# Trodelvy® (sacituzumab govitecan-hziy)
## (Intravenous)

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Document Number: EOCCO-0587

**Last Review Date: 05/02/2024**
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**Dates Reviewed: 02/2021, 06/2021, 05/2022, 04/2023, 05/2024**

## I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

## II. Dosing Limits

**A. Quantity Limit (max daily dose) [NDC Unit]:**

- Trodelvy 180 mg single-dose vial: 12 vials every 21 days

**B. Max Units (per dose and over time) [HCPCS Unit]:**

- 432 billable units weekly for two doses every 21 days

## III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

**Universal Criteria [1]**

- Therapy will NOT be substituted for or used in combination with irinotecan; **AND**
- Patients that are homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele will be closely monitored for adverse reactions; **AND**
- Therapy will not be used in combination with UGT1A1 inhibitors (e.g., nilotinib, regorafenib, etc.) or inducers (e.g., phenytoin, carbamazepine, etc.); **AND**
- Used as a single agent; **AND**

### Breast Cancer † ‡ [1-3]

- Patient has triple-negative breast cancer [TNBC] **Ψ** (i.e., estrogen, progesterone, and HER2-negative); **AND**
    - Patient was previously treated with at least two systemic therapies (including a taxane), at least one of them for metastatic disease; **AND**

Patient has unresectable locally advanced disease; **OR**

- Patient has recurrent unresectable or metastatic disease; **OR**

- Patient has hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative disease*; **AND**
  - Patient has received prior treatment including endocrine therapy, a CDK4/6 inhibitor (e.g., palbociclib, ribociclib, abemaciclib, etc.), and at least two lines of chemotherapy (including a taxane) at least one of which was in the metastatic setting; **AND**
    - Patient has unresectable locally advanced or metastatic disease; **OR**
    - Patient has recurrent unresectable disease ‡; **AND**
      - Patient is not a candidate for fam-trastuzumab deruxtecan

## Urothelial Cancer (Bladder Cancer) † ‡ [1,2,10]

- Patient has one of the following diagnoses:
  - Locally advanced or metastatic urothelial carcinoma †; **OR**
  - Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder treated with curative intent ‡; **OR**
  - Metastatic or local bladder cancer recurrence post-cystectomy treated with curative intent ‡; **OR**
  - Primary carcinoma of the urethra ‡; **AND**
    - Used for recurrent *(excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes)* or metastatic disease; **OR**
  - Metastatic upper genitourinary (GU) tract tumors ‡; **OR**
  - Metastatic urothelial carcinoma of the prostate ‡; **AND**
- Patient was previously treated with platinum-containing chemotherapy** and programmed death (PD-1 or PD-L1)-directed therapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, etc.)

***ote:*** [12-14]

- *Cisplatin-ineligible comorbidities may include the following: CrCl < 60 mL/min, ECOG PS ≥ 2 or KPS ≤ 70%, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, grade ≥ 2 peripheral neuropathy, or NYHA Heart Failure class ≥ 3. Carboplatin may be substituted for cisplatin in the metastatic setting for cisplatin-ineligible patients such as those with a GFR less than 60 mL/min.*
- *Platinum-ineligible comorbidities may include the following: CrCl < 30 mL/min, ECOG PS ≥ 3, grade ≥ 2 peripheral neuropathy, or NYHA Heart Failure class > 3, etc.*

**Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.**

| *HER2-negative expression criteria: [3,8] |
|---|
| Immunohistochemistry (IHC) assay is 0 or 1+; **OR**<br>Dual-probe in situ hybridization (ISH) assay indicating (Group 5) HER2/CEP17 ratio <2.0 AND average HER2 copy number <4.0 signals/cell; **OR**<br>Concurrent dual-probe ISH and IHC assay results indicating one of the following:<br>○ (Group 2) HER2/CEP17 ratio ≥2.0 AND average HER2 copy number <4.0 signals/cell and concurrent IHC 0-1+ or 2+; **OR**<br>○ (Group 3) HER2/CEP17 ratio <2.0 AND average HER2 copy number ≥6.0 signals/cell and concurrent IHC 0-1+; **OR**<br>○ (Group 4) HER2/CEP17 ratio <2.0 AND average HER2 copy number ≥4.0 and <6.0 signals/cell and concurrent IHC 0-1+ or 2+ |

| Ψ ER Scoring Interpretation *(following ER testing by validated IHC assay)* | |
|---|---|
| **Results** | **Interpretation** |
| – 0% – <1% of nuclei stain | – ER-negative |
| – 1%–10% of nuclei stain | – ER-low–positive* |
| – >10% of nuclei stain | – ER-positive |
| **Note: Patients with cancers with ER-low–positive (1%–10%) results are a heterogeneous group with reported biologic behavior often similar to ER-negative cancers; thus, as such these cancers inherently behave aggressively and may be treated similar to triple-negative disease. Individualized consideration of risks versus benefits should be incorporated into decision-making.* | |

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

## IV. Renewal Criteria [1]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity and infusion-related reactions (including anaphylactic reactions), severe nausea/vomiting, severe neutropenia/febrile neutropenia, severe anemia, severe diarrhea, etc.

