REIMBURSEMENT, BILLING, AND CODING GUIDE FOR TRODELVY® (sacituzumab govitecan-hziy)

The tables below include examples of codes that may be appropriate for use when billing and seeking reimbursement for treatment with TRODELVY.

Coding requirements may vary by insurer or plan. Gilead Sciences, Inc., has provided these codes only as a reference. When submitting a claim for TRODELVY, always verify coding requirements with the relevant payer. Healthcare professionals are solely responsible for selecting codes that appropriately reflect the patient's diagnosis, the services rendered, and the applicable payer's guidelines. The use of this information does not guarantee payment or that any payment received will cover costs.

INDICATIONS

TRODELVY® (sacituzumab govitecan-hziy) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with:

- **Unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC)** who have received two or more prior systemic therapies, at least one of them for metastatic disease.
- Unresectable locally advanced or metastatic hormone receptor **(HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH–)** breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.
- **Locally advanced or metastatic urothelial cancer (mUC)** who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Please see Important Safety Information, including BOXED WARNING on Neutropenia and Diarrhea below.

HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS)

HCPCS coding requirements will vary by payer, setting of care, and date of service. Please verify patient-specific insurance benefits to confirm specific coding and billing guidelines for TRODELVY.

HCPCS Level II Code	Description	Note
J9317 (effective January 1, 2021)	Injection, sacituzumab govitecan-hziy, 2.5 mg	For all providers and settings of care for which HCPCS codes are reported

As of January 1, 2017, Medicare claims require the use of the JW modifier (drug amount discarded/not administered to any patient) when applicable. Other payers may have similar requirements.

NATIONAL DRUG CODE (NDC)

Payer requirements regarding the use of a 10-digit or 11-digit NDC may vary. Both formats are listed here for your reference. Please consult with the payer to understand specific billing requirements.

NDC	Code	Description
10-digit code 11-digit code (with leading 0)	55135-132-01 55135-0132-01	TRODELVY for injection is supplied as 180 mg of sacituzumab govitecan-hziy as lyophilized powder in a single-dose vial

IMPORTANT SAFETY INFORMATION

BOXED WARNING: NEUTROPENIA AND DIARRHEA

- **Severe or life-threatening neutropenia may occur. Withhold TRODELVY for absolute neutrophil count below 1500/mm³ or neutropenic fever. Monitor blood cell counts periodically during treatment. Consider G-CSF for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.**
- **Severe diarrhea may occur. Monitor patients with diarrhea and give fluid and electrolytes as needed. At the onset of diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold TRODELVY until resolved to ≤Grade 1 and reduce subsequent doses.**

Please see additional Important Safety Information throughout and full Prescribing Information, including BOXED WARNING.

TRODELVY®
sacituzumab govitecan-hziy
180 mg for injection

CURRENT PROCEDURAL TERMINOLOGY (CPT®) CODE FOR DRUG ADMINISTRATION SERVICE

The recommended dose of TRODELVY is administered as an intravenous infusion once weekly on Days 1 and 8 of continuous 21-day treatment cycles. Continue treatment until disease progression or unacceptable toxicity. Do not administer TRODELVY at doses greater than 10 mg/kg. Administer TRODELVY as an intravenous infusion only. Do not administer as an intravenous push or bolus. Please refer to the full Prescribing Information for complete dosing and administration guidelines.

CPT 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 (list separately in addition to code for primary procedure)

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REVENUE CODES (FOR HOSPITAL CLAIMS ONLY)

All hospital claim forms must include a revenue code for each charge line item. The following revenue codes are most relevant for physician-administered drugs.

Revenue Code	Description
0250	Pharmacy
0636	Pharmacy—drugs requiring detailed coding

ICD-10-CM DIAGNOSIS CODES

ICD-10 diagnosis codes represent medical terminology for diseases, disorders, or other medical conditions affecting the patient. Proper diagnosis coding involves using the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) volumes to select the appropriate codes based on documentation in the patient's medical record and assigning those codes correctly on claims.

