TRODELVY™
sacituzumab govitecan-hziy
180 mg for injection

PATIENT ACCESS AND REIMBURSEMENT SUPPORT FOR TRODELVY IS AVAILABLE

New C-code C-9066, effective October 2020

TRODELVY™ ACCESS SERVICES

TRODELVY ACCESS SERVICES is a patient access and reimbursement support program. It will help you and your patient understand specific coverage and reimbursement guidelines for TRODELVY 180 mg single-dose vial.

Reimbursement support services include:

- Coverage verification
- Prior authorization information
- Claims status information
- Billing and coding information
- Alternate assistance options

Patient access support includes:

- TRODELVY Savings Program*
- Immunomedics Patient Assistance Program (PAP)†
- Referrals to independent third-party assistance organizations‡

TRODELVY support may vary based on application criteria and is subject to change or discontinuation. Physician office must submit prior authorizations and appeals.

*TRODELVY Savings Program is not available to patients with any form of government insurance. Patients must meet certain eligibility criteria to qualify for this program. Once enrolled the patient pays $0 out-of-pocket for TRODELVY with maximum benefit of $25,000 per year.

†Immunomedics PAP provides TRODELVY free of charge for eligible patients who are uninsured or underinsured. In order to qualify for assistance, patients must meet certain eligibility criteria.

‡Patients with Medicare or other government insurance who need assistance with cost-share requirements for TRODELVY may be eligible for copay or coinsurance assistance through an independent copay assistance foundation. Case managers can help patients assess their high-level eligibility for possible coverage for TRODELVY through an independent copay assistance foundation. If copay assistance needs are identified, the case managers can provide information about any available foundations. The foundation will determine the patient's eligibility for copay or coinsurance assistance based on their own criteria, completely independent of Immunomedics and its agents, and will contact the patient directly regarding the application process. Immunomedics and its agents make no guarantee regarding reimbursement for any service or item.

To enroll a patient into TRODELVY ACCESS SERVICES, please complete the Enrollment Form with your patient and fax to 1-833-851-4344.

Patient Enrollment Form

For further information, please contact TRODELVY ACCESS SERVICES:

- **Phone: 1-844-TRODELVY (1-844-876-3358)**
  Monday – Friday, 9 am – 7 pm ET
- Or **fax inquiries to 1-833-851-4344**

Get complete information about TRODELVY ACCESS SERVICES >

TRODELVY SAVINGS PROGRAM

TRODELVY Savings Program provides savings on out-of-pocket expenses for TRODELVY 180 mg single-dose vial, up to $25,000 annually for commercially or privately insured patients. Terms and conditions apply.§

- Patients pay $0 out of pocket for TRODELVY, which includes co-pay and co-insurance up to $25,000 annually
- The Program only assists with cost of TRODELVY; patient is responsible for cost-share of treatments and office visits
- This Program does not support any claims covered, paid, or reimbursed, in whole or in part, by Medicaid, Medicare, or other federal or state healthcare programs
- See Reimbursement Process below for simple steps to receive savings
- For additional information, contact **TRODELVY ACCESS SERVICES at 1-844-TRODELVY (1-844-876-3358)**, option 4

Reimbursement process
Have your patient complete the Enrollment Form and attach the following:

- An Explanation of Benefits or a dated pharmacy receipt indicating TRODELVY payment should be submitted, if available, within 120 days of the date of service to TRODELVY ACCESS SERVICES
- Submit reimbursement claim and attachments via mail or fax.

MAIL	FAX	PHONE
TRODELVY ACCESS SERVICES 2730 S. Edmonds Ln Suite 300 Lewisville, TX 75067	1-833-851-4344	**Call 1-844-TRODELVY (1-844-876-3358),** select option 4 for assistance.

