

Trodelvy® (sacituzumab govitecan-hziy) (Intravenous)

Document Number: IC-0532

Last Review Date: 01/06/2025

Date of Origin: 06/02/2020

Dates Reviewed: 06/2020, 09/2020, 01/2021, 05/2021, 03/2022, 03/2023, 03/2024, 01/2025

I. Length of Authorization

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

II. Dosing Limits

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

- 864 billable units 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 has unresectable locally advanced disease; **AND**
 - Patient was previously treated with at least two systemic therapies, at least one of them for metastatic disease; **OR**
 - Patient has recurrent unresectable or metastatic disease OR inflammatory breast cancer with no response to preoperative systemic therapy; **AND**
 - Patient was previously treated with at least one prior therapy for metastatic disease; **OR**
- Patient has hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative disease*; **AND**
 - Patient has unresectable locally advanced, or metastatic disease; **AND**

- Patient was previously treated with endocrine therapy and at least two additional lines of systemic therapy for metastatic disease; **OR**
- Patient has recurrent unresectable disease OR inflammatory breast cancer with no response to preoperative systemic therapy ‡; **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 is not a candidate for fam-trastuzumab deruxtecan

Urothelial Cancer (Bladder Cancer) ‡^{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.)

**** Note:** 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.*

***HER2-negative expression criteria:** ^{3,8}

- Immunohistochemistry (IHC) assay is 0 or 1+; **OR**
- 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**
- Concurrent dual-probe ISH and IHC assay results indicating one of the following:

- (Group 2) HER2/CEP17 ratio ≥ 2.0 AND average HER2 copy number < 4.0 signals/cell and concurrent IHC 0-1+ or 2+; OR
- (Group 3) HER2/CEP17 ratio < 2.0 AND average HER2 copy number ≥ 6.0 signals/cell and concurrent IHC 0-1+; OR
- (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: Invasive cancers with between 1%–10% ER positivity are considered ER-low–positive. However, this group is noted to be heterogeneous and the biologic behavior of ER-low–positive cancers may be more similar to ER-negative cancers. This should be considered in decision making for other adjuvant therapy and overall treatment pathway..*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ 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
All indications	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

1. Trodelvy [package insert]. Foster City, CA; Gilead Sciences, Inc.; November 2024. Accessed December 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 December 2024.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Breast Cancer 6.2024. 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 December 2024.
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12. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 5.2024. 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 December 2024.
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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
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.
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