Seagen Secure®
Patient Assistance Program

Coding and Billing Guide

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

SeagenSecure.com
1-855-4SECURE (855-473-2873)
Monday-Friday, 8 AM-8 PM ET

Table of Contents

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 for resources and information about benefit and reimbursement assistance.]

Please click here for Indication and Important Safety Information.
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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

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

Click here for a sample prior authorization request letter

Click here for a sample letter of medical necessity

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 Neoplasm[4]

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 Situ[4]

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 Findings[4]

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

Digit 5

Subcodes for Abnormal Cytological Findings[4]

Code	Description
1	Abnormal cytological findings in specimens from cervix uteri

Digit 6 (always bill to the 6th digit)

Subcodes for Abnormal Cytological Findings[4]

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.

Please click here for Indication and Important Safety Information.
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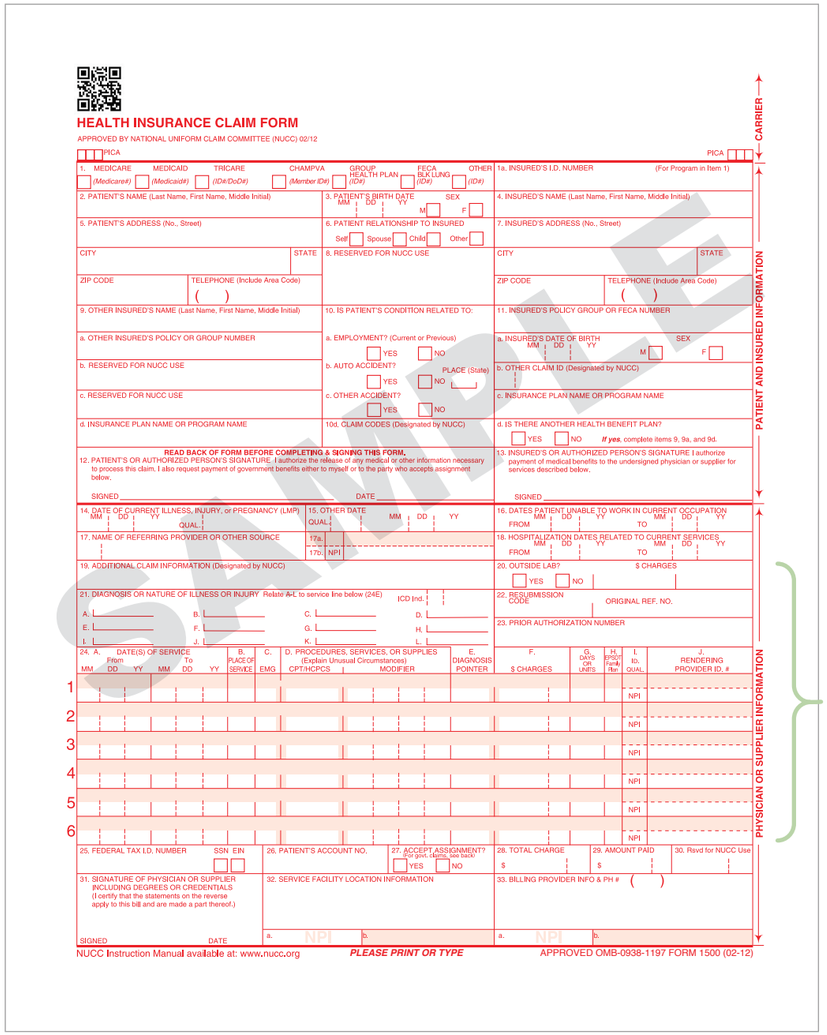
Sample Claim Forms

Health Insurance Claim Form (CMS-1500)[5]


HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a. 17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From To MM DD YY MM DD YY | B. PLACE OF SERVICE | C. EMG | D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER | E. DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. EPSDT Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. #

