VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Trodelvy Utilization Management Medical Policy
- Trodelvy® (sacituzumab govitecan-hziy intravenous infusion – Gilead)

REVIEW DATE: 01/08/2025

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+/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:** NCCN guidelines (version 5.2024 – October 28, 2024) list Trodelvy as an option for subsequent-line systemic therapy for locally advanced or metastatic disease (Stage IV) [Other Recommended Regimen; category 2A].[2] The guidelines have not been updated since the FDA withdrawal of this indication for Trodelvy.
- **Breast Cancer:** NCCN guidelines (version 6.2024 – November 11, 2024) list Trodelvy as a "Preferred Regimen" for patients with metastatic triple-negative breast cancer who have received at least one prior regimen in the metastatic setting (category 1); it may be considered for later line if not used as a second line therapy.[3] 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 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 a 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 meets BOTH of the following (a and b):
    - **a)** Patient has hormone receptor (HR) negative disease; AND
    - **b)** Patient has received at least one systemic regimen in the metastatic setting; OR
      Note: Examples of systemic regimens include: cisplatin, carboplatin, doxorubicin, liposomal doxorubicin, paclitaxel, capecitabine, gemcitabine, vinorelbine, Halaven (eribulin intravenous infusion), Keytruda (pembrolizumab intravenous infusion) + chemotherapy (Abraxane [albumin-bound paclitaxel intravenous infusion], paclitaxel, or gemcitabine and carboplatin).
  - **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 CDK4/6 inhibitors include: Kisqali (ribociclib tablets), Ibrance (palbociclib capsules or tablets), or 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; November 2024.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 5.2024 – October 28, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 6, 2025.
3. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 6.2024 – November 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 6, 2025.
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 13, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
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.	--
Annual Revision	No criteria changes.	12/20/2023
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