PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Tivdak Prior Authorization Policy
- Tivdak® (tisotumab vedotin-tftv intravenous infusion – Seagen and Genmab)

REVIEW DATE: 11/13/2024

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]

Guidelines
The National Comprehensive Cancer Network (NCCN) has addressed Tivdak.
- **Cervical cancer** (version 4.2024 – September 24, 2024) 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 2.2025 – August 8, 2024) 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 prescription benefit coverage of Tivdak. 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, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has tried at least one chemotherapy agent; AND
     Note: Examples of chemotherapy agents include cisplatin, carboplatin, paclitaxel, topotecan.
   - **C)** Medication is prescribed by or in consultation with an oncologist.

Other Uses with Supportive Evidence

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

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. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 7, 2024. Search term: tisotumab.
3. The NCCN Cervical Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – September 24, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 7, 2024.
4. The NCCN Vaginal Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – August 8, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 7, 2024.

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