA positive myeloma cells, which causes T-cell activation and subsequent lysis and death of BCMA positive cells.

Safety: Tecvayli has a Boxed Warning for cytokine release syndrome and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome which may be serious or life-threatening.

Length of Authorization

Coverage will be provided for 12 months and may be renewed.

Coverage will be provided for 2 step-up induction doses (at day 1 and day 4) and first treatment dose at day 7. Then to be followed by weekly doses (after day 7) thereafter until disease progression or unacceptable toxicity.

Dosing Limits [Medical Benefit]

The recommended dosage of Tecvayli includes step-up doses of 0.06 mg/kg on Day 1 and 0.3 mg/kg on Day 4, followed by the first treatment dose of 1.5 mg/kg on Day 7. Tecvayli is administered once weekly thereafter, until disease progression or unacceptable toxicity.
(468 billable units (234 mg) every 7 days)

Guideline

I. INITIAL APPROVAL CRITERIA

1. **Multiple Myeloma**. Approve if the patient meets ALL of the following:
    A. Patient is ≥ 18 years of age; **AND**
    B. Patient has tried at least four systemic regimens; **AND**
    C. Among the previous regimens tried, the patient has received at least **ONE** drug from each of the following classes (i, ii, **AND** iii):
        i. Proteasome inhibitor; **AND**
            Note: Examples include bortezomib, Kyprolis (carfilzomib intravenous infusion), Ninlaro (ixazomib capsules).
        ii. Immunomodulatory drug; **AND**
            Note: Examples include lenalidomide, Pomalyst (pomalidomide capsules), Thalomid (thalidomide capsules).
        iii. Anti-CD38 monoclonal antibody; **AND**
            Note: Examples include Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), or Sarclisa (isatuximab-irfc intravenous infusion).
    D. The medication will be prescribed by, or in consultation with, an oncologist certified in the Tecvayli REMS program; **AND**
    E. Patient has not received prior treatment with any B-cell maturation antigen (BCMA) targeted therapy; **AND**
    F. Patient had an absence of unacceptable toxicity while on inpatient administration; **AND**
    G. Patient does not have an active infection, including clinically important localized infections; **AND**
    H. Prophylaxis for infection (e.g., herpes zoster reactivation) will be followed according to guidelines; **AND**
    I. Patient immunoglobulin levels will be monitored throughout treatment; **AND**
    J. Patient does not have any of the following comorbidities:
        i. Stroke
        ii. Seizure
        iii. CNS involvement or clinical signs of meningeal involvement of multiple myeloma; **AND**
    K. Patient has not had an allogenic stem cell transplant within the previous six months or an autologous stem cell transplant within the previous 12 weeks; **AND**
    L. Used as a single-agent

II. RENEWAL CRITERIA:

1. Member is responding positively to therapy, as determined by the prescriber; **AND**

2. Member has not experienced unacceptable toxicity from the drug

Dosing/Administration:

1. The recommended dosage of Tecvayli includes step-up doses of 0.06 mg/kg on Day 1 and 0.3 mg/kg on Day 4, followed by the first treatment dose of 1.5 mg/kg on Day 7. Tecvayli is administered once weekly thereafter, until disease progression or unacceptable toxicity.
2. Patients should be hospitalized for 48 hours after administration of the step-up doses and the first treatment dose. Pretreatment medication is given prior to each step-up dose and the first treatment dose. Tecvayli should be given by a healthcare provider.

Applicable Procedure Codes

Code	Description
J9380	Injection, teclistamab-cqyv, 0.5 mg; 1 billable unit = 0.5 mg

Applicable NDCs

Code	Description
57894-0449-01	Tecvayli 30 mg/3 mL containing one single-dose vial
57894-0450-01	Tecvayli 153 mg/1.7 mL containing one single-dose vial

ICD-10 Diagnoses

Code	Description
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.32	Solitary plasmacytoma in relapse
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/12/2025	Annual Review: Initial Criteria: Multiple Myeloma: added: "Patient has not received prior treatment with any B-cell maturation antigen (BCMA) targeted therapy; **AND** Patient had an absence of unacceptable toxicity while on inpatient administration; **AND** Patient does not have an active infection, including clinically important localized infections; **AND** Prophylaxis for infection (e.g., herpes zoster reactivation) will be followed according to guidelines; **AND** Patient immunoglobulin levels will be monitored throughout treatment; **AND** Patient does not have any of the following comorbidities: Stroke, Seizure, CNS involvement or clinical signs of meningeal involvement of

		multiple myeloma; **AND** Patient has not had an allogenic stem cell transplant within the previous six months or an autologous stem cell transplant within the previous 12 weeks; **AND** Used as a single-agent
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: No Criteria changes
EmblemHealth & ConnectiCare	5/03/2023	Annual Review: Removed code C9399, added code C9148; Added ICD-10 Codes C90.1, C90.12, C90.20, C90.22, C90.30, C90.32 and Z85.79
EmblemHealth & ConnectiCare	12/15/2022	New Policy

References

1. Tecvayli™ subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech.; October 2022.
2. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 2.2023 – October 31, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 11, 2022.
3. Tecvayli. Lexicomp (database online). Horsham, PA. Available at https://online.lexi.com. Accessed December 11, 2022.
4. Tecvayli IPD Analytics. Available at: http://secure.ipdanalytics.com. Accessed on December 11, 2022.