## V. Dosage/Administration [1]

| Indication | Dose |
|---|---|
| Breast Cancer/ Bladder Cancer | Administer 10 mg/kg as an intravenous infusion once weekly on Days 1 and 8 of 21-day treatment cycles. Continue treatment until disease progression or unacceptable toxicity. Do not administer doses greater than 10 mg/kg. |

## VI. Billing Code/Availability Information

HCPCS Code:

J9317 – Injection, sacituzumab govitecan-hziy, 2.5 mg; 1 billable unit = 2.5 mg

NDC:

Trodelvy 180 mg lyophilized powder in a single-dose vial: 55135-0132-xx

## VII. References (STANDARD)


1. Trodelvy [package insert]. Foster City, CA; Gilead Sciences, Inc.; February 2023. Accessed March 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) sacituzumab govitecan. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2024.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer 2.2024. National Comprehensive Cancer Network, 2024. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed March 2024.
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5. Hematology/Oncology Pharmacy Association (2019). *Intravenous Cancer Drug Waste Issue Brief*. Retrieved from http://www.hoparx.org/images/hopa/advocacy/Issue-Briefs/Drug_Waste_2019.pdf

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10. Tagawa S, Balar A, Petrylak, et al. TROPHY-U-01: A Phase II Open-Label Study of Sacituzumab Govitecan in Patients With Metastatic Urothelial Carcinoma Progressing After Platinum-Based Chemotherapy and Checkpoint Inhibitors. J Clin Oncol. 2021 Aug 1;39(22):2474-2485. doi: 10.1200/JCO.20.03489. Epub 2021 Apr 30.
11. Rugo HS, Bardia A, Marme F, et al. Sacituzumab Govitecan in Hormone Receptor-Positive/Human Epidermal Growth Factor Receptor 2-Negative Metastatic Breast Cancer. J Clin Oncol. 2022 Oct 10;40(29):3365-3376. doi: 10.1200/JCO.22.01002. Epub 2022 Aug 26.
12. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 1.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2024.
13. Bellmunt, J. (2024). Treatment of metastatic urothelial cancer of the bladder and urinary tract. In Lerner SP, Shah S (Eds.), *UptoDate*. Last updated: February 7, 2024. Accessed February 20, 2024. Available from https://www.uptodate.com/contents/treatment-of-metastatic-urothelial-cancer-of-the-bladder-and-urinary-tract?search=cisplatin%20ineligible&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1.
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## VIII. References (ENHANCED)

1e. Loriot Y, Necchi Am, Park SH, et al. Erdafitinib in Locally Advanced or Metastatic Urothelial Carcinoma. N Engl J Med 2019; 381:338-348.
2e. Sideris S, Aoun F, Zanaty M, et al. Efficacy of weekly paclitaxel treatment as a single agent chemotherapy following first-line cisplatin treatment in urothelial bladder cancer. Mol Clin Oncol. 2016 Jun;4(6):1063-1067. doi: 10.3892/mco.2016.821. Epub 2016 Mar 17.

3e. McCaffrey JA, Hilton S, Mazumdar M, et al. Phase II trial of docetaxel in patients with advanced or metastatic transitional-cell carcinoma. J Clin Oncol. 1997 May;15(5):1853-7. doi: 10.1200/JCO.1997.15.5.1853.
4e. Prime Therapeutics Management. Trodelvy Clinical Literature Review Analysis. Last updated March 2024. Accessed March 2024.

## Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|---|---|
| C50.011 | Malignant neoplasm of nipple and areola, right female breast |
| C50.012 | Malignant neoplasm of nipple and areola, left female breast |
| C50.019 | Malignant neoplasm of nipple and areola, unspecified female breast |
| C50.021 | Malignant neoplasm of nipple and areola, right male breast |
| C50.022 | Malignant neoplasm of nipple and areola, left male breast |
| C50.029 | Malignant neoplasm of nipple and areola, unspecified male breast |
| C50.111 | Malignant neoplasm of central portion of right female breast |
| C50.112 | Malignant neoplasm of central portion of left female breast |
| C50.119 | Malignant neoplasm of central portion of unspecified female breast |
| C50.121 | Malignant neoplasm of central portion of right male breast |
| C50.122 | Malignant neoplasm of central portion of left male breast |
| C50.129 | Malignant neoplasm of central portion of unspecified male breast |
| C50.211 | Malignant neoplasm of upper-inner quadrant of right female breast |
| C50.212 | Malignant neoplasm of upper-inner quadrant of left female breast |
| C50.219 | Malignant neoplasm of upper-inner quadrant of unspecified female breast |
| C50.221 | Malignant neoplasm of upper-inner quadrant of right male breast |
| C50.222 | Malignant neoplasm of upper-inner quadrant of left male breast |
| C50.229 | Malignant neoplasm of upper-inner quadrant of unspecified male breast |
| C50.311 | Malignant neoplasm of lower-inner quadrant of right female breast |
| C50.312 | Malignant neoplasm of lower-inner quadrant of left female breast |
| C50.319 | Malignant neoplasm of lower-inner quadrant of unspecified female breast |
| C50.321 | Malignant neoplasm of lower-inner quadrant of right male breast |
| C50.322 | Malignant neoplasm of lower-inner quadrant of left male breast |
| C50.329 | Malignant neoplasm of lower-inner quadrant of unspecified male breast |
| C50.411 | Malignant neoplasm of upper-outer quadrant of right female breast |
| C50.412 | Malignant neoplasm of upper-outer quadrant of left female breast |

