



Coding and Billing Guide

For Tivdak[®] (tisotumab vedotin-tftv) for Injection 40 mg

[SeagenSecure.com](https://www.seagensecure.com)

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Monday-Friday, 8 AM-8 PM ET

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Please click [here](#) for Indication and Important Safety Information.
Please see [full Prescribing Information](#), including **BOXED WARNING** for TIVDAK.

Introduction

Accurate and appropriate completion of coding and billing requirements can reduce delays or inaccurate denials in claims processing and facilitate timely reimbursement.

This guide is intended to be an educational reference, providing general coding and billing information to facilitate medically appropriate patient access to Tivdak® (tisotumab vedotin-tftv) for injection. It is offered for informational purposes only and is not intended to provide reimbursement or legal advice.

Each healthcare provider (HCP) is responsible for determining the appropriate codes, coverage, and payment for individual patients. Seagen does not guarantee third-party coverage or payment or reimbursement for denied claims.

Because insurance coverage, coding, claims filing, and reimbursement vary by setting of care as well as by payer type, the information included in this guide is general. HCPs should always verify coverage prior to initiating therapy and determine the appropriate codes on a case-by-case basis.

While Seagen has made every effort to be current as of the publication of this guide, the information may not be as current when you view it. Similarly, all CPT and HCPCS codes are supplied for informational purposes only. This information does not represent any statement, promise, or guarantee by Seagen about coverage, levels of reimbursement, payment, or charge. Additional information may exist, and actual coverage and reimbursement decisions are made by individual payers. Providers should contact the applicable third-party payers for specific information on coding and billing requirements.

IMPORTANT INFORMATION: The coding, coverage, and payment information contained herein is gathered from various resources, general in nature, and subject to change without notice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims conforming to the requirements of the relevant payer for those products and services rendered. Pharmacies (or any other provider submitting a claim) should contact third-party payers for specific information on their coding, coverage, and payment policies. Information and materials provided by Seagen Secure are to assist providers, but the responsibility to determine coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains at all times with the provider, and information provided by Seagen should in no way be considered a guarantee of coverage or reimbursement for any product or service.

Navigating Claim Delays and Denials

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.

Understanding the reasons why insurers may deny medical claims can help limit the number of denials. Common causes of delayed or denied claims may include:

- ✘ Inaccurate or missing codes (eg, J-codes [HCPCS Codes], CPT codes, ICD-10-CM codes)
- ✘ Incorrect product information
- ✘ Missing or incorrect NDC, prior authorization number, National Provider Identifier
- ✘ Incorrect patient identifier information (eg, insurance identification number, date of birth)
- ✘ Failure to follow payer-specific requirements

Call or visit [SeagenSecure.com](https://www.seagensecure.com) for resources and information about benefit and reimbursement assistance.

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Considerations When

Requesting Prior Authorizations

- ✓ Determine if Tivdak® (tisotumab vedotin-tftv) is covered as a medical or pharmacy benefit prior to infusion
- ✓ Verify and record that all of the prior authorization requirements for the plan have been met
- ✓ Ensure medical records include full and proper documentation of the patient's history including diagnosis codes, prior therapy, and rationale for treatment to justify coding
 - For exception requests, when medically appropriate, explain why a particular requirement is not medically appropriate for the patient
- ✓ If required, include a Letter of Medical Necessity that provides the patient's medical history and rationale for the therapy
- ✓ Verify that all identification numbers and names are correct

➤ [Click here](#) for a sample prior authorization request letter

➤ [Click here](#) for a sample letter of medical necessity

Submitting a Claim

- ✓ Specify the correct number of billing units on the health insurance claim form (CMS-1500) or on the UB-04/CMS-1450 Claim Form. Dosing for Tivdak is weight-based. Therefore, ensure the actual dose administered to the patient is reflected in the billing units (see [pages 10-13](#) for instructions on filling out claim forms)
- ✓ Use the correct ICD-10-CM, CPT, and HCPCS codes, including modifiers if applicable
- ✓ Verify the proper use of billing codes
- ✓ For the hospital outpatient setting, confirm that the correct revenue code is used with the appropriate supporting HCPCS code
- ✓ Submit the claim within the time frame specified by the payer
- ✓ Track clearinghouse claims to ensure successful transmission

Relevant Billing Codes for Tivdak® (tisotumab vedotin-tftv)

The billing codes listed below may be appropriate when billing for Tivdak and its administration for the treatment of FDA-approved indications.

