Utilization Review Policy 237

POLICY: Oncology (Injectable – Antibody-Drug Conjugate – Trop-2) – Trodelvy Utilization Management Medical Policy

- Trodelvy® (sacituzumab govitecan-hziy intravenous infusion – Gilead)

EFFECTIVE DATE: 12/1/2020
LAST REVISION DATE: 01/28/2026

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Trodelvy, a Trop-2-directed antibody and topoisomerase inhibitor conjugate, is indicated for the following uses in adults:[1]

- **Breast cancer,** unresectable locally advanced or metastatic triple-negative disease in adults who have received two or more prior systemic therapies, at least one of them for metastatic disease.
- **Breast cancer,** unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (immunohistochemistry [IHC] 0, IHC 1+, or IHC 2+/in situ hybridization [ISH]–) breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.

The manufacturer voluntarily withdrew Trodelvy's indication for urothelial cancer, following its failure to demonstrate significant overall survival benefits in the confirmatory trial, TROPICS-04.[4]

Guidelines

Trodelvy is addressed in National Comprehensive Cancer Network (NCCN) guidelines:

- **Bladder Cancer:** Guidelines (version 3.2025 – December 19, 2025) list Trodelvy as an option for subsequent-line systemic therapy for locally advanced or metastatic disease (Stage IV) [Other Recommended Regimen; category 2A].[2]
- **Breast Cancer:** Guidelines (version 1.2026 – January 16, 2026) list Trodelvy as a "Preferred Regimen" for patients with metastatic triple-negative breast cancer in the first-line setting either in combination with Keytruda (pembrolizumab intravenous injection) or as a single agent (both category 1, "Preferred").[3] It can also be used as second-line or subsequent therapy. Trodelvy is also a "Preferred Regimen" for patients with HR-positive, HER2-negative cancers after prior treatment, including endocrine therapy, a cyclin dependent kinase (CDK) 4/6 inhibitor, and at least two lines of chemotherapy (one of which was a taxane, and at least one of which was in the metastatic setting), and if patient not a candidate for Enhertu® (fam-trastuzumab deruxtecan-nxki intravenous infusion) for advanced breast cancer (category 1). It may be considered for later line if not used as second-line therapy.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Trodelvy. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of specialized skills required for evaluation and diagnosis of patients treated with Trodelvy as well as the monitoring required

for adverse events and long-term efficacy, approval requires Trodelvy to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Trodelvy is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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1. **Breast Cancer**. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has human epidermal growth factor receptor (HER2)-negative breast cancer; AND
   - **C)** Patient has recurrent or metastatic disease; AND
   - **D)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has hormone receptor (HR)-negative disease; OR
       Note: This is triple-negative disease.
     - **ii.** Patient meets ALL of the following (a, b, c, d, and e):
       - **a)** Patient has hormone receptor (HR)-positive disease; AND
       - **b)** Patient has tried endocrine therapy; AND
       - **c)** Patient has tried a cyclin-dependent kinase (CDK) 4/6 inhibitor; AND
         Note: Examples of CDK 4/6 inhibitors include: Kisqali (ribociclib tablets), Ibrance (palbociclib capsules or tablets), and Verzenio (abemaciclib tablets).
       - **d)** Patient has tried at least two systemic chemotherapy regimens, one of which was tried in the metastatic setting; AND
         Note: Examples of chemotherapy regimens include: paclitaxel, cisplatin, carboplatin, doxorubicin, liposomal doxorubicin, gemcitabine, vinorelbine, Halaven (eribulin intravenous infusion).
       - **e)** Patient is not a candidate for Enhertu (fam-trastuzumab deruxtecan-nxki intravenous infusion) therapy; AND
   - **E)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve if each dose does not exceed 10 mg/kg, administered intravenously once weekly on Days 1 and 8 of each 3-week treatment cycle.

Other Uses with Supportive Evidence

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2. **Urothelial Cancer**. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has locally advanced or metastatic urothelial cancer; AND
   - **C)** Patient tried at least one systemic chemotherapy; AND
     Note: Examples of systemic chemotherapy include cisplatin, carboplatin, gemcitabine, paclitaxel, ifosfamide, doxorubicin.
   - **D)** Patient has tried at least one programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor; AND
     Note: Examples of PD-1 and PD-L1 inhibitors include Bavencio (avelumab intravenous infusion), Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion).
   - **E)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve if each dose does not exceed 10 mg/kg, administered intravenously once weekly on Days 1 and 8 of each 3-week treatment cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Trodelvy is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Trodelvy® intravenous infusion [prescribing information]. Morris Plains, NJ: Gilead; March 2025.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – December 19, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 23, 2026.
3. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 1.2026 – January 16, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 23, 2026.
4. Gilead provides update on U.S. indication for Trodelvy in metastatic urothelial cancer. Press Release. October 18, 2024. Available at: https://www.gilead.com/company/company-statements/2024/gilead-provides-update-on-us-indication-for-trodelvy-in-metastatic-urothelial-cancer. Accessed on January 23, 2026.
5. The NCCN Drugs & Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 23, 2026. Search term: Sacituzumab govitecan-hziy.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Breast Cancer:** The requirement that the patient has "triple-negative" breast cancer was changed to patient has "human epidermal growth factor receptor 2 (HER2) negative" breast cancer. The criterion, "Patient has hormone receptor (HR) negative disease" was added to the requirement of trial of at least two systemic regimens. Criteria was added for patients with hormone receptor positive disease who have tried endocrine therapy, cyclin-dependent kinase (CDK) 4/6 inhibitor, and at least two systemic chemotherapy regimens. A note was added with examples of CDK 4/6 inhibitors and a note was added with examples of chemotherapy.	12/14/2022
Update	**02/08/2023:** The following new FDA-labeled indication was added to the overview section: Breast cancer, unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (immunohistochemistry [IHC] 0, IHC 1+ or IHC 2+/ISH–) breast cancer who have received endocrine based therapy and at least two additional systemic therapies in the metastatic setting.	N/A
Annual Revision	No criteria changes.	12/20/2023
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024
Annual Revision	**Breast Cancer:** Under hormone-receptor negative disease, for criterion requiring at least two systemic regimens, modified it to state "patient has received at least one systemic regimen in the metastatic setting". Under the criteria for hormone receptor positive disease, for the criterion requiring two systemic regimens, added qualifier that one of the regimens was tried in the metastatic setting. For hormone receptor positive disease, also added new criterion requiring that the patient is not a candidate for Enhertu® (fam-trastuzumab deruxtecan-nxki intravenous infusion) therapy. **Urothelial Cancer:** This indication for Trodelvy has been withdrawn by the FDA and removed from the labeling. However, the guidelines recommend Trodelvy for this indication. Moved indication from "FDA-approved Indications" section to "Other Uses with Supportive Evidence".	01/08/2025
Update	04/21/2025: The policy name was changed from "Oncology (Injectable) – Trodelvy UM Medical Policy" to "Oncology (Injectable - Antibody-Drug Conjugate – Trop-2) – Trodelvy UM Medical Policy."	N/A

UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/15/2025
Annual Revision	**Breast Cancer:** Deleted requirement of prior therapy for Trodelvy use in hormone receptor [HR] negative and human epidermal growth factor receptor 2 [HER2] negative disease. Added note that this is triple-negative disease.	01/28/2026

N/A – Not applicable.