Seagen Secure®
Patient Assistance Program

855-4SECURE (855-473-2873)
Monday-Friday, 8 AM-8 PM ET

Tivdak® (tisotumab vedotin-tftv) for Injection 40 mg
Prior Authorization Request Guide

Drafting a Prior Authorization Request Letter

The following information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Providers are encouraged to contact third-party payers for specific information on their prior authorization policies. For more information, call Seagen Secure at 855-4-SECURE (855-473-2873).

Most health plans require a prior authorization request and supporting documentation to process and cover a claim for biologic treatments. A request allows the payer to review the reason for the requested treatment and determine its medical appropriateness.

Plans often have specific Prior Authorization Request Forms that must be used for requests. These forms may be downloaded from each plan's website. Follow the plan's requirements when requesting Tivdak® (tisotumab vedotin-tftv) for injection; otherwise, treatment may be delayed.

Prior Authorization Requests: Guidance and Recommendations

1. Your Seagen Secure Oncology Access Advocate may be able to provide you with prior authorization requirements for specific plans and pharmacy benefit managers. Benefit verifications performed by the Seagen Secure and/or specialty pharmacies can assist with identifying prior authorization criteria, including any previous therapies and other plan-specific requirements
2. All Prior Authorization Request Forms should be completed and submitted to the plan by the office of the healthcare provider (HCP)
3. Fax the completed Prior Authorization Request Form to the health plan
4. Fax the Seagen Secure Enrollment Form to Seagen Secure at 855-557-2480
5. If a prior authorization is denied and the HCP wishes to submit an appeal, the Seagen Secure Oncology Access Advocate can identify which payer appeal form may be required. Seagen Secure can track appeals with a payer once submitted
6. Plans will usually allow up to 3 levels of appeal for prior authorization denials. The third appeal may include a review by an external review board or hearing. Refer to the Seagen Secure Preparing a Prior Authorization Appeals Letter document

Prior Authorization Considerations

- ✔ Verify and record that all of the prior authorization requirements for the plan have been met
- ✔ If applicable, provide evidence that all plan-specified prerequisites have been met. For exception requests, when medically appropriate, explain why a particular requirement is not medically appropriate for the patient
- ✔ Review the attached sample letter as an example
- ✔ If required, use the health plan's Prior Authorization Request Form that can be found on the plan's website. Your Seagen Secure Oncology Access Advocate may also be able to assist you in locating the plan-specific form

Please see Indication and Important Safety Information on pages 3 and 4.
Please see full Prescribing Information, including BOXED WARNING for TIVDAK.

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Sample Prior Authorization Request Letter

Most health plans require a prior authorization request and supporting documentation to cover a claim for Tivdak® (tisotumab vedotin-tftv) for injection. This resource, Drafting a Prior Authorization Request Letter, provides general information to HCPs when drafting the necessary letter.

[Date]
[Prior authorization department]
[Name of health plan]
[Mailing address]

Re: [Patient's name]
[Plan identification number]
[Date of birth]

To whom it may concern:

This letter serves as a prior authorization request for Tivdak® (tisotumab vedotin-tftv) for [patient's name, plan identification number, and group number] for the treatment of [diagnosis and ICD code].

Indicate the patient's diagnosis and affirm conditions for use:
Tivdak is indicated for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

If this is a prior authorization renewal for continuation of therapy, please indicate if the patient has experienced disease progression or unacceptable toxic effects:
[Insert rationale for prescribing Tivdak here, including your professional opinion of the patient's likely prognosis without Tivdak treatment.]

Provide supporting references for your recommendation:
[Provide clinical rationale for treatment; this information may be found in the Tivdak Prescribing Information and/or clinical peer-reviewed literature.]

Physician contact information:
The ordering physician is [physician name, NPI #]. The prior authorization decision may be faxed to [fax #] or mailed to [physician office mailing address]. Please send a copy of the prior authorization determination decision to [patient's name, street address, state, ZIP].

Sincerely,

_____

[Physician's name and signature]
[Physician's medical specialty]
[Physician's NPI]
[Physician's practice name]
[Phone #]
[Fax #]

Encl: Medical records, supporting documentation, photo(s), clinical references.

Reauthorization of Tivdak
If the prior authorization request is for a patient who is currently taking Tivdak, which may be due to a change in payer coverage, sample copy may include the following: [Describe the diagnosis and symptoms of patient diagnosis disease at the time when the patient was first prescribed Tivdak. In addition, include a summary of the patient's clinical response to Tivdak. It may be necessary to review past medical records to gather this information.]

Indication

TIVDAK is indicated for the treatment of adult patients with recurrent or metastatic cervical cancer (r/mCC) with disease progression on or after chemotherapy.

