Clinical Policy: Talquetamab-tgvs (Talvey)

Reference Number: LA.PHAR.649
Effective Date: 12.01.23
Last Review Date: 01.21.25~~07.24.24~~ Coding Implications
Line of Business: Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

Description
Talquetamab-tgvs (Talvey™) is bispecific GPRC5D-directed CD3 T-cell engager.

FDA Approved Indication(s)
Talvey is indicated 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.

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).

Policy/Criteria
It is the policy of Louisiana Healthcare Connections that Talvey is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Multiple Myeloma (must meet all)**:**

1. Diagnosis of MM;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Disease is relapsed or refractory;
5. One of the following (a or b):
   a. Member has measurable disease as evidenced by one of the following assessed within the last 30 days (i, ii, or iii):
      i. Serum M-protein ≥ 0.5 g/dL;
      ii. Urine M-protein ≥ 200 mg/24 h;
      iii. Serum free light chain (FLC) assay: involved FLC level ≥ 10 mg/dL (100 mg/L) provided serum FLC ratio is abnormal;
   b. Member has progressive disease, as defined by the IMWG response criteria (see *Appendix D*), assessed within 60 days following the last dose of the last anti-myeloma drug regimen received;

~~5.~~6. Member has received or has documented intolerance to ≥ 4 prior lines of therapies* (*see Appendix B*) that include all of the following (a, b, and c):

a. One proteasome ~~inhibitors~~inhibitor (e.g., bortezomib, Kyprolis®, Ninlaro®~~)~~®~~);~~
b. One immunomodulatory ~~drugs~~drug (e.g., Thalomid®, lenalidomide, pomalidomide~~)~~~~);~~
c. One anti-CD38 monoclonal antibodies (e.g., Darzalex®, Sarclisa®~~)~~®~~);~~

**Prior authorization may be required*

~~6.~~7. Request meets one of the following (a, b, or c):*
a. Dose does not exceed 0.4 mg/kg once weekly;
b. Dose does not exceed 0.8 mg/kg every 2 weeks;
c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2):
a. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255;
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to LA.PMN.53.

II. Continued Therapy

A. Multiple Myeloma (must meet all)**:**
1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Talvey for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b, or c):*
a. Dose does not exceed 0.4 mg/kg once weekly;
b. Dose does not exceed 0.8 mg/kg every 2 weeks;
c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:12 months

B. Other diagnoses/indications (must meet 1 or 2):
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255;
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to LA.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – LA.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
FLC: free light chain
IMWG: International Myeloma Working Group
MM: multiple myeloma
NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
MM: regimens containing proteasome inhibitors, immunomodulatory agents and/or anti-CD38 monoclonal antibodies (examples – NCCN)		
bortezomib / lenalidomide (Revlimid®) or pomalidomide or Thalomid® (thalidomide) / dexamethasone	Varies	Varies
Kyprolis® (carfilzomib – weekly or twice weekly) / dexamethasone	Varies	Varies
Kyprolis® (carfilzomib) / lenalidomide (Revlimid®) / dexamethasone	Varies	Varies
Ninlaro® (ixazomib) / lenalidomide (Revlimid®) / dexamethasone	Varies	Varies
Darzalex® (daratumumab) / bortezomib / dexamethasone ± Thalomid® (thalidomide)	Varies	Varies
Darzalex® (daratumumab) / lenalidomide (Revlimid®) / dexamethasone	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): None
- Boxed warning(s): cytokine release syndrome, neurologic toxicity

Appendix D: General Information

- The IMWG response criteria for multiple myeloma definition of progressive disease requires only one of the following:
  - Increase of 25% from lowest response value in any of the following:
    - Serum M-component (absolute increase must be ≥ 0.5 g/dL), and/or
    - Urine M-component (absolute increase must be ≥ 200 mg/24 h), and/or
  - Only in patients without measurable serum and urine M-protein levels: the difference between involved and uninvolved FLC levels (absolute increase must be > 10 mg/dL)

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- Only in patients without measurable serum and urine M protein levels and without measurable disease by FLC levels, bone marrow plasma cell percentage irrespective of baseline status (absolute increase must be ≥ 10%)
- Appearance of a new lesion(s), ≥ 50% increase from nadir in SPD (sum of the products of the maximal perpendicular diameters of measured lesions) of > 1 lesion, or ≥ 50% increase in the longest diameter of a previous lesion >1 cm in short axis
- ≥ 50% increase in circulating plasma cells (minimum of 200 cells per µL) if this is the only measure of disease

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Relapsed or refractory MM	Weekly dosing schedule: • Day 1: 0.01 mg/kg • Day 4: 0.06 mg/kg • Day 7 (first treatment dose): 0.4 mg/kg • One week after first treatment dose (subsequent treatment doses): 0.4 mg/kg weekly Biweekly (every 2 weeks) dosing schedule: • Day 1: 0.01 mg/kg • Day 4: 0.06 mg/kg • Day 7: 0.4 mg/kg • Day 10 (first treatment dose): 0.8 mg/kg • Two ~~week~~weeks after first treatment dose (subsequent treatment doses): 0.8 mg/kg every 2 weeks Dose calculation is based on actual body weight.	0.4 mg/kg once weekly or 0.8 mg/kg every 2 weeks

VI. Product Availability

Single-dose vials for injection: 3 mg/1.5 mL (2 mg/mL); 40 mg/mL

VII. References

1. Talvey Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; Aug 2023. Available at: www.talvey.com. Accessed ~~August 23, 2023~~July 15, 2024.
2. National Comprehensive Cancer Network~~.~~ Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 1, 2024.
~~2.~~3. National Comprehensive Cancer Network. Multiple Myeloma Version ~~3.2023~~4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed August ~~23, 2023~~1, 2024.
~~3.~~4. Chari A, Minnema MC, Berdeja JG, et al. Talquetamab, a t-cell–redirecting gprc5d bispecific antibody for multiple myeloma. New England Journal of Medicine. 2022;387(24):2232-2244.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3055	Injection, talquetamab-tgvs, 0.25 mg

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy	01.04.24	05.06.24
Removed HCPCS codes [C9399, J3590] and added HCPCS code [J3055]	07.24.24	09.26.24
Annual review: added IMWG criterion defining progressive MM disease as MM class alignment; references reviewed and updated	01.21.25	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise

professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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