Medical Drug Clinical Criteria

Subject:	Tecvayli (teclistamab-cqyv)		
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Overview

This document addresses the use of Tecvayli (teclistamab-cqyv), a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager, for adults with relapsed or refractory multiple myeloma.

The FDA approved indication for Tecvayli is for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

Tecvayli has a black box warning for cytokine release syndrome (CRS), including life-threatening or fatal reactions. Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious and life-threatening reactions can also occur. Due to these black box warnings, Tecvayli is only available through a Risk Evaluation and Mitigation Strategy (REMS) program.

Tecvayli is a subcutaneous injection administered as step-up doses of 0.06 mg/kg and 0.3 mg/kg followed by 1.5 mg/kg once weekly until disease progression or unacceptable toxicity.

The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the following uses:

- Multiple Myeloma

Definitions and Measures

ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:

- 0 = Fully active, able to carry on all pre-disease performance without restriction
- 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
- 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5 = Dead

Multiple Myeloma: Is an infiltration of plasma cells into the bone or other organs 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.

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Tecvayli (teclistamab-cqyv)

Requests for Tecvayli (teclistamab-cqyv) may be approved if the following criteria are met:

I. Individual has a diagnosis of relapsed or refractory multiple myeloma (Label, NCCN 2A); **AND**
II. Individual has had at least four prior therapies, including an anti-CD38 monoclonal antibody (e.g. daratumumab), a proteasome inhibitor (e.g. bortezomib, ixazomib, or carfilzomib), and an immunomodulatory agent (e.g. lenalidomide or pomalidomide); **AND**
III. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-1; **AND**
IV. No prior treatment with any B cell maturation antigen (BCMA) targeted therapy.

Tecvayli (teclistamab-cqyv)) may not be approved for the following:

I. If the individual has plasma cell leukemia, Waldenström's macroglobulinemia, POEMS syndrome, or primary amyloid light-chain amyloidosis; **OR**
II. If the individual has any active central nervous system involvement or clinical signs of meningeal involvement of multiple myeloma; **OR**
III. When the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9380	Injection, teclistamab-cqyv, 0.5 mg TECVAYLI™

ICD-10 Diagnosis

C90.00-C90.02	Multiple myeloma

Document History

Reviewed: 12/11/2023
Document History:

- 12/11/2023 – Annual Review: No criteria updates. Added references for NCCN. Coding Reviewed: No changes.
- 11/18/2022 – Select Review: New clinical criteria document for Tecvayli (teclistamab-cqyv). Coding Reviewed: Added HCPCS J9999, J3490, J3590. Added ICD-10-CM C90.00, C90.02. Effective 4/1/2023 Added HCPCS C9148. Added ICD-10-CM C90.00-C90.02. Effective 7/1/2023 Added HCPCS J9380. Deleted HCPS J9999, J3490, J3590, C9148.

References

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.