1 NPI
2 NPI
3 NPI
4 NPI
5 NPI
6 NPI

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

32. SERVICE FACILITY LOCATION INFORMATION a. NPI b.

33. BILLING PROVIDER INFO & PH # ( ) a. NPI b.

SIGNED DATE

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

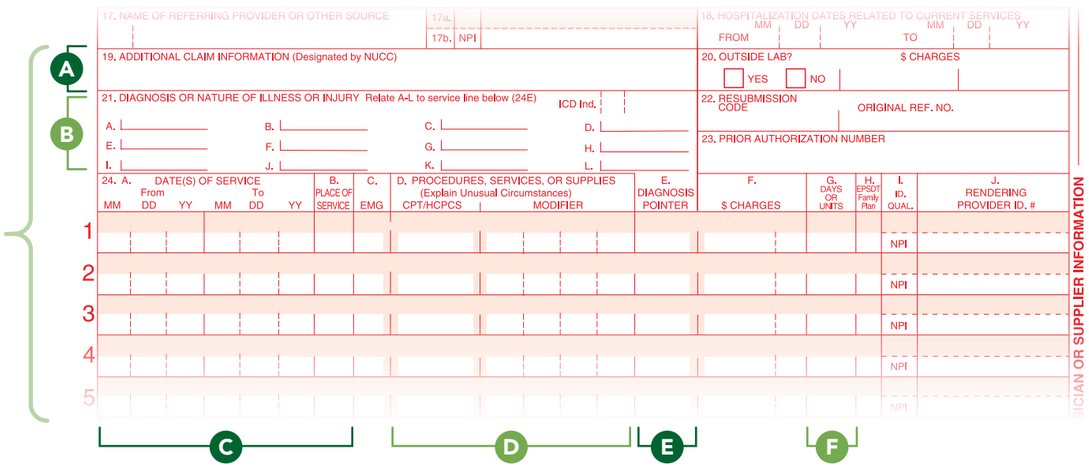
CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

SAMPLE

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.



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]

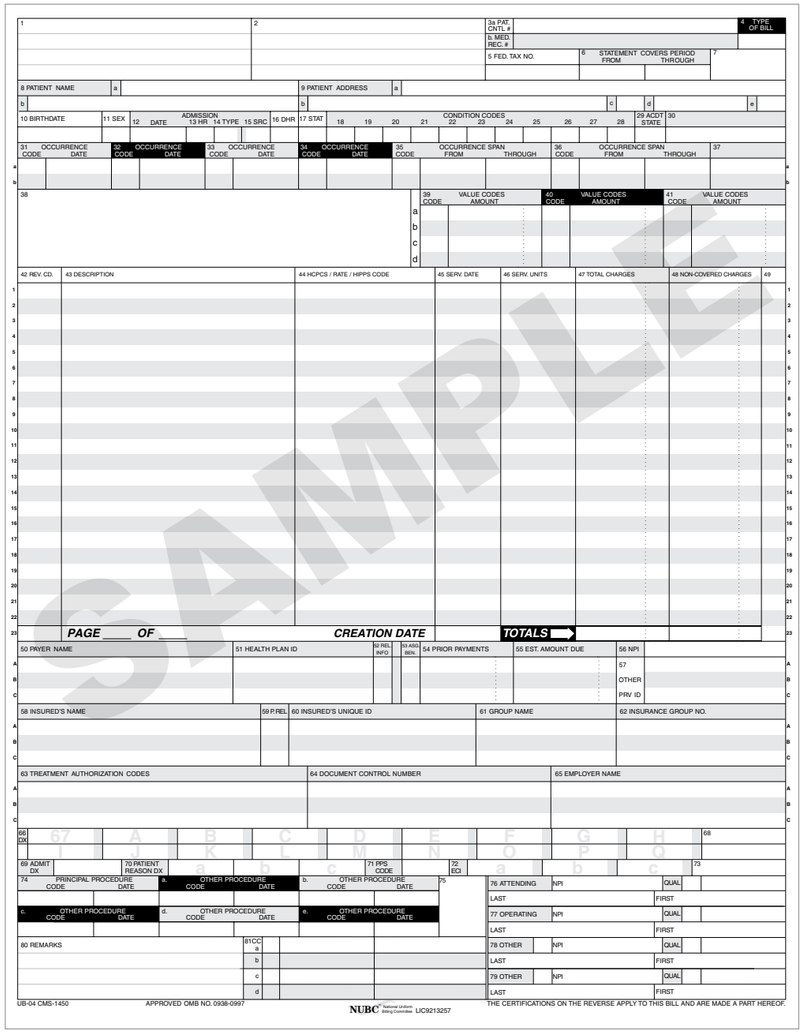
E Item 24E
Enter the diagnosis code reference letter or number from Item 21 that relates to the product or procedure listed in Item 24D.[7]

