Evolent Clinical Guideline 3243 for Tecvayli™ (teclistamab-cqyv)

Guideline Number:	Applicable Codes	
Evolent_CG_3243		
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STATEMENT

Purpose

To define and describe the accepted indications for Tecvayli (teclistamab-cqyv) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Multiple Myeloma

- Tecvayli (teclistamab-cqyv) may be used as monotherapy for adult members with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib), an immunomodulatory agent (e.g., lenalidomide, thalidomide, pomalidomide), and an anti-CD38 monoclonal antibody (e.g.,daratumumab, isatuximab-irfc).
- Tecvayli (teclistamab-cqyv) may be used in combination with Darzalex Faspro (subcutaneous daratumumab) in adult members for relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy.
    - Prior therapy must include a proteasome inhibitor (e.g., bortezomib) and Revlimid (lenalidomide).
    - Member is not refractory to an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab), and has not received prior bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engagers [e.g., Tecvayli (teclistamab-cqyv), Elrexfio (elranatamab-bcmm), Lynozyfic (linvoseltamab-gcpt)].

CONTRAINDICATIONS/WARNINGS

- US Boxed Warning
  - Cytokine release syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving teclistamab-cqyv. Initiate treatment with teclistamab-cqyv step-up dosing schedule to reduce risk of CRS. Withhold teclistamab-cqyv until CRS resolves or permanently discontinue based on severity.
  - Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS) and serious, life-threatening, or fatal reactions, can occur with teclistamab-cqyv. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withhold teclistamab-cqyv until neurologic toxicity resolves or permanently discontinue based on severity.
  - Because of the risk of CRS and neurologic toxicity, including ICANS, teclistamab-cqyv is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the TECVAYLI and TALVEY REMS.

EXCLUSION CRITERIA

- Disease progression while taking Tecvayli (teclistamab-cqyv).
- Dosing exceeds single dose limit of Tecvayli (teclistamab-cqyv) 1.5 mg/kg.
- Investigational use of Tecvayli (teclistamab-cqyv) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
  - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
  - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
  - Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
  - That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
  - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
  - That abstracts (including meeting abstracts) without the full article from the

approved peer- reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J9380 - Injection, teclistamab-cqyv, 0.5 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
March 2026	• Updated indication section • Updated exclusion criteria • Updated references
December 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1470 Tecvayli (teclistamab-cqyv) • Updated references
December 2024	• Added Evolent disclaimer language • Added Coding Information section with HCPCS code • Updated NCH verbiage to Evolent • Added continuation request verbiage

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

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