Reference number(s)
4991-A

Standard Medicare Part B Management Tivdak

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tivdak	tisotumab vedotin-tftv

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[1]

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 listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Compendial Uses[2]

- Cervical Cancer
- Vaginal Cancer

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Documentation

The following documentation must be available, upon request, for all submissions:

- Documentation of programmed death ligand 1 (PD-L1) tumor expression, where applicable.

Coverage Criteria

Cervical Cancer[1,2]

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 or in combination with pembrolizumab if no prior immune-oncology therapy received and tumor is PD-L1 positive.

Vaginal Cancer[2]

Authorization of 12 months may be granted as a single agent for subsequent treatment of recurrent or metastatic vaginal cancer.

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:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen, and
    - No evidence of disease progression while on the current regimen

Summary of Evidence

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

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

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    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Cervical cancer
- NCCN Guideline: Vaginal cancer

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

Explanation of Rationale

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

Support for using Tivdak for cervical cancer and vaginal cancer can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Tivdak [package insert]. Bothell, WA: Seagen Inc.; April 2024.
2. The NCCN Drugs & Biologics Compendium 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed July 24, 2025.

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