

STANDARD MEDICARE PART B MANAGEMENT

TALVEY (talquetamab-tgvs)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

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

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Multiple Myeloma

Authorization of 12 months may be granted for treatment of relapsed or refractory multiple myeloma in members who have received at least 4 prior therapies, including at least one drug from each of the following categories:

- A. Proteasome inhibitor (e.g., bortezomib, ixazomib, carfilzomib)
- B. Immunomodulatory agent (e.g., lenalidomide, pomalidomide)
- C. Anti-CD38 monoclonal antibody (e.g., daratumumab)

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with the requested medication
- B. The requested medication is being used to treat an indication enumerated in Section II
- C. The member is receiving benefit from therapy. Benefit is defined as:
 - 1. No evidence of unacceptable toxicity while on the current regimen, and
 - 2. No evidence of disease progression while on the current regimen

Reference number(s)
6123-A

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Talvey.
2. The available compendium
 - a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
 - b. Micromedex DrugDex
 - c. American Hospital Formulary Service- Drug Information (AHFS-DI)
 - d. Lexi-Drugs
 - e. Clinical Pharmacology

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VI. REFERENCES

1. Talvey [package insert]. Horsham, PA: Janssen Biotech, Inc.; August 2023.