Utilization Review Policy 273

POLICY: Oncology (Injectable) – Tivdak Utilization Management Medical Policy

- Tivdak™ (tisotumab vedotin-tftv intravenous infusion – Seagen and Genmab)

EFFECTIVE DATE: 02/01/2022
REVIEW DATE: 11/19/2025

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Tivdak, a tissue factor-directed antibody and microtubule inhibitor conjugate, is indicated for the treatment of recurrent or metastatic cervical cancer in adults with disease progression on or after chemotherapy.[1]

Dosing Information

The recommended dose of Tivdak is 2 mg/kg (to a maximum of 200 mg for patients weighing ≥ 100 kg) administered by intravenous infusion over 30 minutes once every 3 weeks until disease progression or unacceptable adverse events.[1] Ophthalmic exams, including visual acuity and slit lamp exam, should be conducted at baseline, prior to each dose, and as needed. Patients should receive topical corticosteroid eye drops prior to and for 72 hours following each dose. Patients should also receive ocular vasoconstrictor drops prior to each infusion and cooling eye packs should be used during the infusion. Finally, lubricating eye drops should be used daily and for 30 days after the last dose of Tivdak.

Guidelines

The National Comprehensive Cancer Network (NCCN) has addressed Tivdak.

- **Cervical cancer** (version 2.2026 – November 10, 2025) clinical practice guidelines recommend Tivdak for the second-line or subsequent therapy as a single agent for local/regional recurrence, stage IVB, or distant metastatic disease.[2,3]
- **Vaginal cancer** (version 1.2026 – November 7, 2025) clinical practice guidelines recommend Tivdak for the second-line and subsequent treatment of local/regional recurrence, stage IVB, or distant metastatic disease.[2,4]

Safety

Tivdak has a Boxed Warning for ocular toxicity.[1] Tivdak can cause changes in corneal epithelium and conjunctiva resulting in changes in vision, including severe vision loss, and corneal ulceration. Withhold, reduce the dose, or permanently discontinue Tivdak depending on the severity of ocular toxicity.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Tivdak. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Tivdak as well as the monitoring required for adverse events and long-term efficacy, approval requires Tivdak to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tivdak is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Cervical Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent or metastatic disease; AND
   - **C)** Patient has tried at least one chemotherapy agent; AND
     Note: Examples of chemotherapy agents include cisplatin, carboplatin, paclitaxel, topotecan.
   - **D)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 200 mg administered by intravenous infusion no more frequently than once every 3 weeks.

Other Uses with Supportive Evidence

2. **Vaginal Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent or metastatic disease; AND
   - **C)** Patient has tried at least one chemotherapy agent; AND
     Note: Examples of chemotherapy agents include cisplatin, carboplatin, paclitaxel, topotecan.
   - **D)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 200 mg administered by intravenous infusion no more frequently than once every 3 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tivdak is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Tivdak® intravenous infusion [prescribing information]. Bothell, WA: Seagen, and Plainsboro, NJ: Genmab; April 2024.
2. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 17, 2025. Search term: tisotumab.
3. The NCCN Cervical Cancer Clinical Practice Guidelines in Oncology (version 2.2026 – November 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 17, 2025.
4. The NCCN Vaginal Cancer Clinical Practice Guidelines in Oncology (version 1.2026 – November 7, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 17, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/09/2022
Annual Revision	No criteria changes.	11/08/2023

UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024
Annual Revision	**Vaginal Cancer:** Added new condition of approval.	11/13/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/15/2025
Annual Revision	**Cervical Cancer:** The requirement that the patient has recurrent or metastatic disease was added. **Vaginal Cancer:** The requirement that the patient has recurrent or metastatic disease was added.	11/19/2025