§**Terms & Conditions**
Eligible patients receive up to a max benefit of $25,000 per year. This offer is not valid for prescriptions covered by or submitted for reimbursement, in whole or in part, under Medicare (including Medicare Part D), Medicaid, similar federal or state funded programs (including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico), or where otherwise prohibited by law. No claims for reimbursement for TRODELVY units dispensed under the TRODELVY Savings Program may be submitted to any public payor (ie, Medicare, Medicaid, Medigap, Tricare, VA, and DoD). Product dispensed pursuant to program rules and federal and state laws. Immunomedics reserves the right to rescind, revoke, or amend this offer without notice at any time. Not valid if reproduced. This offer is valid for US residents only. Void where prohibited by law. Terms expire at the end of each calendar year and may change.

IMMUNOMEDICS PATIENT ASSISTANCE PROGRAM

Patients who are uninsured or underinsured may be eligible to obtain access to TRODELVY at no cost through the Immunomedics Patient Assistance Program. To qualify for assistance, patients must meet certain eligibility criteria.

- To determine patient eligibility, fax a completed PAP Enrollment Form to 1-833-851-4344

or

- Mail to:
  TRODELVY ACCESS SERVICES
  2730 S. Edmonds Ln
  Suite 300
  Lewisville, TX 75067

A Case Manager will contact your office with determination of patient's eligibility.

For more information regarding the Patient Assistance Program, please contact **TRODELVY ACCESS SERVICES** at **1-844-TRODELVY (1-844-876-3358)**

THIRD-PARTY ASSISTANCE REFERRALS

TRODELVY ACCESS SERVICES Case Managers can provide patients who are unable to afford their medication (including those with Medicare, Medicaid, or other government-sponsored insurance) with information about independent third-party organizations that may be able to help with the cost of treatment.

- Your practice or your patients can call **1-844-TRODELVY (1-844-876-3358)**, option 4 for more information

Reimbursement, billing, and coding
Coverage, coding, and billing requirements for TRODELVY may vary by plan and patient. Please download the resource guide below to assist you with proper coding to help optimize reimbursement support.

Reimbursement & Billing Guide

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 2 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.

IMPORTANT SAFETY INFORMATION

WARNING: NEUTROPENIA AND DIARRHEA

TRODELVY can cause severe or life-threatening neutropenia. Withhold TRODELVY for absolute neutrophil count (ANC) below 1500/mm^3 on Day 1 of any cycle or ANC below 1000/mm^3 on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever.

Monitor blood cell counts periodically during treatment. Consider Granulocyte Colony-Stimulating Factor (G-CSF) for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.

- Dose modifications may be required due to neutropenia. Febrile neutropenia occurred in 6% (24/408) of patients treated with TRODELVY, including 8% (9/108) of patients with mTNBC after at least 2 prior therapies. Less than 1% (1/408) of patients had febrile neutropenia leading to permanent discontinuation. The incidence of Grade 1-4 neutropenia was 64% in patients with mTNBC (n=108). In all patients treated with TRODELVY (n=408), the incidence of Grade 1-4 neutropenia was 54%; Grade 4 neutropenia occurred in 13%. Less than 1% (2/408) of patients permanently discontinued treatment due to neutropenia.

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.

- Diarrhea occurred in 63% (68/108) of patients with mTNBC and 62% (254/408) of all patients treated with TRODELVY. In each population, events of Grade 3-4 occurred in 9% (10/108) of mTNBC patients and 9% (36/408) of all patients treated with TRODELVY. Four out of 408 patients (<1%) discontinued treatment because of diarrhea. Neutropenic colitis was observed in 2% (2/108) of patients in the mTNBC cohort and 1% of all patients treated with TRODELVY.

Contraindications: Severe hypersensitivity reaction to TRODELVY.

Hypersensitivity

- TRODELVY can cause severe and life-threatening hypersensitivity, including anaphylactic reactions. Hypersensitivity reactions occurred within 24 hours of dosing in 37% (151/408) and Grade 3-4 hypersensitivity occurred in 1% (6/408) of all patients treated with TRODELVY (n=408). 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.

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 2- or 3-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 events following initiation of TRODELVY treatment. 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.
- 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.

Embryo-Fetal Toxicity

- TRODELVY contains a genotoxic component and can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant woman. 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 following 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

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%).

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Immunomedics

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