Important Safety Information

BOXED WARNING: OCULAR TOXICITY

TIVDAK can cause severe ocular toxicities resulting in changes in vision, including severe vision loss, and corneal ulceration. Conduct an ophthalmic exam, including an assessment of ocular symptoms, visual acuity, and slit lamp exam of the anterior segment of the eye prior to initiation of TIVDAK, prior to every cycle for the first nine cycles, and as clinically indicated. Adhere to the required premedication and eye care before, during, and after infusion. Withhold TIVDAK until improvement and resume, reduce the dose, or permanently discontinue, based on severity.

Warnings and Precautions

Ocular adverse reactions: TIVDAK can cause severe ocular adverse reactions, including conjunctivitis, keratopathy (keratitis, punctate keratitis, and ulcerative keratitis), and dry eye (increased lacrimation, eye pain, eye discharge, pruritus, irritation, and foreign body sensation), that may lead to changes in vision and/or corneal ulceration.

Ocular adverse reactions occurred in 55% of patients with cervical cancer treated with TIVDAK across clinical trials. The most common were conjunctivitis (32%), dry eye (24%), keratopathy (17%), and blepharitis (5%). Grade 3 ocular adverse reactions occurred in 3.3% of patients, including severe ulcerative keratitis in 1.2% of patients. Nine patients (2.1%) experienced ulcerative keratitis (including one with perforation requiring corneal transplantation), six (1.4%) conjunctival ulcer, four (0.9%) corneal erosion, two (0.5%) conjunctival erosion, and two (0.5%) symblepharon.

In innovaTV 301, 8 patients (3.2%) experienced delayed ocular adverse reactions occurring more than 30 days after discontinuation of TIVDAK. These adverse reactions included 3 patients with ulcerative keratitis, and one patient (each) with keratitis, punctate keratitis and corneal erosion, blepharitis and conjunctival hyperemia, conjunctival scar, and conjunctivitis and xerophthalmia.

Refer patients to an eye care provider to conduct an ophthalmic exam prior to initiation of TIVDAK, prior to every cycle for the first nine cycles, and as clinically indicated. The exam should include visual acuity, slit lamp exam of the anterior segment of the eye, and an assessment of normal eye movement and ocular signs or symptoms which include dry or irritated eyes, eye secretions, or blurry vision.

Adhere to the required premedication and eye care before, during, and after infusion to reduce the risk of ocular adverse reactions. Monitor for ocular toxicity and promptly refer patients to an eye care provider for any new or worsening ocular signs and symptoms. Withhold, reduce, or permanently discontinue TIVDAK based on the severity or persistence of the ocular adverse reaction.

Peripheral neuropathy (PN) occurred in 39% of cervical cancer patients treated with TIVDAK across clinical trials; 6% of patients experienced Grade 3 PN. PN adverse reactions included peripheral sensory neuropathy (23%), PN (5%), paresthesia (3.8%), peripheral sensorimotor neuropathy (3.3%), muscular weakness (2.8%), and peripheral motor neuropathy (2.4%). One patient with another tumor type treated with TIVDAK at the recommended dose developed Guillain-Barre syndrome.

Monitor patients for signs and symptoms of neuropathy such as paresthesia, tingling or a burning sensation, neuropathic pain, muscle weakness, or dysesthesia. For new or worsening PN, withhold, then dose reduce, or permanently discontinue TIVDAK based on the severity of PN.

Hemorrhage occurred in 51% of cervical cancer patients treated with TIVDAK across clinical trials. The most common all grade hemorrhage adverse reaction was epistaxis (33%). Grade 3 hemorrhage occurred in 4% of patients.

Monitor patients for signs and symptoms of hemorrhage. For patients experiencing pulmonary or central nervous system hemorrhage, permanently discontinue TIVDAK. For Grade ≥2 hemorrhage in any other location, withhold until bleeding has resolved, blood hemoglobin is stable, there is no bleeding diathesis that could increase the risk of continuing therapy, and there is no anatomical or pathologic condition that can increase the risk of hemorrhage recurrence. After resolution, either resume treatment or permanently discontinue TIVDAK.

Pneumonitis that is severe, life-threatening, or fatal can occur in patients treated with antibody-drug conjugates containing vedotin, including TIVDAK. Among cervical cancer patients treated with TIVDAK across clinical trials, 4 patients (0.9%) experienced pneumonitis, including 1 patient who had a fatal outcome.

Monitor patients for pulmonary symptoms of pneumonitis. Symptoms may include hypoxia, cough, dyspnea or interstitial infiltrates on radiologic exams. Infectious, neoplastic, and other causes for such symptoms should be excluded through appropriate investigations. Withhold TIVDAK for patients who develop persistent or recurrent Grade 2 pneumonitis and consider dose reduction. Permanently discontinue TIVDAK in all patients with Grade 3 or 4 pneumonitis.

