Medical Policy:

Trodelvy™ (Sacituzumab govitecan-hziy) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.218	February 10, 2025	June 23, 2020

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

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:*

- Patient is at least 18 years of age; **AND**
- Therapy will **NOT** be substituted for or used in combination with irinotecan; **AND**
- Patients that are homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele will be closely monitored for adverse reactions; **AND**
- Therapy will not be used in combination with UGT1A1 inhibitors (e.g., nilotinib, regorafenib, etc.) or inducers (e.g., phenytoin, carbamazepine, etc.); **AND**
- Used as a single agent; **AND**

1. **Breast Cancer**

A. Patient has triple-negative breast cancer [TNBC] (i.e., estrogen, progesterone, and HER2-negative); **AND**

i. Patient has unresectable locally advanced disease; **AND**

a. Patient was previously treated with at least two systemic therapies, at least one of them for metastatic disease; **OR**

ii. Patient has recurrent unresectable or metastatic disease OR inflammatory breast cancer with no response to preoperative systemic therapy; **AND**

a. Patient was previously treated with at least one prior therapy for metastatic disease; **OR**

B. Patient has hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**

i. Patient has unresectable locally advanced, or metastatic disease; **AND**

a. Patient was previously treated with endocrine therapy and at least two additional lines of systemic therapy for metastatic disease; **OR**

ii Patient has recurrent unresectable disease OR inflammatory breast cancer with no response to preoperative systemic therapy ‡; **AND**

a. Patient has received prior treatment including endocrine therapy, a CDK4/6 inhibitor (e.g., palbociclib, ribociclib, abemaciclib, etc.), and at least two lines of chemotherapy (including a taxane) at least one of which was in the metastatic setting; **AND**

b. Patient is not a candidate for fam-trastuzumab deruxtecan

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

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; **AND**
2. Tumor response with disease stabilization or reduction of tumor size and spread; **AND**
3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity and infusion-related reactions (including anaphylactic reactions), severe nausea/vomiting, severe neutropenia/febrile neutropenia, severe anemia, severe diarrhea, etc.

Dosage/Administration

Indication	Dose

Breast 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

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/10/2025	Annual Review: Initial Criteria: Added: "Patient is at least 18 years of age; AND Therapy will NOT be substituted for or used in combination with irinotecan; AND Patients that are homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele will be closely monitored for adverse reactions; AND Therapy will not be used in combination with UGT1A1 inhibitors (e.g., nilotinib, regorafenib, etc.) or inducers (e.g., phenytoin, carbamazepine, etc.); AND Used as a single agent; AND" Breast Cancer Removed the following, some was reworded: "The medication must be prescribed by, or in consultation with, an oncologist; AND 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): Patient meets BOTH of the following (a and b): Patient has hormone receptor (HR) negative disease; AND 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).* Patient meets ALL of the following (a, b, c, and d): Patient has hormone receptor (HR) positive disease; AND Patient has tried endocrine therapy; AND 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).*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).” Reworded or added as follows:”Patient has triple-negative breast cancer [TNBC] (i.e., estrogen, progesterone, and HER2-negative); AND Patient has unresectable locally advanced disease; AND Patient was previously treated with at least two systemic therapies, at least one of them for metastatic disease; OR Patient has recurrent unresectable or metastatic disease OR inflammatory breast cancer with no response to preoperative systemic therapy; AND Patient was previously treated with at least one prior therapy for metastatic disease; OR Patient has hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative disease*; AND Patient has unresectable locally advanced, or metastatic disease; AND Patient was previously treated with endocrine therapy and at least two additional lines of systemic therapy for metastatic disease; OR Patient has recurrent unresectable disease OR inflammatory breast cancer with no response to preoperative systemic therapy ‡; AND Patient has received prior treatment including endocrine therapy, a CDK4/6 inhibitor (e.g., palbociclib, ribociclib, abemaciclib, etc.), and at least two lines of chemotherapy (including a taxane) at least one of which was in the metastatic setting; AND Patient is not a candidate for fam-trastuzumab deruxtecan” Renewal Criteria: Added: “Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity and infusion-related reactions (including anaphylactic reactions), severe nausea/vomiting, severe neutropenia/febrile neutropenia, severe anemia, severe diarrhea, etc”
EmblemHealth & ConnectiCare	10/28/2024	Removed Urothelial Cancer indication, criteria and references due to FDA indication withdrawal (10/18/24).
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; **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 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.