It is the HCP's responsibility to determine the appropriate codes and to submit accurate claims for products and services provided. Seagen does not guarantee coverage and/or reimbursement for Tivdak. Coverage, coding, and reimbursement policies vary significantly by payer, patient, and setting of care. Actual coverage and reimbursement decisions are made by individual payers following the receipt of claims. HCPs should verify coverage, coding, and reimbursement guidelines on a case-by-case basis.

Healthcare Common Procedure Coding System (HCPCS)

The HCPCS is used to identify products, supplies, and services that are billed to private and government payers by hospitals, physicians, and other HCPs.¹

HCPCS Code ²	Description
J9273	Injection, tisotumab vedotin-tftv, 1 mg

Note: Beginning in January 2020, Centers for Medicare & Medicaid Services (CMS) implemented quarterly updates to HCPCS code application opportunities for drugs and biological products.

National Drug Code (NDC)

You may be required to include an NDC for Tivdak on a claim form. The 10-digit NDC for Tivdak is listed below.

NDC Code ³	Description
51144-003-01	40-mg single dose vial

Note: Payer requirements regarding use of a 10-digit or 11-digit NDC may vary.

FDA=US Food and Drug Administration.

Current Procedural Terminology (CPT) Codes for Drug Administration Service

Five-digit codes that describe the procedures and services performed by physicians and other HCPs.

CPT Code ²	Description
96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique, each additional hour

HCPs should consult the current CPT manual and always select the code that accurately describes the administration service performed for the patient. HCPs should also contact the payer for additional coding information required.

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Relevant Billing Codes for Tivdak® (tisotumab vedotin-tftv) (cont'd)

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM)

ICD-10-CM codes are used to identify a patient's diagnosis. At least 1 ICD-10-CM diagnosis code must be included in all hospital and physician office claims to describe the patient's diagnosis.

The ICD-10-CM diagnosis codes listed are provided only as examples of potentially relevant codes. Providers should consult a current ICD-10-CM manual and select the most appropriate diagnosis code(s) to accurately describe a patient's condition. All diagnosis codes should be supported with adequate documentation.

Digits 1-4: Diagnosis Code

Malignant Neoplasm⁴

Code	Description
C53.0	Malignant neoplasm of endocervix
C53.1	Malignant neoplasm of exocervix
C53.8	Malignant neoplasm of overlapping sites of cervix uteri
C53.9	Malignant neoplasm of cervix uteri, unspecified

Carcinoma In Situ⁴

Code	Description
D06.0	Carcinoma in situ of endocervix
D06.1	Carcinoma in situ of exocervix
D06.7	Carcinoma in situ of other parts of cervix
D06.9	Carcinoma in situ of cervix, unspecified

Abnormal Cytological Findings⁴

Code	Description
R87.6	Abnormal cytological findings in specimens from female genital organs

Digit 5

Subcodes for Abnormal Cytological Findings⁴

Code	Description
1	Abnormal cytological findings in specimens from cervix uteri

Digit 6 (always bill to the 6th digit)

Subcodes for Abnormal Cytological Findings⁴

Code	Description
0	Atypical squamous cells of undetermined significance on cytologic smear of cervix (ASC-US)
1	Atypical squamous cells cannot exclude high grade squamous intraepithelial lesion on cytologic smear of cervix (ASC-H)
2	Low grade squamous intraepithelial lesion on cytologic smear of cervix (LGSIL)
3	High grade squamous intraepithelial lesion on cytologic smear of cervix (HGSIL)
4	Cytologic evidence of malignancy on smear of cervix
5	Unsatisfactory cytologic smear of cervix - Inadequate sample of cytologic smear of cervix
6	Satisfactory cervical smear but lacking transformation zone
8	Other abnormal cytological findings on specimens from cervix uteri
9	Unspecified abnormal cytological findings in specimens from cervix uteri



Did you know?

Dedicated Field Reimbursement Managers are able to share certain coverage and on-label coding information to support patient access inquires. Contact your local Seagen representative to learn more.

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Sample Claim Forms

Health Insurance Claim Form (CMS-1500)⁵

- A Item 19**
Some payers may require drug name, total dosage, and method of administration to be provided in Item 19.⁶
- B Item 21**
Enter appropriate site-specific ICD-10-CM diagnosis code(s) based on the patient's documented medical record.⁷
- C Item 24A and 24B**
Enter the date of service and the appropriate place of service code.⁸
- D Item 24D**
Enter the appropriate HCPCS code for Tivdak® (tisotumab vedotin-tftv): J9273.² Enter the appropriate CPT code for the administration service.⁷ If applicable, discarded product should be reported on a separate line with the JW modifier.⁸
- E Item 24E**
Enter the diagnosis code reference letter or number from Item 21 that relates to the product or procedure listed in Item 24D.⁷
- F Item 24G**
Report billing units here. Actual units reported will vary by dosage required for each individual patient.⁷

This sample form is provided for informational purposes only. The accurate completion of claims documentation is the responsibility of the HCP. Seagen does not guarantee reimbursement for any services or product.