Severe cutaneous adverse reactions (SCAR), including events of fatal or life-threatening Stevens-Johnson syndrome (SJS), can occur in patients treated with TIVDAK. SCAR occurred in 1.6% of cervical cancer patients treated with TIVDAK across clinical trials. Grade ≥3 SCAR occurred in 0.5% of patients, including 1 patient who had a fatal outcome.

Monitor patients for signs or symptoms of SCAR, which include target lesions, worsening skin reactions, blistering or peeling of the skin, painful sores in mouth, nose, throat, or genital area, fever or flu-like symptoms, and swollen lymph nodes. If signs or symptoms of SCAR occur, withhold TIVDAK until the etiology of the reaction has been determined. Early consultation with a specialist is recommended to ensure greater diagnostic accuracy and appropriate management. Permanently discontinue TIVDAK for confirmed Grade 3 or 4 SCAR, including SJS.

Embryo-fetal toxicity: TIVDAK can cause fetal harm when administered to a pregnant woman. Advise patients of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TIVDAK and for 2 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TIVDAK and for 4 months after the last dose.

Please see additional Important Safety Information on page 4.

Please see full Prescribing Information, including BOXED WARNING for TIVDAK.

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Important Safety Information (cont'd)

Adverse Reactions

Across clinical trials of TIVDAK in 425 patients with r/mCC, the most common (≥25%) adverse reactions, including laboratory abnormalities, were hemoglobin decreased (45%), PN (39%), conjunctival adverse reactions (38%), nausea (37%), fatigue (36%), aspartate aminotransferase increased (33%), epistaxis (33%), alopecia (31%), alanine aminotransferase increased (30%), and hemorrhage (28%).

innovaTV 301 Study: 250 patients with r/mCC with disease progression on or after systemic therapy

Serious adverse reactions occurred in 33% of patients receiving TIVDAK; the most common (≥2%) were urinary tract infection (4.8%), small intestinal obstruction (2.4%), sepsis, abdominal pain, and hemorrhage (each 2%). **Fatal adverse reactions** occurred in 1.6% of patients who received TIVDAK, including acute kidney injury, pneumonia, sepsis, and SJS (each 0.4%).

Adverse reactions leading to permanent discontinuation occurred in 15% of patients receiving TIVDAK; the most common (≥3%) were PN and ocular adverse reactions (each 6%). **Adverse reactions leading to dose interruption** occurred in 39% of patients receiving TIVDAK; the most common (≥3%) were ocular adverse reactions (16%) and PN (6%). **Adverse reactions leading to dose reduction** occurred in 30% of patients receiving TIVDAK; the most common (≥3%) were PN and ocular adverse reactions (each 10%). The ocular adverse reactions included conjunctival disorders (4.8%), keratopathy (4%), and dry eye (0.8%).

innovaTV 204 Study: 101 patients with r/mCC with disease progression on or after chemotherapy

Serious adverse reactions occurred in 43% of patients; the most common (≥3%) were ileus (6%), hemorrhage (5%), pneumonia (4%), PN, sepsis, constipation, and pyrexia (each 3%). **Fatal adverse reactions** occurred in 4% of patients who received TIVDAK, including septic shock, pneumonitis, sudden death, and multisystem organ failure (each 1%).

Adverse reactions leading to permanent discontinuation occurred in 13% of patients receiving TIVDAK; the most common (≥3%) were PN (5%) and corneal adverse reactions (4%). **Adverse reactions leading to dose interruption** occurred in 47% of patients; the most common (≥3%) were PN (8%), conjunctival adverse reactions, and hemorrhage (each 4%). **Adverse reactions leading to dose reduction** occurred in 23% of patients; the most common (≥3%) were conjunctival adverse reactions (9%) and corneal adverse reactions (8%).

Drug Interactions

Strong CYP3A4 inhibitors: Concomitant use with strong CYP3A4 inhibitors may increase unconjugated monomethyl auristatin E (MMAE) exposure, which may increase the risk of TIVDAK adverse reactions. Closely monitor patients for TIVDAK adverse reactions.

Use in Specific Populations

Moderate or severe hepatic impairment: MMAE exposure and adverse reactions are increased. Avoid use.

Lactation: Advise lactating women not to breastfeed during TIVDAK treatment and for at least 3 weeks after the last dose.

Please see full Prescribing Information, including BOXED WARNING for TIVDAK.

Reference: TIVDAK [Prescribing Information]. Bothell, WA: Seagen Inc. April 2024.

Pfizer Oncology

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