F Item 24G
Report billing units here. Actual units reported will vary by dosage required for each individual patient.[7]

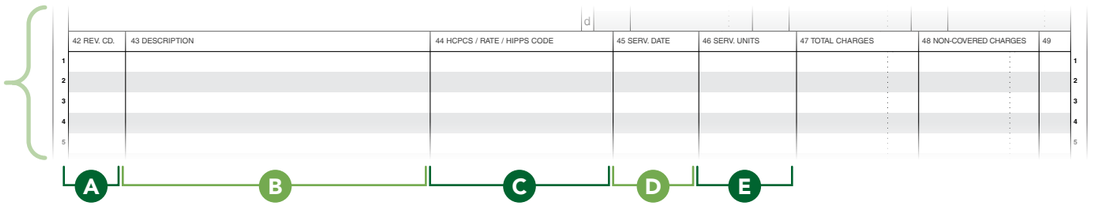
Please click here for Indication and Important Safety Information.
Please see full Prescribing Information, including BOXED WARNING for TIVDAK.

Sample Claim Forms (cont'd)

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



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.



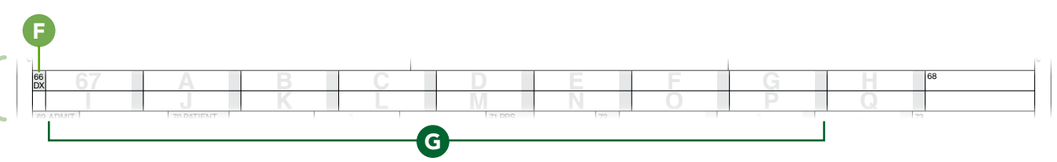
A **Item 42**
Enter a 4-digit revenue code that best describes the service provided, in accordance with the hospital billing policy.[10]

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]



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]

Please click here for Indication and Important Safety Information.
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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

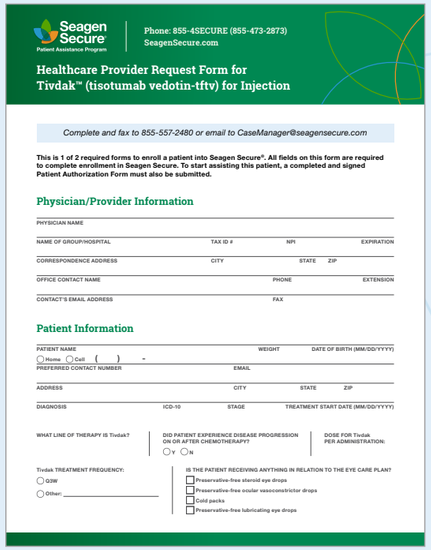
When a HCP needs to order Tivdak for eligible patients enrolled in the Patient Assistance Program (PAP)

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.



Seagen Secure® Patient Assistance Program

Phone: 855-4SECURE (855-473-2873)
SeagenSecure.com

Healthcare Provider Request Form for Tivdak™ (tisotumab vedotin-tftv) for Injection

Complete and fax to 855-557-2480 or email to CaseManager@seagensecure.com

This is 1 of 2 required forms to enroll a patient into Seagen Secure®. All fields on this form are required to complete enrollment in Seagen Secure. To start assisting this patient, a completed and signed Patient Authorization Form must also be submitted.