ICD-10-CM Diagnosis Code	Indication	Description
C50.011 - C50.929[a]	mTNBC, HR+/HER2- mBC	Malignant neoplasm of breast
C67.0 - C67.9[a]	mUC	Malignant neoplasm of bladder (urothelial cancer)
C68.0 - C68.9[a]	mUC	Malignant neoplasm of other and unspecified urinary organs (primary carcinoma of the urethra and upper genitourinary tract tumors)

[a]Visit the Centers for Medicare & Medicaid Services website to see all ICD-10-CM codes for breast cancer (https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/P0230.html) and bladder cancer (https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/P0245.html).

Gilead Sciences, Inc. is not responsible for the accuracy of this site.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

- Severe hypersensitivity reaction to TRODELVY.

WARNINGS AND PRECAUTIONS

Neutropenia: Severe, life-threatening, or fatal neutropenia can occur and may require dose modification. Neutropenia occurred in 64% of patients treated with TRODELVY. Grade 3-4 neutropenia occurred in 49% of patients. Febrile neutropenia occurred in 6%. Neutropenic colitis occurred in 1.4%.

Please see additional Important Safety Information throughout and full Prescribing Information, including BOXED WARNING.

TRODELVY®
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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Neutropenia (cont'd): Withhold TRODELVY for absolute neutrophil count below 1500/mm^3 on Day 1 of any cycle or neutrophil count below 1000/mm^3 on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever. Administer G-CSF as clinically indicated or indicated in Table 1 of USPI.

Diarrhea: Diarrhea occurred in 64% of all patients treated with TRODELVY. Grade 3-4 diarrhea occurred in 11% of patients. One patient had intestinal perforation following diarrhea. Diarrhea that led to dehydration and subsequent acute kidney injury occurred in 0.7% of all patients. Withhold TRODELVY for Grade 3-4 diarrhea and resume when resolved to ≤Grade 1. At onset, evaluate for infectious causes and if negative, promptly initiate loperamide, 4 mg initially followed by 2 mg with every episode of diarrhea for a maximum of 16 mg daily. Discontinue loperamide 12 hours after diarrhea resolves. Additional supportive measures (e.g., fluid and electrolyte substitution) may also be employed as clinically indicated. Patients who exhibit an excessive cholinergic response to treatment can receive appropriate premedication (e.g., atropine) for subsequent treatments.

Hypersensitivity and Infusion-Related Reactions: Serious hypersensitivity reactions including life-threatening anaphylactic reactions have occurred with TRODELVY. Severe signs and symptoms included cardiac arrest, hypotension, wheezing, angioedema, swelling, pneumonitis, and skin reactions. Hypersensitivity reactions within 24 hours of dosing occurred in 35% of patients. Grade 3-4 hypersensitivity occurred in 2% of patients. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.2%. The incidence of anaphylactic reactions was 0.2%. Pre-infusion medication is recommended. Have medications and emergency equipment to treat such reactions available for immediate use. Observe patients closely for hypersensitivity and infusion-related reactions during each infusion and for at least 30 minutes after completion of each infusion. Permanently discontinue TRODELVY for Grade 4 infusion-related reactions.

Nausea and Vomiting: Nausea occurred in 64% of all patients treated with TRODELVY and Grade 3-4 nausea occurred in 3% of these patients. Vomiting occurred in 35% of patients and Grade 3-4 vomiting occurred in 2% of these patients. Premedicate with a two or three drug combination regimen (e.g., dexamethasone with either a 5-HT3 receptor antagonist or an NK_1 receptor antagonist as well as other drugs as indicated) for prevention of chemotherapy-induced nausea and vomiting (CINV). Withhold TRODELVY doses for Grade 3 nausea or Grade 3-4 vomiting and resume with additional supportive measures when resolved to Grade ≤1. Additional antiemetics and other supportive measures may also be employed as clinically indicated. All patients should be given take-home medications with clear instructions for prevention and treatment of nausea and vomiting.

