POLICY: Oncology – Trodelvy™ (sacituzumab govitecan-hziy injection for intravenous use – Immunomedics, Inc.)

EFFECTIVE DATE: 1/1/2021
LAST REVISION DATE: 12/20/2023

COVERAGE CRITERIA FOR: All Aspirus Medicare 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+/ISH–) breast cancer who have received endocrine based therapy and at least two additional systemic therapies in the metastatic setting.
- **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:** NCCN guidelines (version 3.2023 – May 25, 2023) list Trodelvy as an option for subsequent-line systemic therapy for locally advanced or metastatic disease (Stage IV) [Other Recommended Regimen; category 2A].[2] 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). Keytruda® (pembrolizumab intravenous infusion) is recommended for patients who are not eligible for any platinum-containing chemotherapy.
- **Breast Cancer:** NCCN guidelines (version 5.2023 – December 5, 2023) 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 (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)

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

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 tried at least two systemic regimens; 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, and d):
       - **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; AND
         Note: Examples of chemotherapy regimens include: paclitaxel, cisplatin, carboplatin, doxorubicin, liposomal doxorubicin, gemcitabine, vinorelbine, Halaven (eribulin 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.

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; February 2023.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 3.2023 – May 25, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 18, 2023.
3. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 5.2023 – December 5, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 18, 2023.

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.	--
Annual Revision	No criteria changes.	12/20/2023