# Medical Policy:

## TRODELVY™ (Sacituzumab govitecan-hziy)

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---|---|---|
| MG.MM.PH.218 | January 2, 2024 | June 23, 2020 |



## Definitions

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

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
2. 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.

## Length of Authorization

Coverage will be provided for 12 months and may be renewed.

## Dosing Limits [Medical Benefit]

**Max Units (per dose and over time):**

- 10mg/kg once weekly on days 1 and 8 of 21-day treatment cycles
- 432 billable units weekly for two doses every 21 days

## Guideline

### I. Initial Approval Criteria

***Trodelvy*** *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. **Breast Cancer**
   A. The medication must be prescribed by, or in consultation with, an oncologist; **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 (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).*

2. **Urothelial Cancer**
   A. The medication is prescribed by or in consultation with an oncologist; **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
   *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).*

### Limitations/Exclusions

Trodelvy is not considered medically necessary for when any of the following selection criteria is met:

1. The patient is less than 18 years of age
2. Disease progression while on Trodelvy
3. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

**II. Renewal Criteria**

1. Patient continues to meet INITIAL APPROVAL CRITERIA.
2. Tumor response with disease stabilization or reduction of tumor size and spread.

### Dosage/Administration

| Indication | Dose |
|---|---|
| Breast Cancer &<br>Urothelial Cancer | The recommended dose of Trodelvy is 10 mg/kg administered as an intravenous infusion once weekly on Days 1 and 8 of 21-day treatment cycles. Continue treatment until disease progression or unacceptable toxicity. Do not administer Trodelvy at doses greater than 10 mg/kg. |

## Applicable Procedure Codes

| Code | Description |
|---|---|
| J9317 | Injection, sacituzumab govitecan-hziy, 2.5 mg |

## Applicable NDCs

| Code | Description |
|---|---|
| 55135-0132-01 | Trodelvy™ (sacituzumab govitecan-hziy) supplied as 180 mg of sacituzumab govitecan-hziy as lyophilized powder in a single-use vial |

## ICD-10 Diagnoses

| Code | Description |
|---|---|
| C50.919 | Malignant neoplasm of unspecified site of unspecified female breast |
| C50.929 | Malignant neoplasm of unspecified site of unspecified male breast |
| C65.09 | Malignant neoplasm of renal pelvis |
| C66.09 | Malignant neoplasm of ureter |
| C67.00 | Malignant neoplasm of bladder |
| C68.00 | Malignant neoplasm of other and unspecified urinary organs |

## Revision History

| Company(ies) | DATE | REVISION |
|---|---|---|
| EmblemHealth &<br>ConnectiCare | 1/2/2024 | Annual Review: Initial Criteria: Breast Cancer<br>Removed: "The patient has metastatic triple-negative breast cancer; AND The patient has been previously treated with at least two systemic therapy regimens, at least one of them for metastatic disease." |

| | | |
|---|---|---|
| | | Replaced with: "Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND Patient has recurrent or metastatic disease; AND Patient meets ONE of the following (i or ii):<br>i. Patient meets BOTH of the following (a and b):<br>a. Patient has hormone receptor (HR) negative disease; AND<br>b. Patient has tried at least two systemic regimens; OR<br>ii. Patient meets ALL of the following (a, b, c, and d):<br>a. Patient has hormone receptor (HR) positive disease; AND<br>b. Patient has tried endocrine therapy; AND<br>c. Patient has tried a cyclin-dependent kinase (CDK) 4/6 inhibitor; AND<br>d. Patient has tried at least two systemic chemotherapy regimens;" |
| EmblemHealth & ConnectiCare | 4/14/2023 | Annual Review: No criteria changes |
| EmblemHealth & ConnectiCare | 11/02/2022 | Updated Breast Cancer criteria: received two or more prior systemic therapies, at least one of them for metastatic disease; **and** |
| EmblemHealth & ConnectiCare | 7/29/2022 | Transferred policy to new template |
| EmblemHealth & ConnectiCare | 7/29/2022 | Annual Revision: Added criteria for new indication: Urothelial cancer<br>Removed C9066 added J9317 |
| EmblemHealth & ConnectiCare | 9/11/2020 | Added C-Code (C9066) Injection, sacituzumab govitecan-hziy, 10 mg (Trodelvy). C-Code effective date: 10/01/2020 |
| EmblemHealth & ConnectiCare | 06/23/2020 | New Medical Policy |

## References


1. Trodelvy® intravenous injection [prescribing information]. Morris Plains, NJ: Gilead; October 2022.
2. 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.
3. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 4.2022 – June 21, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 2, 2022.