

## Medical Policy:

### TRODELVY™ (Sacituzumab govitecan-hziy)

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## 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

*Trodely* 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

Trodely 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 & 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 & ConnectiCare	1/2/2024	Annual Review: Initial Criteria: <u>Breast Cancer</u> 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): 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 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 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; <b>and</b>
EmblemHealth & ConnectiCare	7/29/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	7/29/2022	Annual Revision: Added criteria for new indication: Urothelial cancer Removed C9066 added J9317
EmblemHealth & ConnectiCare	9/11/2020	Added C-Code (C9066) Injection, sacituzumab govitecan-hziy, 10 mg (Trodelvy). C-Code effective date: <b>10/01/2020</b>
EmblemHealth & ConnectiCare	06/23/2020	New Medical Policy

## References

1. Trodelvy<sup>®</sup> 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.