BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.21.183

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	October 8, 2021
Subject:	Tivdak	**Page:**	1 of 4

Last Review Date: December 13, 2024

Tivdak

Description

Tivdak (tisotumab vedotin-tftv)

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).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tivdak may be considered **medically necessary** if the conditions indicated below are met.

Tivdak may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Recurrent or metastatic cervical cancer
    a. Patient has had disease progression on or after chemotherapy

AND ALL of the following:

1. Prescriber agrees that an ophthalmic exam including visual acuity and slit lamp exam will be done at baseline, prior to each dose, and as clinically indicated
2. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Tivdak and for 2 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Recurrent or metastatic cervical cancer
    a. **NO** disease progression or unacceptable toxicity

AND ALL of the following:

1. Prescriber agrees that an ophthalmic exam including visual acuity and slit lamp exam will be done prior to each dose and as clinically indicated
2. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Tivdak and for 2 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 20 vials per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

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

Policy History

Date	Action
October 2021	Addition to PA
December 2021	Annual review and reference update
March 2022	Annual review and reference update
December 2023	Annual review and reference update
December 2024	Annual editorial review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.