Physician/Provider Information

PHYSICIAN NAME

NAME OF GROUP/HOSPITAL | TAX ID # | NPI | EXPIRATION

CORRESPONDENCE ADDRESS | CITY | STATE | ZIP

OFFICE CONTACT NAME | PHONE | EXTENSION

CONTACT'S EMAIL ADDRESS | FAX

Patient Information

PATIENT NAME | WEIGHT | DATE OF BIRTH (MM/DD/YYYY)

◯ Home ◯ Cell ( ) -

PREFERRED CONTACT NUMBER | EMAIL

ADDRESS | CITY | STATE | ZIP

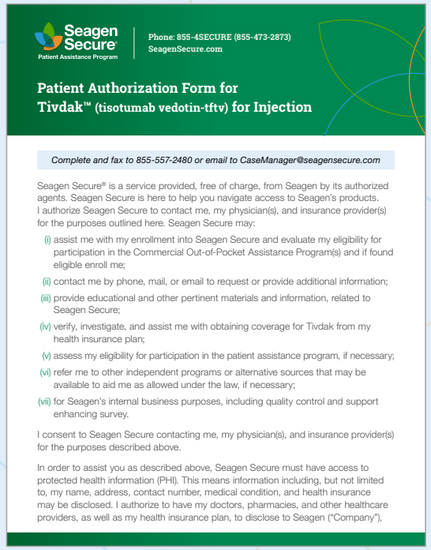
DIAGNOSIS | ICD-10 | STAGE | TREATMENT START DATE (MM/DD/YYYY)

WHAT LINE OF THERAPY IS Tivdak? | DID PATIENT EXPERIENCE DISEASE PROGRESSION ON OR AFTER CHEMOTHERAPY? ◯ Y ◯ N | DOSE FOR Tivdak PER ADMINISTRATION:

Tivdak TREATMENT FREQUENCY:
◯ Q3W
◯ Other: _____

IS THE PATIENT RECEIVING ANYTHING IN RELATION TO THE EYE CARE PLAN?
☐ Preservative-free steroid eye drops
☐ Preservative-free ocular vasoconstrictor drops
☐ Cold packs
☐ Preservative-free lubricating eye drops

Click to access the
HCP Request Form



Seagen Secure® Patient Assistance Program

Phone: 855-4SECURE (855-473-2873)
SeagenSecure.com

Patient Authorization Form for Tivdak™ (tisotumab vedotin-tftv) for Injection

Complete and fax to 855-557-2480 or email to CaseManager@seagensecure.com

Seagen Secure® is a service provided, free of charge, from Seagen by its authorized agents. Seagen Secure is here to help you navigate access to Seagen's products. I authorize Seagen Secure to contact me, my physician(s), and insurance provider(s) for the purposes outlined here. Seagen Secure may:

(i) assist me with my enrollment into Seagen Secure and evaluate my eligibility for participation in the Commercial Out-of-Pocket Assistance Program(s) and if found eligible enroll me;

(ii) contact me by phone, mail, or email to request or provide additional information;

(iii) provide educational and other pertinent materials and information, related to Seagen Secure;

(iv) verify, investigate, and assist me with obtaining coverage for Tivdak from my health insurance plan;

(v) assess my eligibility for participation in the patient assistance program, if necessary;

(vi) refer me to other independent programs or alternative sources that may be available to aid me as allowed under the law, if necessary;

(vii) for Seagen's internal business purposes, including quality control and support enhancing survey.

I consent to Seagen Secure contacting me, my physician(s), and insurance provider(s) for the purposes described above.

In order to assist you as described above, Seagen Secure must have access to protected health information (PHI). This means information including, but not limited to, my name, address, contact number, medical condition, and health insurance may be disclosed. I authorize to have my doctors, pharmacies, and other healthcare providers, as well as my health insurance plan, to disclose to Seagen ("Company"),

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 (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.

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)

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.

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.

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.]

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