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|---|---|
| C50.419 | Malignant neoplasm of upper-outer quadrant of unspecified female breast |
| C50.421 | Malignant neoplasm of upper-outer quadrant of right male breast |
| C50.422 | Malignant neoplasm of upper-outer quadrant of left male breast |
| C50.429 | Malignant neoplasm of upper-outer quadrant of unspecified male breast |
| C50.511 | Malignant neoplasm of lower-outer quadrant of right female breast |
| C50.512 | Malignant neoplasm of lower-outer quadrant of left female breast |
| C50.519 | Malignant neoplasm of lower-outer quadrant of unspecified female breast |
| C50.521 | Malignant neoplasm of lower-outer quadrant of right male breast |
| C50.522 | Malignant neoplasm of lower-outer quadrant of left male breast |
| C50.529 | Malignant neoplasm of lower-outer quadrant of unspecified male breast |
| C50.611 | Malignant neoplasm of axillary tail of right female breast |
| C50.612 | Malignant neoplasm of axillary tail of left female breast |
| C50.619 | Malignant neoplasm of axillary tail of unspecified female breast |
| C50.621 | Malignant neoplasm of axillary tail of right male breast |
| C50.622 | Malignant neoplasm of axillary tail of left male breast |
| C50.629 | Malignant neoplasm of axillary tail of unspecified male breast |
| C50.811 | Malignant neoplasm of overlapping sites of right female breast |
| C50.812 | Malignant neoplasm of overlapping sites of left female breast |
| C50.819 | Malignant neoplasm of overlapping sites of unspecified female breast |
| C50.821 | Malignant neoplasm of overlapping sites of right male breast |
| C50.822 | Malignant neoplasm of overlapping sites of left male breast |
| C50.829 | Malignant neoplasm of overlapping sites of unspecified male breast |
| C50.911 | Malignant neoplasm of unspecified site of right female breast |
| C50.912 | Malignant neoplasm of unspecified site of left female breast |
| C50.919 | Malignant neoplasm of unspecified site of unspecified female breast |
| C50.921 | Malignant neoplasm of unspecified site of right male breast |
| C50.922 | Malignant neoplasm of unspecified site of left male breast |
| C50.929 | Malignant neoplasm of unspecified site of unspecified male breast |
| C61 | Malignant neoplasm of prostate |
| C65.1 | Malignant neoplasm of right renal pelvis |
| C65.2 | Malignant neoplasm of left renal pelvis |
| C65.9 | Malignant neoplasm of unspecified renal pelvis |
| C66.1 | Malignant neoplasm of right ureter |

| | |
|---|---|
| C66.2 | Malignant neoplasm of left ureter |
| C66.9 | Malignant neoplasm of unspecified ureter |
| C67.0 | Malignant neoplasm of trigone of bladder |
| C67.1 | Malignant neoplasm of dome of bladder |
| C67.2 | Malignant neoplasm of lateral wall of bladder |
| C67.3 | Malignant neoplasm of anterior wall of bladder |
| C67.4 | Malignant neoplasm of posterior wall of bladder |
| C67.5 | Malignant neoplasm of bladder neck |
| C67.6 | Malignant neoplasm of ureteric orifice |
| C67.7 | Malignant neoplasm of urachus |
| C67.8 | Malignant neoplasm of overlapping sites of bladder |
| C67.9 | Malignant neoplasm of bladder, unspecified |
| C68.0 | Malignant neoplasm of urethra |
| D09.0 | Carcinoma in situ of bladder |
| Z85.3 | Personal history of malignant neoplasm of breast |
| Z85.51 | Personal history of malignant neoplasm of bladder |
| Z85.59 | Personal history of malignant neoplasm of other urinary tract organ |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| **Jurisdiction** | **Applicable State/US Territory** | **Contractor** |
| E (1) | CA, HI, NV, AS, GU, CNMI | Noridian Healthcare Solutions, LLC |
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |
| 5 | KS, NE, IA, MO | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6 | MN, WI, IL | National Government Services, Inc. (NGS) |
| H (4 & 7) | LA, AR, MS, TX, OK, CO, NM | Novitas Solutions, Inc. |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| **Jurisdiction** | **Applicable State/US Territory** | **Contractor** |
| 8 | MI, IN | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9) | FL, PR, VI | First Coast Service Options, Inc. |
| J (10) | TN, GA, AL | Palmetto GBA |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |
| 15 | KY, OH | CGS Administrators, LLC |