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Sample Claim Forms (cont'd)

Outpatient Hospital Claim Form (CMS-1450 [UB-04])⁹

42 REV CD	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV DATE	46 SERV UNITS	47 TOTAL CHARGES	48 NON COVERED CHARGES	49
1							1
2							2
3							3
4							4
5							5



- A Item 42**
Enter a 4-digit revenue code that best describes the service provided, in accordance with the hospital billing policy.¹⁰
- B Item 43**
Enter the corresponding description for the revenue code listed in Item 42. When required to submit drug rebate data for Medicaid rebates, enter the NDC qualifier "N4" followed by the 11-digit NDC, the quantity qualifier, and the quantity administered.¹⁰
- C Item 44**
Enter the appropriate HCPCS code for Tivdak® (tisotumab vedotin-tftv): J9273.¹ If applicable, discarded product should be reported on a separate line with the HCPCS code and JW modifier.⁸
- D Item 45**
Enter the date of service.¹⁰
- E Item 46**
Report billing units here. Actual units reported will vary by dosage required for each individual patient.¹⁰

66 DX	67	A	B	C	D	E	F	G	H	68
1										1
2										2
3										3
4										4
5										5

- F Item 66**
Enter the appropriate diagnosis code(s).¹⁰
- G Item 67A-67G**
Enter the site-specific ICD-10-CM diagnosis codes for the malignancy being treated as documented in the patient's medical records.¹⁰

This sample form is provided for informational purposes only. The accurate completion of claims documentation is the responsibility of the HCP. Seagen does not guarantee reimbursement for any services or product.

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Seagen Secure

Support Throughout the Prior Authorization and Coverage Process

Coverage support is a key way in which Seagen Secure helps patients access prescribed therapies. Seagen Secure is available to assist patients throughout the patient journey. Seagen Secure may be able to help



When initiating a benefit investigation for patients who will receive Tivdak® (tisotumab vedotin-tftv) through the network specialty distributor of the provider's choice



When a HCP needs to order Tivdak for eligible patients enrolled in the Patient Assistance Program (PAP)



When the HCP has a question about billing the patient's insurance for Tivdak

Enrolling in Seagen Secure

There are 2 required forms to enroll a patient in Seagen Secure.

Whenever possible, submit these forms together to ensure efficient processing.

Click to access the
HCP Request Form

Click to access the
Patient Authorization Form

Please click [here](#) for Indication and Important Safety Information.
 Please see [full Prescribing Information](#), including **BOXED WARNING** for TIVDAK.

Indication

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

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Important Safety Information

BOXED WARNING: OCULAR TOXICITY

TIVDAK caused changes in the corneal epithelium and conjunctiva resulting in changes in vision, including severe vision loss, and corneal ulceration. Conduct an ophthalmic exam at baseline, prior to each dose, and as clinically indicated. Adhere to premedication and required 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 occurred in 60% of patients with cervical cancer treated with TIVDAK across clinical trials. The most common were conjunctival adverse reactions (40%), dry eye (29%), corneal adverse reactions (21%), and blepharitis (8%). Grade 3 ocular adverse reactions occurred in 3.8% of patients, including severe ulcerative keratitis in 3.2% of patients. One patient experienced ulcerative keratitis with perforation requiring corneal transplantation. Cases of symblepharon were reported in patients with other tumor types treated with TIVDAK at the recommended dose.

In innovaTV 204, 4% of patients experienced visual acuity changes to 20/50 or worse including 1% of patients who experienced a visual acuity change to 20/200. Of the patients who experienced decreased visual acuity to 20/50 or worse, 75% resolved, including the patient who experienced decreased visual acuity to 20/200.

Refer patients to an eye care provider for an ophthalmic exam, including visual acuity and slit lamp exam, at baseline, prior to each dose, and as clinically indicated. Adhere to premedication and required eye care to reduce the risk of ocular adverse reactions.

Promptly refer patients to an eye care provider for any new or worsening ocular signs and symptoms. Withhold dose, reduce the dose, or permanently discontinue TIVDAK based on the severity of the adverse reaction.

