

Medical Drug Clinical Criteria

Subject: Talvey (talquetamab-tgvs)

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Overview

This document addresses the use of Talvey (talquetamab-tgvs) injection for subcutaneous use. Talvey is a bispecific GPRC5D-directed CD3 T-cell engager indicated for the treatment of those 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. Talvey has a black box warning for cytokine release syndrome (CRS) and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome (ICANS). Talvey is only available through a restricted program under a REMS because of the risks of CRS and neurologic toxicity, including ICANS.

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

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

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.

Clinical Criteria

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.

Talvey (talquetamab-tqvs)

Requests for Talvey (talquetamab-tqvs) may be approved if the following criteria are met:

- I. Individual has a diagnosis of relapsed or refractory multiple myeloma; 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;

Talvey (talquetamab-tqvs) may not be approved for the following when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

<u>J3490</u>	<u>Unclassified drugs (when specified as [Talvey] (talquetamab-tqvs))</u>
<u>J3590</u>	<u>Unclassified biologicals (when specified as [Talvey] (talquetamab-tqvs))</u>
<u>J9999</u>	<u>Not otherwise classified, antineoplastic drugs (when specified as [Talvey] (talquetamab-tqvs))</u>
<u>C9399</u>	<u>Unclassified drugs or biologicals (when specified as [Talvey] (talquetamab-tqvs))</u>

ICD-10 Diagnosis

All diagnoses pend

Document History

New: 09/11/2023

Document History:

- 09/11/2023 – Select Review: New clinical criteria document for Talvey. Coding Reviewed: Added HCPCS J3490, J3590, J9999, C9399. All diagnoses pend.

References

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.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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