Medical Policy:

Talvey (talquetamab-tgvs) subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.395	February 12, 2025	October 3, 2023

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

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. Talquetamab-tgvs is a bispecific T-cell engaging antibody that binds to the CD3 receptor expressed on the surface of T-cells 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, talquetamab-tgvs activated T-cells caused the release of proinflammatory cytokines and resulted in the lysis of multiple myeloma cells.

Length of Authorization

Coverage will be provided for 12 months and may be renewed.

Dosing Limits [Medical Benefit]

Table 1: TALVEY Weekly Dosing Schedule

Dosing schedule	Day	Dose *	
Step-up dosing schedule	Day 1	Step-up dose 1	0.01 mg/kg
	Day 4 †	Step-up dose 2	0.06 mg/kg
	Day 7 †	First treatment dose	0.4 mg/kg
Weekly dosing schedule	One week after first treatment dose and weekly thereafter ‡	Subsequent treatment doses	0.4 mg/kg once weekly

* Based on actual body weight.

† 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.

‡ Maintain a minimum of 6 days between weekly doses.

Guideline

I. INITIAL CRITERIA

1. **Multiple Myeloma**
   A. Patient is 18 years of age or older; **AND**
   B. Patient has tried and failed at least four prior therapies including a proteasome inhibitor, an immunomodulatory drug, and an anti-CD38 Antibody

II. RENEWAL CRITERIA

1. Member has responded positively to the treatment as determined by the prescribing physician; **AND**
2. Member has not experienced unacceptable toxicity from the drug.

Applicable Procedure Codes

Code	Description
J3055	Injection, talquetamab-tgvs, 0.25 mg

Applicable NDCs

Code	Description
57894-0470-01	Talvey 40mg/mL Solution
57894-0469-01	Talvey 3mg/1.5mL Solution

ICD-10 Diagnoses

Code	Description
C90.00	Multiple myeloma not having achieved remission

C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.11	Plasma cell leukemia in remission
C90.12	Plasma cell leukemia in relapse

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/12/2025	Annual Review: Length of Authorization: removed: "Initial Approval: 21 days Continuation: 12 months" and replaced with: "Coverage will be provided for 12 months and may be renewed." Updated ICD-10 Codes
EmblemHealth & ConnectiCare	5/2/2024	Annual Review: Removed J9999 and C9399; add J3055, no criteria changes
EmblemHealth & ConnectiCare	10/3/2023	New Policy

References

1. Product Information: TALVEY™ subcutaneous injection, talquetamab-tgvs subcutaneous injection. Janssen Biotech, Inc (per FDA), Horsham, PA, 2023.