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. Immunomedics 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.

INDICATION

TRODELVY™ (sacituzumab govitecan-hziy) is indicated for the treatment of adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease.

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.

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
• J9999	Not otherwise classified, antineoplastic drugs	For all payers and settings of care for which HCPCS codes are reported
• J3590	Unclassified biologics	
• J3490	Unclassified drugs	
• C9399	Unclassified drugs or biologics	This code is for Medicare patients and applies to hospitals and facilities who bill under the Outpatient Prospective Payment System (OPPS). A few Medicaid and private payers may also use this code

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 code 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 is supplied as 180 mg of sacituzumab govitecan-hziy as lyophilized powder in a single-use vial

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. Please refer to the Full Prescribing Information for complete Dosage 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)

Please see Important Safety Information on the following pages and click here for full Prescribing Information, including boxed Warning, and Patient Information.

TRODELVY™
sacituzumab govitecan-hziy
180 mg for injection

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	Description
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast

These are only 2 examples of applicable ICD-10-CM codes.
To see all ICD-10-CM codes for breast cancer see **https://www.cms.gov/Medicare/Coding/ICD10/index.html**.
Immunomedics Inc., is not responsible for the accuracy of this site.

IMPORTANT SAFETY INFORMATION

WARNING: NEUTROPENIA AND DIARRHEA
Severe 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. Administer atropine, if not contraindicated, for early diarrhea of any severity. At the onset of late 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.

Contraindications

TRODELVY is contraindicated in patients who have experienced a severe hypersensitivity reaction to TRODELVY.

Hypersensitivity

TRODELVY can cause severe and life-threatening hypersensitivity. Anaphylactic reactions have been observed in clinical trials with TRODELVY.

Hypersensitivity reactions within 24 hours of dosing occurred in 37% (151/408) of patients treated with TRODELVY. Grade 3-4 hypersensitivity occurred in 1% (6/408) of patients treated with TRODELVY. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 1% (3/408).

Pre-infusion medication for patients receiving TRODELVY is recommended. Observe patients closely for infusion-related reactions during each TRODELVY infusion and for at least 30 minutes after completion of each infusion. Medication to treat such reactions, as well as emergency equipment, should be available for immediate use.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Nausea and Vomiting

TRODELVY is emetogenic. Nausea occurred in 69% (74/108) of patients with mTNBC and 69% (281/408) of all patients treated with TRODELVY. Grade 3 nausea occurred in 6% (7/108) and 5% (22/408) of these populations, respectively. Vomiting occurred in 49% (53/108) of patients with mTNBC and 45% (183/408) of all patients treated with TRODELVY. Grade 3 vomiting occurred in 6% (7/108) and 4% (16/408) of these patients, respectively.

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 at the time of scheduled treatment administration 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.

Use in Patients with Reduced UGT1A1 Activity

Individuals who are homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk for neutropenia and may be at increased risk for other adverse reactions following initiation of TRODELVY treatment.

In 84% (343/408) of patients who received TRODELVY (up to 10 mg/kg on Days 1 and 8 of a 21-day cycle) and had retrospective UGT1A1 genotype results available, the incidence of Grade 4 neutropenia was 26% (10/39) in patients homozygous for the UGT1A1*28 allele, 13% (20/155) in patients heterozygous for the UGT1A1*28 allele and 11% (16/149) in patients homozygous for the wild-type allele.

Closely monitor patients with reduced UGT1A1 activity for severe neutropenia. The appropriate dose for patients who are homozygous for UGT1A1*28 is not known and should be considered based on individual patient tolerance to treatment.

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.

Lactation

There is no information regarding the presence of sacituzumab govitecan-hziy or SN-38 in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment and for 1 month after the last dose of TRODELVY.

Adverse Reactions

Most common adverse reactions (incidence ≥25%) in patients with mTNBC are nausea (69%), neutropenia (64%), diarrhea (63%), fatigue (57%), anemia (52%), vomiting (49%), alopecia (38%), constipation (34%), rash (31%), decreased appetite (30%), abdominal pain (26%), and respiratory infection (26%).

Click here for full Prescribing Information, including boxed Warning, and Patient Information.

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

Immunomedics

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