

**TIVDAK  
(tisotumab vedotin-tftv)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Tivdak (tisotumab vedotin-tftv) is a tissue factor (TF)-directed antibody drug conjugate (ADC). The antibody is a human IgG1 directed against cell surface TF, which is the primary initiator of the extrinsic blood coagulation cascade. The anticancer activity of Tivdak is due to the binding of the ADC to TF expressing cancer cells and ultimate release of MMAE via proteolytic cleavage. MMAE disrupts the microtubule network of actively dividing cells, leading to cell cycle arrest and apoptotic cell death (1).

**Regulatory Status**

FDA-approved indication: Tivdak is a tissue factor-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy (1).

Tivdak contains a boxed warning regarding ocular toxicity. Tivdak caused changes in the corneal epithelium and conjunctiva resulting in changes in vision, including severe vision loss, and corneal ulceration. An ophthalmic exam including visual acuity and slit lamp exam should be conducted at baseline, prior to each dose, and as clinically indicated. Patients should adhere to premedication and required eye care before, during, and after infusion (1).

Tivdak also contains warnings regarding the following: peripheral neuropathy, hemorrhage, pneumonitis, , severe cutaneous adverse reactions, and embryo-fetal toxicity (1).

Tivdak can cause fetal harm when administered to a pregnant woman. Female patients of reproductive potential should be advised to use effective contraception during treatment with Tivdak and for 2 months after the last dose (1).

The safety and effectiveness of Tivdak in pediatric patients less than 18 years of age have not been established (1).

**Summary**

Tivdak (tisotumab vedotin-tftv) is a tissue factor-directed and microtubule inhibitor conjugate used



**BlueCross  
BlueShield**

Federal Employee Program.

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to treat recurrent or metastatic cervical cancer. Tivdak has a boxed warning regarding ocular toxicity and patients must have ophthalmic exams done at baseline, prior to each dose, and as clinically indicated. The safety and effectiveness of Tivdak in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Tivdak while maintaining optimal therapeutic outcomes.

### **References**

1. Tivdak [package insert]. Bothell, WA: Seagen Inc.; April 2024.
2. NCCN Drugs & Biologics Compendium® Tisotumab vedotin-tftv 2023. National Comprehensive Cancer Network, Inc. Accessed on October 3, 2024.