PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Trodelvy Prior Authorization Policy
- Trodelvy® (sacituzumab govitecan-hziy intravenous infusion – Gilead)

REVIEW DATE: 12/14/2022

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, in adults who have received two or more prior systemic therapies, at least one of them for metastatic disease; and
- **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; and
- **Urothelial cancer**, locally advanced or metastatic, 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 2.2022 – May 20, 2022) 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.[2] 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. Other 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 post-platinum), 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:** NCCN guidelines (version 2.2023 – February 7, 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 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 prescription benefit coverage of Trodelvy. All approvals are provided for the duration noted below. Because of the 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 2 (HER2)- negative breast cancer; AND
   - **C)** Patient has recurrent or metastatic disease; AND
   - **D)** Patient meets one of the following criteria (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 criteria (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.

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 has 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.

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 injection [prescribing information]. Morris Plains, NJ: Gilead; February 2023.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – May 20, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 12, 2022.
3. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 2.2023 – February 7, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 8, 2023.