Peripheral neuropathy (PN) occurred in 42% of cervical cancer patients treated with TIVDAK across clinical trials; 8% of patients experienced Grade 3 PN. PN adverse reactions included peripheral neuropathy (20%), peripheral sensory neuropathy (11%), peripheral sensorimotor neuropathy (5%), motor neuropathy (3%), muscular weakness (3%), and demyelinating peripheral polyneuropathy (1%). 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 62% of cervical cancer patients treated with TIVDAK across clinical trials. The most common all grade hemorrhage adverse reactions were epistaxis (44%), hematuria (10%), and vaginal hemorrhage (10%). Grade 3 hemorrhage occurred in 5% of patients.

Monitor patients for signs and symptoms of hemorrhage. For patients experiencing pulmonary or central nervous system (CNS) 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 patients with cervical cancer treated with TIVDAK across clinical trials, 2 patients (1.3%) experienced pneumonitis, including 1 patient who had a fatal outcome.

Please see additional Important Safety Information on pages 18 and 19. Please see full Prescribing Information, including BOXED WARNING for TIVDAK.

Important Safety Information (cont'd)

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 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, including events of fatal or life-threatening Stevens-Johnson syndrome (SJS), can occur in patients treated with TIVDAK.

Monitor patients for signs or symptoms of severe cutaneous adverse reactions, 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 severe cutaneous adverse reactions 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 severe cutaneous adverse reactions, 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.

Adverse Reactions

Serious adverse reactions occurred in 43% of patients; the most common ($\geq 3\%$) 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 ($\geq 3\%$) were PN (5%) and corneal adverse reactions (4%). Adverse reactions leading to dose interruption occurred in 47% of patients; the most common ($\geq 3\%$) were PN (8%), conjunctival adverse reactions (4%), and hemorrhage (4%). Adverse reactions leading to dose reduction occurred in 23% of patients; the most common ($\geq 3\%$) were conjunctival adverse reactions (9%) and corneal adverse reactions (8%).

The most common ($\geq 25\%$) adverse reactions, including laboratory abnormalities, were hemoglobin decreased (52%), fatigue (50%), lymphocytes decreased (42%), nausea (41%), PN (39%), alopecia (39%), epistaxis (39%), conjunctival adverse reactions (37%), hemorrhage (32%), leukocytes decreased (30%), creatinine increased (29%), dry eye (29%), prothrombin international normalized ratio increased (26%), activated partial thromboplastin time prolonged (26%), diarrhea (25%), and rash (25%).

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.

Contact Seagen Secure

Seagen Secure is a dynamic and comprehensive suite of solutions to help patients access prescribed Seagen therapies.

There are 3 ways to contact Seagen Secure for assistance:



Call

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



Go online

SeagenSecure.com or email
casemanager@seagensecure.com




Fax

855-557-2480

For more information on Seagen Secure, please contact your Field Reimbursement Manager.

References: **1.** Centers for Medicare & Medicaid Services. HCPCS – general information (last modified 8-1-2022). <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo>. Accessed August 22, 2022. **2.** CMS.gov. Physician fee schedule - July 2022 release. <https://www.cms.gov/files/zip/rvu22c-updated-06172022.zip> File name: PRRVU22_JUL. Accessed August 22, 2022. **3.** Tivdak [Prescribing Information]. Bothell, WA: Seagen Inc.; July 2023. **4.** CMS.gov. ICD-10-CM tabular list of diseases and injuries. Centers for Medicare and Medicaid Services; 2019. <https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2019-ICD-10-CM-Tables-and-Index.zip>. File name: icd10cm_tabular_2019.pdf. Accessed August 22, 2022. **5.** Centers for Medicare & Medicaid Services. Health Insurance Claim Form (approved February 2012). <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf>. Accessed August 22, 2022. **6.** Centers for Medicare & Medicaid Services. Billing and coding guidelines for drugs and biologics (non-chemotherapy) (revised April 1, 2018). https://downloads.cms.gov/medicare-coverage-database/lcd_attachments/34741_55/BCG_L34741.pdf. Accessed August 22, 2022. **7.** Centers for Medicare & Medicaid Services. Medicare claims processing manual chapter 26 – completing and processing form CMS-1500 data set (revised May 8, 2020). <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c26.pdf>. Accessed August 22, 2022. **8.** Centers for Medicare & Medicaid Services. Medicare claims processing manual chapter 17 – drugs and biologicals. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf>. Accessed August 22, 2022. **9.** Centers for Medicare & Medicaid Services. CMS-1450. <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/Downloads/CMS-1450.zip>. File name: CMS-1450 UB04-front.pdf. Accessed August 22, 2022. **10.** Centers for Medicare & Medicaid Services. Medicare claims processing manual chapter 25 – completing and processing the form CMS-1450 data set (revised January 11, 2019). <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf>. Accessed August 22, 2022.



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