Increased Risk of Adverse Reactions in Patients with Reduced UGT1A1 Activity: Patients homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk for neutropenia, febrile neutropenia, and anemia and may be at increased risk for other adverse reactions with TRODELVY. The incidence of Grade 3-4 neutropenia was 58% in patients homozygous for the UGT1A1*28, 49% in patients heterozygous for the UGT1A1*28 allele, and 43% in patients homozygous for the wild-type allele. The incidence of Grade 3-4 anemia was 21% in patients homozygous for the UGT1A1*28 allele, 10% in patients heterozygous for the UGT1A1*28 allele, and 9% in patients homozygous for the wild-type allele. Closely monitor patients with known reduced UGT1A1 activity for adverse reactions. Withhold or permanently discontinue TRODELVY based on clinical assessment of the onset, duration and severity of the observed adverse reactions in patients with evidence of acute early-onset or unusually severe adverse reactions, which may indicate reduced UGT1A1 function.

Embryo-Fetal Toxicity: Based on its mechanism of action, TRODELVY can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant woman. TRODELVY contains a genotoxic component, SN-38, and targets rapidly dividing cells. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TRODELVY and for 6 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRODELVY and for 3 months after the last dose.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

In the pooled safety population, the most common (≥ 25%) adverse reactions including laboratory abnormalities were decreased leukocyte count (84%), decreased neutrophil count (75%), decreased hemoglobin (69%), diarrhea (64%), nausea (64%), decreased lymphocyte count (63%), fatigue (51%), alopecia (45%), constipation (37%), increased glucose (37%), decreased albumin (35%), vomiting (35%), decreased appetite (30%), decreased creatinine clearance (28%), increased alkaline phosphatase (28%), decreased magnesium (27%), decreased potassium (26%), and decreased sodium (26%).

In the ASCENT study (locally advanced or metastatic triple-negative breast cancer), the most common adverse reactions (incidence ≥25%) were fatigue, diarrhea, nausea, alopecia, constipation, vomiting, abdominal pain, and decreased appetite. The most frequent serious adverse reactions (SAR) (>1%) were neutropenia (7%), diarrhea (4%), and pneumonia (3%). SAR were reported in 27% of patients, and 5% discontinued therapy due to adverse reactions. The most common Grade 3-4 lab abnormalities (incidence ≥25%) in the ASCENT study were reduced neutrophils, leukocytes, and lymphocytes.

In the TROPiCS-02 study (locally advanced or metastatic HR-positive, HER2-negative breast cancer), the most common adverse reactions (incidence ≥25%) were diarrhea, fatigue, nausea, alopecia, and constipation. The most frequent serious adverse reactions (SAR) (>1%) were diarrhea (5%), febrile neutropenia (4%), neutropenia (3%), abdominal pain, colitis, neutropenic colitis, pneumonia, and vomiting (each 2%). SAR were reported in 28% of patients, and 6% discontinued therapy due to adverse reactions. The most common Grade 3-4 lab abnormalities (incidence ≥25%) in the TROPiCS-02 study were reduced neutrophils and leukocytes.

In the TROPHY study (locally advanced or metastatic urothelial cancer), the most common adverse reactions (incidence ≥25%) were diarrhea, fatigue, nausea, any infection, alopecia, decreased appetite, constipation, vomiting, rash, and abdominal pain. The most frequent serious adverse reactions (SAR) (≥5%) were infection (18%), neutropenia (12%, including febrile neutropenia in 10%), acute kidney injury (6%), urinary tract infection (6%), and sepsis or bacteremia (5%). SAR were reported in 44% of patients, and 10% discontinued due to adverse reactions. The most common Grade 3-4 lab abnormalities (incidence ≥25%) in the TROPHY study were reduced neutrophils, leukocytes, and lymphocytes.

DRUG INTERACTIONS

UGT1A1 Inhibitors: Concomitant administration of TRODELVY with inhibitors of UGT1A1 may increase the incidence of adverse reactions due to potential increase in systemic exposure to SN-38. Avoid administering UGT1A1 inhibitors with TRODELVY.

UGT1A1 Inducers: Exposure to SN-38 may be reduced in patients concomitantly receiving UGT1A1 enzyme inducers. Avoid administering UGT1A1 inducers with TRODELVY.

Please see accompanying full Prescribing Information, including BOXED WARNING.

For more information about reimbursement, billing, and coding for TRODELVY, please contact:
TRODELVY ACCESS SUPPORT
Phone: 1-844-TRODELVY (876-3358) Monday-Friday, 9 AM-7 PM ET
www.TRODELVY.com

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