Seagen Secure®
Patient Assistance Program

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

Sample Codes for Diagnoses, Ordering, and Administration

Diagnosis: ICD-10-CM

Digits 1-4: Diagnosis Code[1]

Malignant Neoplasm

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

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

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

Digit 5

Subcodes for Abnormal Cytological Findings

Code	Description
1	Abnormal cytological findings in specimens from cervix uteri

Digit 6 (Always bill to the 6th digit)

Subcodes for Abnormal Cytological Findings

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 oncytologic 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

NDC Code[2]

Tivdak™ (tisotumab vedotin-tftv) for injection

Dosage	NDC Code
40-mg single dose vial	51144-003-01

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

HCPCS Codes[3]

Code	Code Description
J3490	Unclassified drugs
J3590	Unclassified biologics
J9999	Not otherwise classified, antineoplastic drugs

CPT Codes[4]

5-digit codes that describe procedures and services performed by physicians and other healthcare providers (HCPs)

Code	Code 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

Call or visit **SeagenSecure.com** for resources and information about Benefit and Reimbursement Assistance

This document is provided by Seagen as general guidance only. Coverage, coding, and payment may vary by payer, plan, and treatment setting. It is the sole responsibility of the provider to ensure accuracy of coding and documentation on claim forms.

CPT = Current Procedural Terminology; HCPCS = Healthcare Common Procedure Coding System; ICD-10-CM = International Classification of Diseases, Tenth Revision, Clinical Modification. NDC = National Drug Code.

Please see Indication and Important Safety Information on pages 2 and 3. Click here for full Prescribing Information, including BOXED WARNING.

Indication

TIVDAK™ (tisotumab vedotin-tftv) 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. For new or worsening PN, withhold, 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 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: Severe, life-threatening, or fatal pneumonitis 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.

Monitor patients for pulmonary symptoms of pneumonitis. 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.

Please see additional Important Safety Information on page 3.
Click here for full Prescribing Information, including BOXED WARNING.

Important Safety Information (cont'd)

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 (≥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 (4%), and hemorrhage (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%).

The most common (≥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.

Click here for full Prescribing Information, including BOXED WARNING for TIVDAK.

References: 1. 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 July 9, 2021. **2.** Tivdak [Prescribing Information]. Bothell, WA: Seagen Inc.; September 2021. **3.** CMS.gov. HCPCS codes. Centers for Medicare & Medicaid Services. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update. July 2021 Alpha-Numeric HCPCS File. File name: HCPC2021_JULY_ANWEB_v2.xls. Accessed July 20, 2021. **4.** American Medical Association. CPT® 2019 Professional. Chicago, IL: American Medical Association; 2020.

Seagen®