Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Talquetamab-tgvs (Talvey®)	MP-RX-FP-142-24	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of *Talquetamab-tgvs (Talvey®),* a bispecific GPRC5D-directed CD3 T-cell engager approved by the Food and Drug Administration (FDA) for the treatment of adult patients 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.

Background Information

Talquetamab-tgvs is a bispecific T-cell engaging antibody targeting CD3 on T-cells and GPRC5D on multiple myeloma cells, non-malignant plasma cells, and keratinized tissues. In vitro, it activates T-cells to release proinflammatory cytokines and lyse multiple myeloma cells. It also demonstrated anti-tumor activity in mouse models of multiple myeloma.

Talvey is a subcutaneous injection administer as step-up weight-based dosing.

Talvey has a black box warning for cytokine release syndrome (CRS) and neurologic toxicity. Due to these black box warnings, Tecvayli is only available through a Risk Evaluation and Mitigation Strategy (REMS) program.

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

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- 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.

Approved Indications

A. Treatment of patients 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.

   This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Other Uses

i. None.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J3055	Injection, talquetamab-tgvs, 0.25 mg [Talvey]

ICD-10	Description
C90.0 – C90.02	Multiple myeloma

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Medical Necessity Guidelines

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.

Talquetamab-tgvs (Talvey®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

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 Group (ECOG) performance status of 0-2;

OR

iv. Individual has a diagnosis of relapsed or refractory multiple myeloma (Label, NCCN 2A); **AND**
v. Individual has had at least THREE 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**
vi. Individual is using in combination with teclistamab-cqyv; **AND**
vii. Individual has a current Eastern Cooperative Group (ECOG) performance status of 0-2.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Talquetamab-tgvs (Talvey®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. The following information should be submitted for reauthorization:
    A. A current oncology note documenting the patient's response to treatment showing no progression of disease.
    B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

C. Authorization Duration

i. Initial Approval Duration: Up to 6 months
ii. Reauthorization Approval Duration: Up to 6 months

D. Conditions Not Covered

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Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Requests for Talquetamab-tgvs (Talvey®) may not be approved when the above criteria (Section A: Criteria for Initial Approval) are not met and for all other indications.

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Talvey (talquetamab-tgvs) injection: 3 mg/1.5 mL (2 mg/mL) SDV; 40 mg/mL SDV

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Talvey Weekly Dosing Schedule			
Dosing Schedule	**Day**	**Dose**	
Step-up dosing schedule	Day 1	Step-up dose 1	0.01 mg/kg
	Day 4[b]	Step-up dose 2	0.06 mg/kg
	Day 7[b]	First treatment dose	0.4 mg/kg
Weekly dosing schedule	One week after first treatment dose and weekly thereafter[c]	Subsequent treatment doses	0.4 mg/kg once weekly
Exceptions			
• Due to the risk of CRS and neurologic toxicity, including ICANS, patients should be hospitalized for 48 hours after administration of all doses within the TALVEY step-up dosing schedule.			

[a] Based on actual body weight.

[b] Dose may be administered between 2 to 4 days after the previous dose and may be given up to 7 days after the previous dose to allow for resolution of adverse reactions.

[c] Maintain a minimum of 6 days between weekly doses

Talvey Biweekly (Every 2 Weeks) Dosing Schedule			
Dosing Schedule	**Day**	**Dose**	
Step-up dosing schedule	Day 1	Step-up dose 1	0.01 mg/kg
	Day 4[b]	Step-up dose 2	0.06 mg/kg
	Day 7[b]	First treatment dose	0.4 mg/kg
	Day 10[d]	First treatment dose	0.8 mg/kg
Biweekly (every 2 weeks) dosing schedule	One week after first treatment dose and weekly thereafter[c]	Subsequent treatment doses	0.8 mg/kg every 2 weeks
Exceptions			
• Due to the risk of CRS and neurologic toxicity, including ICANS, patients should be hospitalized for 48 hours after administration of all doses within the TALVEY step-up dosing schedule.			

[a] Based on actual body weight.

[b] Dose may be administered between 2 to 4 days after the previous dose and may be given up to 7 days after the previous dose to allow for resolution of adverse reactions.

[c] Dose may be administered between 2 to 7 days after step-up dose 3.

[d] Maintain a minimum of 12 days between biweekly (every 2 weeks) doses.

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Reference Information

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: August 22, 2023
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on October 8, 2024. a. Multiple Myeloma. V1.2025. Revised September 17, 2024.

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.

Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review 11/24/2025	Update clinical criteria clarify use of at least three prior therapies when used in regimen with teclistamab-cqyv as stated in NCCN.	12/3/2025	12/11/2025
Annual Review 12/27/2024	Updted background section to add mechanism of action. Added dosage forms and strenghts to quantity limit table. Added references for label and NCCN. Minor formatting changes. Added HCPCS J3055 forn Talvey. Removed HCPCS J3490, J590, J9999, C9163. Merged ICD-10-CM C90.00-C90.02.	3/20/2025	4/2/2025
Policy Inception 01/30/2024	New Medical Policy creation	4/18/2024	6/28/2024