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Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Antineoplastic Agents	**Original Policy Date:**	September 1, 2023
Subject:	Talvey	**Page:**	1 of 5

Last Review Date: March 6, 2026

Talvey

Description

Talvey (talquetamab-tgvs)

Background
Talvey (talquetamab-tgvs) is a bispecific T-cell engaging antibody that binds to the CD3 receptor expressed on the surface of T-cells and and G protein-coupled receptor class C group 5 member D (GPRC5D) expressed on the surface of multiple myeloma cells and non-malignant plasma cells, as well as healthy tissues such as epithelial cells in keratinized tissues of the skin and tongue. In vitro, Talvey activated T-cells caused the release of proinflammatory cytokines and resulted in the lysis of multiple myeloma cells (1).

Regulatory Status
FDA-approved indication: Talvey is a bispecific GPRC5D-directed CD3 T-cell engager 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 (1).

Talvey has a boxed warning regarding cytokine release syndrome (CRS) and neurotoxicity. Initiate treatment with Talvey step-up dosing schedule to reduce risk of CRS. Withold dose until CRS resolves or permanently discontinue based on severity. Neurotoxicity, including immune effector cell-associated neurotoxcitiy syndrome (ICANS), and serious and life-threatening reactions, can occur. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withold dose until neurologic toxicity resolves or permanently discontinue based on severity. Talvey is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), called the Talvey REMS (1).

Talvey may cause hepatotoxicity, cytopenias, oral toxicity and weight loss, skin toxicity, and infections. Monitor liver enzymes, bilirubin and complete blood count (CBC) at baseline and during treatment as clinically indicated. Oral toxicity, weight loss, and skin toxicity should be monitored and Talvey withheld based on severity. Signs and symptoms of infection should be monitored and treated appropriately. Withold or permanently discontinue Talvey in patients with infection based upon severity (1).

Talvey can cause fetal harm when administered to a pregnant woman. Pregnant women should be advised of the potential risk to a fetus. Females of reproductive potential should be advised to use effective contraception during treatment with Talvey and for 3 months after the last dose (1).

The safety and effectiveness of Talvey in pediatric patients have not been established (1).

Related Policies
Blenrep, Elrexfio, Tecvayli

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Talvey may be considered **medically necessary** if the conditions indicated below are met.

Talvey may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsed or refractory multiple myeloma (MM)

AND ALL of the following:

a. Patient has received at least 4 prior therapies, including **ALL** of the following:
   i. Anti-CD38 monoclonal antibody
   ii. Proteasome inhibitor
   iii. Immunomodulatory agent
b. Prescriber is certified with the Talvey REMS program
c. Prescriber agrees to monitor for signs and symptoms of cytokine release syndrome (CRS) and neurologic toxicity
d. Prescriber agrees to monitor liver enzymes, bilirubin, and complete blood cell counts (CBC) at baseline and during treatment as clinically indicated
e. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Talvey and for 3 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsed or refractory multiple myeloma (MM)

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber is certified with the Talvey REMS program
c. Prescriber agrees to monitor for signs and symptoms of cytokine release syndrome (CRS) and neurologic toxicity
d. Prescriber agrees to monitor liver enzymes, bilirubin, and complete blood cell counts (CBC) during treatment as clinically indicated
e. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Talvey and for 3 months after the last dose

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits
Same as above

Rationale

Summary
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. Talvey has a boxed warning for cytokine release syndrome and neurologic toxicity. Hepatotoxicity, cytopenias, oral toxicity and weight loss, skin toxicity, and infections can occur in patients treated with Talvey; therefore liver enzymes, bilirubin, complete blood cell counts, oral toxicity, weight loss, skin toxicity, and signs and symptoms of infections must be monitored. The safety and effectiveness of Talvey in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Talvey while maintaining optimal therapeutic outcomes.

References
1. Talvey [package insert]. Horsham, PA: Janssen Biotech, Inc; October 2025.
2. NCCN Drugs & Biologics Compendium® Talquetamab-tgvs 2026. National Comprehensive Cancer Network, Inc. Accessed on January 15, 2026.

Policy History

Date	Action
September 2023	Addition to PA
December 2023	Annual review and reference update
June 2024	Annual review and reference update
June 2025	Annual review and reference update
March 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.