Talvey™ (talquetamab-tgvs)
(Subcutaneous)

Document Number: SHP-0722

Last Review Date: 09/05/2023
Date of Origin: 09/05/2023
Dates Reviewed: 09/2023

I. Length of Authorization

After the initial hospital administration of three step-up titration doses, coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Talvey 3 mg/1.5 mL solution for injection in a single-dose vial: 3 vials per week
- Talvey 40 mg/1 mL solution for injection in a single-dose vial: 3 vial per week

B. Max Units (per dose and over time) [HCPCS Unit]:

- Titration: 12 billable units (3 mg) on day one, 36 billable units (9 mg) on day four and 160 billable units (40 mg) on day seven
- Maintenance: 160 billable units (40 mg) weekly thereafter

III. Initial Approval Criteria [1]

Submission of medical records (chart notes) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e. genetic and mutational testing) supporting initiation when applicable. Medical records may be submitted via direct upload through the PA web portal or by fax.

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Prescribers are enrolled in the TECVAYLI-TALVEY REMS® program; **AND**
- Used as continuation therapy following inpatient administration of all the step-up doses; **AND**

- Patient had an absence of unacceptable toxicity while on inpatient administration of step-up titration doses; **AND**

Universal Criteria [1]

- Patient does not have an active infection, including clinically important localized infections; **AND**
- Prophylaxis for infection will be followed according to local guidelines; **AND**
- Patient does not have active 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**
- Patient weight and signs of oral and skin toxicity will be monitored at baseline and periodically during therapy; **AND**

Multiple Myeloma † ‡ Φ [1-5]

- Used as single-agent therapy; **AND**
- Patient has relapsed or refractory disease; **AND**
- Patient has received at least four (4) prior therapies, including a proteasome inhibitor (e.g., bortezomib, etc.), an immunomodulatory agent (e.g., lenalidomide, thalidomide, etc.) and an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab, etc.)

† FDA Approved Indication(s); ‡ Compendia Approved Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe oral toxicity and weight loss, serious life-threatening infections, severe cytopenias, severe dermatologic toxicity, hepatotoxicity, neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), cytokine release syndrome (CRS), etc.

V. Dosage/Administration [1]

Indication	Dose

<table>
<tr><td>Multiple Myeloma</td><td>The recommended dosage is administered subcutaneously by a healthcare provider, once or bi-weekly (every 2 weeks) until disease progression or unacceptable toxicity.
<table>
<tr><th>Dosing schedule</th><th>Day</th><th colspan="2">Dose</th></tr>
<tr><td rowspan="3">Step-up dosing schedule [a]</td><td>Day 1</td><td>Step-up dose 1</td><td>0.01 mg/kg</td></tr>
<tr><td>Day 4 [b]</td><td>Step-up dose 2</td><td>0.06 mg/kg</td></tr>
<tr><td>Day 7 [c]</td><td>First treatment dose</td><td>0.4 mg/kg</td></tr>
<tr><td>Weekly dosing schedule [a]</td><td>One week after first treatment dose and weekly thereafter</td><td>Subsequent treatment doses</td><td>0.4 mg/kg once weekly</td></tr>
<tr><td colspan="4">– 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.</td></tr>
</table>
<table>
<tr><th>Dosing schedule</th><th>Day</th><th colspan="2">Dose</th></tr>
<tr><td rowspan="4">Step-up dosing schedule [a]</td><td>Day 1</td><td>Step-up dose 1</td><td>0.01 mg/kg</td></tr>
<tr><td>Day 4 [b]</td><td>Step-up dose 2</td><td>0.06 mg/kg</td></tr>
<tr><td>Day 7 [b]</td><td>Step-up dose 3</td><td>0.4 mg/kg</td></tr>
<tr><td>Day 10 [c]</td><td>First treatment dose</td><td>0.8 mg/kg</td></tr>
<tr><td>Biweekly (every 2 weeks) dosing schedule [a]</td><td>Two weeks after first treatment dose and 2 weeks thereafter [d]</td><td>Subsequent treatment doses</td><td>0.8 mg/kg every 2 weeks</td></tr>
<tr><td colspan="4">– 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.</td></tr>
</table>
<tr><td colspan="2">Note: Administer Talvey subcutaneously according to the step-up dosing schedule noted above to reduce the incidence and severity of cytokine release syndrome (CRS). 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</td></tr>
</table>

VI. Billing Code/Availability Information

HCPCS Code:

- J3055 – Injection, talquetamab-tgvs, 0.25 mg; 1 billable unit = 0.25 mg *(Effective 04/01/2024)*
- J9999 – Not otherwise classified, antineoplastic drugs *(Discontinue use on 04/01/2024)*
- C9163 – Injection, talquetamab-tgvs, 0.25 mg; 1 billable unit = 0.25mg *(Discontinue use on 04/01/2024)*

NDC:

- Talvey 3 mg/1.5 mL solution for injection in a single-dose vial: 57894-0469-xx
- Talvey 40 mg/1 mL solution for injection in a single-dose vial: 57894-0470-xx

VII. References

1. Talvey [package insert]. Horsham, PA; Janssen Biotech, Inc.; August 2023. Accessed August 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for talquetamab. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2023.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma Version 3.2023. National Comprehensive Cancer Network, 2023. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed August 2023.
4. BGM Durie, J-L Harousseau, J S Miguel, et al on behalf of the International Myeloma Working Group. International uniform response criteria for multiple myeloma. Leukemia. Sep; 20(9):1467-73.
5. Schinke CD, Touzeau C, Minnema MC, et al. Pivotal phase 2 MonumenTAL-1 results of talquetamab (tal), a GPRC5DxCD3 bispecific antibody (BsAb), for relapsed/refractory multiple myeloma (RRMM). Journal of Clinical Oncology 2023 41:16_suppl, 8036-8036.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at:

https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC