

STANDARD MEDICARE PART B MANAGEMENT

TIVDAK (tisotumab vedotin-tftv)

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 Indications

Tivdak is indicated for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

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

Cervical Cancer

Authorization of 12 months may be granted for treatment of recurrent or metastatic cervical cancer with disease progression on or after chemotherapy, as a single agent.

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

IV. SUMMARY OF EVIDENCE

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

- 1. The prescribing information for Tivdak.
- 2. The available compendium
 - a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Reference number(s)
4991-A

- b. Micromedex DrugDex
 - c. American Hospital Formulary Service- Drug Information (AHFS-DI)
 - d. Lexi-Drugs
 - e. Clinical Pharmacology
3. NCCN Guideline: Cervical cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Tivdak are covered.

V. EXPLANATION OF RATIONALE

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

VI. REFERENCES

1. Tivdak [package insert]. Bothell, WA: Seagen Inc.; January 2022.