# Medical Policy:
## Talvey (talquetamab-tgvs) subcutaneous injection

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---|---|---|
| MG.MM.PH.395 | October 3, 2023 | October 3, 2023 |



## 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

Initial Approval: 21 days
Continuation: 12 months

## 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

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

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 |
|---|---|
| J9999 | Not otherwise classified, antineoplastic drugs |
| C9399 | Unclassified drugs or biologicals |

## 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 |

## Revision History

| Company(ies) | DATE | REVISION |
|---|---|---|
| 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.