

Trodelvy® (sacituzumab govitecan-hziy) (Intravenous)

Document Number: IC-0532

Last Review Date: 08/04/2026

Date of Origin: 06/02/2020

Dates Reviewed: 06/2020, 09/2020, 01/2021, 05/2021, 03/2022, 03/2023, 03/2024, 01/2025, 02/2026, 08/2026

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter.

II. Dosing Limits

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

- 864 billable units every 21 days

III. Initial Approval Criteria ¹

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**
- Members at increased risk of febrile neutropenia (*including older members, members with previous neutropenia, poor performance status, organ dysfunction, or multiple comorbidities*) will receive primary prophylaxis with a granulocyte colony stimulating factor (G-CSF) starting in the first cycle of treatment; **AND**

Universal Criteria ¹

- Therapy will NOT be substituted for or used in combination with irinotecan; **AND**
- Members 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**

Breast Cancer † ‡ ¹⁻³

- Used as a single agent; **AND**
 - Member has triple-negative breast cancer [TNBC] **Ψ** (i.e., estrogen, progesterone, and HER2-negative); **AND**
 - Member has unresectable or metastatic disease OR inflammatory breast cancer with no response to preoperative therapy; **AND**
 - Used as first-line treatment; **AND**

- Member is not a candidate for programmed death (PD-1 or PD-L1) inhibitor based therapy (i.e., PD-L1 combined positive score [CPS] <10, PD-1 or PD-L1 received in the neoadjuvant or adjuvant setting, or member has a comorbidity precluding treatment); **OR**
 - Used as second-line or later therapy; **OR**
- Member has hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative disease*; **AND**
 - Member has unresectable or metastatic OR inflammatory breast cancer with no response to preoperative therapy; **AND**
 - Member 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; **OR**
- Used in combination with pembrolizumab; **AND**
 - Member has triple-negative breast cancer [TNBC] Ψ (i.e., estrogen, progesterone, and HER2-negative); **AND**
 - Member has unresectable or metastatic disease OR inflammatory breast cancer with no response to preoperative therapy; **AND**
 - Tumor expresses PD-L1 (combined positive score [CPS] ≥ 10) as determined by an FDA-approved or Clinical Laboratory Improvement Amendments (CLIA)-compliant test $\diamond$; **AND**
 - Used as first-line treatment

Urothelial Cancer (Bladder Cancer) ∇ ^{2,10}

- Used as a single agent; **AND**
- Member 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**
- Used as subsequent therapy for members previously treated with platinum-containing chemotherapy** and programmed death (PD-1 or PD-L1)-directed therapy

**** 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 members 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**
- IHC assay indicating (Group 5) HER2 (*ERBB2*)/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 (*ERBB2*)/CEP17 ratio ≥2.0 AND average HER2 (*ERBB2*) copy number <4.0 signals/cell and concurrent IHC 0-1+ or 2+; **OR**
 - (Group 3) HER2 (*ERBB2*)/CEP17 ratio <2.0 AND average HER2 (*ERBB2*) copy number ≥6.0 signals/cell and concurrent IHC 0-1+; **OR**
 - (Group 4) HER2 (*ERBB2*)/CEP17 ratio <2.0 AND average HER2 (*ERBB2*) copy number ≥4.0 and <6.0 signals/cell and concurrent IHC 0-1+ or 2+

***The distinction between HER2 (*ERBB2*) IHC 0/absent membrane staining, IHC 0+/ with membrane staining (faint, partial membrane staining, in ≤10%), IHC 1+, or 2+/ISH negative results (on primary or metastatic samples) is currently clinically relevant since members with metastatic disease may be eligible for treatment targeting non-amplified levels of HER2 expression.

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..

❖ If confirmed using an FDA-approved assay – <http://www.fda.gov/companiondiagnostics>

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

IV. Renewal Criteria ¹

Prior authorization validity can be renewed based upon the following criteria:

- Member 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.; June 2026. Accessed July 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium[®]) sacituzumab govitecan. National Comprehensive Cancer Network, 2026. 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 July 2026.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Breast Cancer 5.2026. National Comprehensive Cancer Network, 2026. 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 July 2026.
4. Fahrenbruch R, Kintzel P, Bott AM, et al. Dose Rounding of Biologic and Cytotoxic Anticancer Agents: A Position Statement of the Hematology/Oncology Pharmacy Association. J Oncol Pract. 2018 Mar;14(3):e130-e136.

5. Hematology/Oncology Pharmacy Association (Updated January 2022). Intravenous Cancer Drug Waste Issue Brief. Retrieved from: https://www.hoparx.org/documents/65/HOPA_Drug_Waste_Issue_Brief_-_Updated_01.19.22_FINAL.pdf
6. Bach PB, Conti RM, Muller RJ, et al. Overspending driven by oversized single dose vials of cancer drugs. *BMJ*. 2016 Feb 29;352:i788.
7. Bardia A, Mayer IA, Vahdat LT, et al. Sacituzumab Govitecan-hziy in Refractory Metastatic Triple-Negative Breast Cancer. *N Engl J Med*. 2019 Feb 21;380(8):741-751. doi: 10.1056/NEJMoa1814213.
8. Wolff AC, Hammond EH, Allison KH, et al. Human epidermal growth factor receptor 2 testing in breast cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. *J Clin Oncol* 2018;36:2105-2122.
9. Allison KH, Hammond EH, Dowsett M, et al. Estrogen and Progesterone Receptor Testing in Breast Cancer: ASCO/CAP Guideline Update. *J Clin Oncol* 38:1346-1366.
10. Tagawa S, Balar A, Petrylak, et al. TROPY-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 3.2025. National Comprehensive Cancer Network, 2025. 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 January 2026.
13. Bellmunt J, Valderrama BP (2026). Treatment of metastatic urothelial cancer of the bladder and urinary tract. In Lerner SP, Shah SM (Eds.), *UptoDate*. Last updated: January 05, 2026. Accessed January 22, 2026. Available from <https://www.uptodate.com/contents/treatment-of-metastatic-urothelial-cancer-of-the-bladder-and-urinary-tract>.
14. Gupta S, Bellmunt J, Plimack ER, et al. Defining “platinum-ineligible” patients with metastatic urothelial cancer (mUC). *J Clin Oncol*. 2022 June 1;40(16_suppl):4577.
15. Cortés J, Punie K, Barrios C, et al; ASCENT-03 Clinical Trial Investigators. Sacituzumab govitecan in untreated, advanced triple-negative breast cancer. *N Engl J Med*. 2025;393(19):1912-1925. doi:10.1056/NEJMoa2511734.
16. Tolaney SM, de Azambuja E, Kalinsky K, et al; ASCENT-04/KEYNOTE-D19 Clinical Trial Investigators. Sacituzumab govitecan plus pembrolizumab for advanced triple-negative breast cancer. *N Engl J Med*. 2026;394(4):354-366. doi:10.1056/NEJMoa2508959.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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