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: 12/08/2021

OVERVIEW

Trodelvy, a Trop-2-directed antibody and topoisomerase inhibitor conjugate, is indicated for:

- **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; and
- **Urothelial cancer**, locally advanced or metastatic disease in adults who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Guidelines

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

- **Bladder Cancer:** The NCCN guidelines (version 5.2021 – October 20, 2021) list Trodelvy as an option for subsequent-line systemic therapy for locally advanced or metastatic disease (Stage IV) [other recommended regimen; category 2A]. In cisplatin eligible patients with locally advanced or metastatic disease, the first-line preferred regimens are gemcitabine and cisplatin or DDMVAC (dose-dense or accelerated, course of methotrexate, vinblastine, doxorubicin, cisplatin) with growth factor support. Bavencio® (avelumab intravenous infusion) is the recommended maintenance regimen for either group. For patients who are cisplatin ineligible, the preferred regimens are gemcitabine and carboplatin, followed by Bavencio for maintenance (category 1); and for patients whose tumors express PD-L1 or who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 expression, the preferred regimens are Tecentriq® (atezolizumab intravenous infusion) and Keytruda® (pembrolizumab intravenous infusion). Other recommended therapies for patients who are cisplatin ineligible include gemcitabine, gemcitabine + paclitaxel, and ifosfamide + doxorubicin + gemcitabine. Recommended second-line systemic therapies for locally advanced or metastatic disease after platinum therapy include Keytruda (category 1), paclitaxel, docetaxel, gemcitabine, Opdivo® (nivolumab intravenous infusion), Bavencio, Balversa® (erdafitinib tablets), Padcev® (enfortumab vedotin-ejfv intravenous infusion), ifosfamide + doxorubicin + gemcitabine, gemcitabine + paclitaxel or cisplatin, and DDMVAC with growth factor support. Recommended second-line therapies for locally advanced or metastatic disease after checkpoint inhibitor therapy include: Padcev, gemcitabine, carboplatin, gemcitabine + cisplatin, DDMVAC with growth factor support, Balversa, paclitaxel, docetaxel, ifosfamide + doxorubicin + gemcitabine, and gemcitabine + paclitaxel.
- **Breast Cancer:** The NCCN breast cancer guidelines (version 1.2022 –November 24, 2021) list Trodelvy as a preferred regimen for patients with metastatic triple-negative breast cancer who have received at least two prior therapies, with at least one for metastatic disease.[3] NCCN recommends several preferred systemic therapies for recurrent unresectable (local or regional) or Stage IV disease, such as carboplatin or cisplatin (specifically for triple-negative breast cancer and germline *BRCA* 1/2 mutation). Preferred first-line targeted therapies for triple-negative breast cancer with PD-L1 expression are Keytruda + chemotherapy (Abraxane® [albumin-bound paclitaxel intravenous infusion], paclitaxel, or gemcitabine and carboplatin). Other recommended regimens for human epidermal growth factor receptor 2 (HER2)-negative recurrent unresectable (local or regional) or Stage IV disease

are: doxorubicin, liposomal doxorubicin, paclitaxel, capecitabine, gemcitabine, vinorelbine, and Halaven® (eribulin intravenous infusion).[3]

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

---

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 triple-negative breast cancer; AND
- **C)** Patient has metastatic disease; AND
- **D)** Patient has tried at least two systemic regimens; AND
  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).
- **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.

---

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, doxorubin.
- **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; October 2021.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 1.2022– November 24, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 29, 2021.
3. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 5.2021 – October 20, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 29, 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	04/23/2020
Annual Revision	**Breast Cancer:** Revised the Note regarding examples of systemic therapies for metastatic disease: removed cyclophosphamide, docetaxel, ixabepilone, epirubicin, and Doxil; added brand names for eribulin, Keytruda + chemotherapy. **Urothelial Cancer:** Added criteria for this (new) indication.	05/05/2021
Early Annual Revision	**Breast Cancer:** The requirement that the "patient has tried at least two systemic regimens for metastatic disease" was revised to "patient has tried at least two systemic regimens".	12/08/2021