Evolent Clinical Guideline 3261 for Trodelvy™ (sacituzumab govitecan-hziy)

Guideline Number: Evolent_CG_3261	**Applicable Codes**	
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STATEMENT

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.

INDICATIONS

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

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Breast Cancer

- Trodelvy (sacituzumab govitecan-hziy) may be used as monotherapy in adult members for the first-line treatment of recurrent or metastatic (Stage IV) triple negative breast cancer (ER/PR and HER-2 negative) with PD-L1 CPS <10 and no germline BRCA 1/2 pathogenic variants (PVs).
- Trodelvy (sacituzumab govitecan-hziy) may be used as monotherapy for adult members with recurrent or metastatic (Stage IV) 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.
- Trodelvy (sacituzumab govitecan-hziy) may be used as monotherapy for adult 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).
- Trodelvy (sacituzumab govitecan-hziy) may be used in combination with Keytruda

(pembrolizumab) in adult members for the first-line treatment of recurrent or metastatic (Stage IV) triple negative breast cancer (ER/PR and HER-2 negative) with PD-L1 CPS ≥10 regardless of germline BRCA 1/2 PV status.

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.

CONTRAINDICATIONS/WARNINGS

- Contraindications
  - Severe hypersensitivity to sacituzumab govitecan-hziy or any component of the formulation
- US Boxed Warning
  - Sacituzumab govitecan-hziy can cause severe, life-threatening, or fatal neutropenia. Withhold sacituzumab govitecan-hziy for ANC below 1,500/mm^3 or neutropenic fever. Monitor blood cell counts periodically during treatment. Primary prophylaxis with G-CSF is recommended for all patients at increased risk of febrile neutropenia. Initiate anti-infective treatment in patients with febrile neutropenia without delay.
  - Sacituzumab govitecan-hziy can cause severe diarrhea. Monitor patients with diarrhea and give fluid and electrolytes as needed. At the onset of diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold sacituzumab govitecan-hziy until resolved to ≤ Grade 1 and reduce subsequent doses.

EXCLUSION CRITERIA

- Disease progression while receiving Trodelvy (sacituzumab govitecan-hziy).
- Member with HER-2 positive breast cancer.
- Dosing exceeds single dose limit of Trodelvy (sacituzumab govitecan-hziy) 10 mg/kg.
- 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:
  - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted

therapy/other oncologic therapy regimen is adequately represented in the published evidence.

- 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.
- 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).
- 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.
- That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
- 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.

CODING AND STANDARDS

Codes

- J9317 - Injection, sacituzumab govitecan-hziy, 2.5 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
July 2026	• Updated references
March 2026	• Updated Breast Cancer indication • Updated exclusion criteria • Updated references
January 2026	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1407 Trodelvy (sacituzumab govitecan-hziy) • Updated indication section • Updated references
January 2025	• Added the following note under urothelial cancer indication: “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.” • Added new reference • Added Evolent disclaimer language • Added Coding Information section with HCPCS code

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

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. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure 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.

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