

Utilization Management and Clinical Medical Policy

Policy Name: Sacituzumab govitecan-hziy (Trodelvy®)	Policy Number: MP-RX-FP-94-23	Scope: ☒ MMM MA ☒ MMM MultiHealth	Origination Date: 11/30/2023 Last Review Date: 08/19/2026	Effective Date: 08/19/2026 Frequently Revision: Annual
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Service Category:

- | | |
|--|---|
| ☐ Anesthesia | ☐ Medicine Services and Procedures |
| ☐ Surgery | ☐ Evaluation and Management Services |
| ☐ Radiology Procedures | ☐ DME/Prosthetics or Supplies |
| ☐ Pathology and Laboratory Procedures | ☐ Other: Part B Drugs |

Service Description:

This document addresses the use of **Sacituzumab govitecan-hziy (Trodelvy®)**, approved by the Food and Drug Administration (FDA) for the treatment of locally advanced or metastatic breast cancer.

Background Information:

Trodelvy is a Trop-2-directed antibody and topoisomerase inhibitor conjugate used to treat select adult patients with unresectable locally advanced or metastatic breast cancer, including triple-negative breast cancer (TNBC) and hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer.

The FDA approved indications for Trodelvy are the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) as follows: as a single agent for first-line treatment in patients who are not candidates for PD-1 or PD-L1 inhibitor-based therapy; in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for first-line treatment in patients whose tumors express PD-L1 [Combined Positive Score (CPS $\geq$ 10)] as determined by an FDA-authorized test; and as a single agent for patients who have received two or more prior systemic therapies, at least one of them for metastatic disease. Trodelvy is also FDA approved for adult patients with unresectable locally advanced or metastatic hormone receptor (HR)-positive, HER2-negative (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.

Based on NCCN recommendations with category of evidence 1 and 2A, Trodelvy is also recommended in selected recurrent, unresectable, locally advanced, metastatic, and inflammatory breast cancer settings, including use as a single agent and, for selected first-line triple-negative breast cancer cases, in combination with pembrolizumab. NCCN also provides recommendations for select urothelial carcinoma settings, including bladder cancer, upper GU tract tumors, urothelial carcinoma of the prostate, and primary carcinoma of the urethra, as a single agent with sequencing based on prior chemotherapy, immunotherapy, and enfortumab vedotin use.

Breast cancer is one of the most common forms of cancer in the United States. Triple-negative breast cancer (TNBC) accounts for about 15% of invasive breast cancer. TNBC refers to breast cancer that does not express estrogen receptor (ER), progesterone receptor (PR), or overexpression of human epidermal growth factors receptor 2 (HER2), making it more difficult to treat and associated with a poor prognosis.

Trodelvy is a Trop-2-directed antibody-drug conjugate. Although Trodelvy consists, in part, of an active metabolite (SN-38) of the drug irinotecan, the FDA label warns against substituting it with irinotecan or using it in a regimen that already contains irinotecan or SN-38. The recommended dosage of Trodelvy, as a single agent or in combination with pembrolizumab, is 10 mg/kg administered intravenously on Days 1 and 8 of each 21-day cycle until disease progression or unacceptable toxicity. When Trodelvy is administered in combination with

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pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, pembrolizumab therapy should be discontinued after approximately 24 months.

Trodelvy has a boxed warning for causing severe neutropenia and diarrhea. Withholding Trodelvy for absolute neutrophil count below 1500/mm³ or neutropenic fever is recommended. Monitoring patients for diarrhea, and providing supportive care if needed are also recommended, in addition to withholding or reducing dose for severe diarrhea. The current label also recommends primary prophylaxis with granulocyte colony-stimulating factor (G-CSF) for all patients at increased risk of febrile neutropenia and recommends premedication prior to each dose to prevent infusion reactions and chemotherapy-induced nausea and vomiting.

Definitions and Measures

- Disease Progression: Cancer that continues to grow or spread.
- Immune checkpoint inhibitor: A type of drug that blocks certain proteins made by some types of immune system cells, such as T cells, and some cancer cells. When these proteins are blocked, the “brakes” on the immune system are released and T cells are able to kill cancer cells better. Examples of checkpoint proteins found on T cells or cancer cells include programmed death (PD)-1, PD-ligand 1 (PD-L1), and cytotoxic T-lymphocyte-associated antigen (CTLA)-4/B7-1/B7-2.
- Metastasis: The spread of cancer from one part of the body to another. A metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.
- Programmed death (PD)-1 proteins: PD-1 proteins are found on T-cells and attach to PD ligands (PD-L1) found on normal (and cancer) cells (see immune checkpoint inhibitor above). Normally, this process keeps T-cells from attacking other cells in the body. However, this can also prevent T-cells from attacking cancer cells in the body. Examples of FDA approved anti-PD-1 agents include Keytruda (pembrolizumab), Opdivo (nivolumab), and Libtayo (cemiplimab).
- Programmed death ligand (PD-L)-1: The ligands found on normal (and cancer) cells to which the PD-1 proteins attach (see immune checkpoint inhibitor above). Cancer cells can have large amounts of PD-L1 on their surface, which helps them to avoid immune attacks. Examples of FDA approved anti-PD-L1 agents include Bavencio (avelumab), Tecentriq (atezolizumab), and Imfinzi (durvalumab).

Approved Indications

A. Locally Advanced or Metastatic Breast Cancer:

- Unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC):
 - Who have received two or more prior systemic therapies, at least one of them for metastatic disease.
 - As a single agent for the first-line treatment of adult patients with unresectable locally advanced or metastatic triple negative breast cancer (TNBC) who are not candidates for PD-1 or PD-L1 inhibitor-based therapy.
 - In combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for the first-line treatment of adult patients with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 (CPS $\geq$ 10) as determined by an FDA-authorized test.

