Drug Policy:

Trodelvy™ (sacituzumab govitecan-hziy)

POLICY NUMBER UM ONC_1407	SUBJECT Trodelvy™ (sacituzumab govitecan-hziy)		DEPT/PROGRAM UM Dept	PAGE 1 of 4
DATES COMMITTEE REVIEWED 06/10/20, 06/09/21, 07/14/21, 11/10/21, 05/11/22, 09/20/22, 11/09/22, 03/08/23, 09/13/23, 09/18/24, 10/09/24, 01/08/25	APPROVAL DATE January 08, 2025	EFFECTIVE DATE January 31, 2025	COMMITTEE APPROVAL DATES 06/10/20, 06/09/21, 07/14/21, 11/10/21, 05/11/22, 09/20/22, 11/09/22, 03/08/23, 09/13/23, 09/18/24, 10/09/24, 01/08/25	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Evolent Specialty Services Clinical Guideline Review Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses clinical guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this clinical guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their plan customer service representative for specific coverage information.

I. PURPOSE

To define and describe the accepted indications for Trodelvy (sacituzumab govitecan-hziy) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The requested medication was used within the last year, AND

2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Breast Cancer

1. Trodelvy (sacituzumab govitecan-hziy) may be used as monotherapy for members with recurrent/metastatic triple negative breast cancer (ER/PR and HER-2 negative) who have experienced disease progression on at least one systemic therapy regimen in the metastatic setting OR
2. Trodelvy (sacituzumab govitecan-hziy) may be used as monotherapy for members with HR positive (ER and/or PR+) AND HER-2 negative recurrent/metastatic breast cancer with disease progression on 2 or more chemotherapy regimens of which neoadjuvant/adjuvant chemotherapy would comprise 1 regimen if disease recurrence occurred within 12 months of therapy. Members must have previously received at least one Taxane (e.g., paclitaxel/docetaxel), one anticancer hormonal treatment (e.g., tamoxifen), and one CDK4/6 inhibitor (e.g., palbociclib, ribociclib) .

C. Urothelial Cancer

NOTE: On November 22, 2024, the FDA announced the final withdrawal of the approval of sacituzumab govitecan-hziy (Trodelvy) for adult patients with locally advanced or metastatic urothelial cancer (mUC) who previously received a platinum-containing chemotherapy and either a programmed death receptor-1 (PD-1) or a programmed death-ligand 1 (PD-L1) inhibitor.

III. EXCLUSION CRITERIA

A. Disease progression while receiving Trodelvy (sacituzumab govitecan-hziy).

B. Concurrent use with other anti-cancer therapy.

C. Member with HER-2 positive and/or ER/PR positive breast cancer.

D. Dosing exceeds single dose limit of Trodelvy (sacituzumab govitecan-hziy) 10 mg/kg.

E. Investigational use of Trodelvy (sacituzumab govitecan-hziy) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.

6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. CODING INFORMATION

HCPCS Code	Description
J9317	Injection, sacituzumab govitecan-hziy, 2.5 mg

V. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

VI. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VII. ATTACHMENTS

A. None

VIII. REFERENCES

A. Rugo HS, et al. TROPiCS-02 Clinical Trial. Sacituzumab Govitecan in Hormone Receptor-Positive/Human Epidermal Growth Factor Receptor 2-Negative Metastatic Breast Cancer. J Clin Oncol. 2022 Aug 26. DOI: 10.1200/JCO.22.01002

B. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-sacituzumab-govitecan-advanced-urothelial-cancer

C. Tagawa ST, et al. ROPHY-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 Apr 30:JCO2003489.

D. Bardia A et al. ASCENT Clinical Trial. Sacituzumab Govitecan in Metastatic Triple-Negative Breast Cancer. N Engl J Med 2021;384: 1529-41.

E. Trodelvy prescribing information 2024. Gilead Sciences, Inc., Foster City, CA

F. Clinical Pharmacology Elsevier Gold Standard 2025.

G. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2025.

H. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2025.

I. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2025.

J. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

K. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.