

Talvey (talquetamab-tgvs) Effective 05/06/2024 Plan ☑ Prior Authorization ☐ Commercial/Exchange **Program Type** ☐ Quantity Limit ☐ Pharmacy Benefit **Benefit** ☐ Step Therapy **Specialty** N/A Limitations **Medical and Specialty Medications All Plans** Phone: 877-519-1908 Fax: 855-540-3693 Contact Information **Non-Specialty Medications All Plans** Phone: 800-711-4555 Fax: 844-403-1029

Overview

Talvey (talquetamab-tgvs) 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.

Coverage Guidelines

Exceptions

Authorization may be granted for members when all the following criteria are met:

- 1. Diagnosis of relapsed/refractory multiple myeloma
- 2. Prescriber is a hematologist or oncologist
- 3. Appropriate dosing (weight is required)

N/A

- 4. Member is ≥ 18 years of age on treatment date (at time of initial administration) †
- 5. Inadequate response or adverse reaction to **FOUR** lines of systemic therapies or contraindication to **ALL** other lines of systemic therapies
- 6. Member's disease is refractory to at least **ONE** proteasome inhibitor or the member has a contraindication to **ALL** proteasome inhibitors §
- 7. Member's disease is refractory to at least **ONE** immunomodulatory agent or the member has a contraindication to **ALL** immunomodulatory agents §
- 8. Member's disease is refractory to at least **ONE** anti-CD38 monoclonal antibody or the member has a contraindication to **ALL** anti-CD38 monoclonal antibodies §
- 9. Administration will take place in a healthcare facility that has been certified pursuant to the REMS program specific to the treatment being provided ‡
- †Anticipated admission and discharge dates (as applicable to inpatient administration) should be noted.
- ‡ Please see Appendix A for a list of healthcare facilities that are certified to administer this drug. Please check manufacturer website for the most updated information.

§Please refer to the Appendix B for additional information on treatments for multiple myeloma.

Continuation of Therapy

Reauthorization by prescriber will infer a positive response to therapy.

Limitations

1. Initial and reauthorization approvals will be granted for 6 months.

Appendix

A. Healthcare Facilities Certified through Risk Evaluation and Mitigation Strategy (REMS) program

Per manufacturer websites, the following healthcare facilities have been certified pursuant to the REMS program to administer the specific treatments defined in the table below. Please check manufacturer websites for the most updated information.

Treatment	Healthcare Facilities
Talvey (talquetamab-tgvs)	Attestation on PA form that prescriber/treatment
	site is REMS certified is sufficient.

B. Treatments for Multiple Myeloma

According to the NCCN guidelines, the following drugs are part of treatment regimens that may be used for the treatment of multiple myeloma:

- Proteasome inhibitor: bortezomib, Velcade® (bortezomib), Kyprolis® (carfilzomib), and Ninlaro® (ixazomib)
- Immunomodulatory agent: Pomalyst® (pomalidomide), Revlimid® (lenalidomide) and Thalomid® (thalidomide)
- Anti-CD38 monoclonal antibody: Darzalex® (daratumumab), Darzalex Faspro® (daratumumabhyaluronidase-fihj), and Sarclisa® (isatuximab-irfc)

References

1. Talvey® [package insert]. Horsham (PA): Janssen Biotech, Inc.; 2023 Aug.

Review History

04/10/24 - Created for P&T. Adopted MH criteria for Talvey to require PA under MB. Effective 5/6/24.

