PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Tecvayli Prior Authorization Policy
- Tecvayli™ (teclistamab-cqyv subcutaneous injection – Janssen Biotech)

REVIEW DATE: 11/09/2022

OVERVIEW
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.[1]

Guidelines
The National Comprehensive Cancer Network (NCCN) multiple myeloma (version 3.2023 – October 31, 2022) clinical practice guidelines recommend Tecvayli for late relapse or progressive disease in patients who have received at least four previous therapies including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.[2,3]

Safety
Tecvayli was approved with a Risk Evaluation and Mitigation Strategy (REMS) program due to the risk of cytokine release syndrome and neurotoxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS).

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Tecvayli. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Tecvayli as well as the monitoring required for adverse events and long-term efficacy, approval requires Tecvayli to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Tecvayli is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Multiple Myeloma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tecvayli is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Tecvayli™ subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech.; October 2022.
2. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 1, 2022. Search term: teclistamab.
3. 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 November 1, 2022.