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- Unresectable locally advanced or metastatic hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative (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.

Other Uses

- A. See Background Information above.

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Medical Necessity Guidelines:

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

sacituzumab govitecan-hziy(Trodelvy®)

A. Criteria For Initial Approval *(Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

Initial requests for Trodelvy (sacituzumab govitecan) for *Breast Cancer* may be approved if the following criteria are met (Label, NCCN 2A):

- i. Individual is an adult patient with a diagnosis of unresectable locally advanced or metastatic triple-negative breast cancer (TNBC); **AND**
- ii. One of the following applies:

A. Trodelvy is used as a single agent for the first-line treatment of adult patients with unresectable locally advanced or metastatic triple negative breast cancer (TNBC) in an individual who is not candidate for PD-1 or PD-L1 inhibitor-based therapy. (Label)

OR

B. Trodelvy is used in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for the first-line treatment of unresectable locally advanced or metastatic TNBC in an individual whose tumors express PD-L1 (CPS ≥ 10) as determined by an FDA-authorized test. (Label)

OR

C. Trodelvy is used as a single agent for the treatment of unresectable locally advanced or metastatic TNBC in an individual who has received two or more prior systemic therapies, at least one of them for metastatic disease (Label, NCCN 1);

OR

D. Individual has had no response to preoperative systemic therapy, or has recurrent unresectable (local or regional) or stage IV (M1) triple-negative breast cancer (TNBC); **AND**

1. Individual is using in combination with pembrolizumab as first-line therapy for PD-L1 positive disease with CPS greater than or equal to 10 (NCCN 1);

OR

2. Individual is using as first-line therapy as a single agent if PD-L1 CPS is less than 10 and there is no germline BRCA 1/2 pathogenic variant (NCCN 1);

OR

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3. Individual is using as second-line therapy as a single agent (may be considered for a later line) (NCCN 1);

OR

- iii. Individual has a diagnosis of unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer (IHC 0, IHC 1+, or IHC 2+/ISH-); **AND**

- A. Individual has received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting (Label);

OR

- B. Individual has inflammatory HR-positive/HER2-negative breast cancer and has had no response to preoperative systemic therapy or has recurrent unresectable (local or regional) or stage IV (M1) HR-positive/HER2-negative disease; **AND**
 1. Individual has received prior endocrine therapy, a CDK4/6 inhibitor, and at least two lines of chemotherapy (including a taxane), with at least one line in the metastatic setting; **AND**
 2. Individual is not a candidate for fam-trastuzumab deruxtecan-nxki; **AND**
 3. Individual is using as second-line therapy or later (if not used in a previous line of therapy) as a single agent (NCCN 1 for use as second-line therapy; NCCN 2A for all others);

OR

Initial requests for Trodelvy (sacituzumab govitecan) for *Bladder Cancer* may be approved if the following criteria are met (NCCN 2A):

- i. Individual has a diagnosis of bladder cancer with urothelial carcinoma histology (NCCN 2A); **AND**

- A. Individual has one of the following disease settings:

1. Stage II (cT2, N0) disease or stage IIIA (cT3, N0; cT4a, N0; cT1-T4a, N1) disease if tumor is present following reassessment of tumor status after primary treatment with concurrent bladder-preserving chemoradiotherapy and TURBT; **OR**
2. Stage II (cT2, N0) disease or stage IIIA (cT3, N0; cT4a, N0; cT1-T4a, N1) disease if tumor is present following reassessment of tumor status after primary treatment with radiotherapy alone; **OR**
3. Stage IIIB (cT1-T4a, N2,3) disease following progression after primary treatment with downstaging systemic therapy; **OR**
4. Stage IVA (cT4b, any N, M0) disease if tumor is present following reassessment of tumor status after primary treatment with first-line systemic therapy; **OR**
5. Stage IVA (any T, any N, M1a) disease if stable disease or progression is present following reassessment of tumor status after primary treatment with first-line systemic therapy; **OR**
6. Metastatic stage IVB (any T, any N, M1b) disease; **OR**

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	7. Muscle invasive local recurrence or persistent disease in a preserved bladder treated with curative intent; OR 8. Metastatic or local recurrence post cystectomy treated with curative intent; AND B. Individual is using Trodelvy in one of the following ways: - As second-line systemic therapy as a single agent when there has been previous chemotherapy and immunotherapy, and there has been no previous enfortumab vedotin-ejfv; OR - As subsequent-line systemic therapy as a single agent when the individual has already received platinum and a checkpoint inhibitor, if eligible, and when there has been previous chemotherapy, immunotherapy, and enfortumab vedotin-ejfv;
OR	
ii.	Individual has a diagnosis of upper GU tract tumor with urothelial carcinoma histology (NCCN 2A); AND A. Individual has metastatic disease; AND B. Individual is using Trodelvy in one of the following ways: - As second-line systemic therapy as a single agent when there has been previous chemotherapy and immunotherapy, and there has been no previous enfortumab vedotin-ejfv; OR - As subsequent-line systemic therapy as a single agent when the individual has already received platinum and a checkpoint inhibitor, if eligible, and there has been previous chemotherapy, immunotherapy, and enfortumab vedotin-ejfv;
OR	
iii.	Individual has a diagnosis of urothelial carcinoma of the prostate (NCCN 2A); AND A. Individual has metastatic disease; AND B. Individual is using Trodelvy in one of the following ways: - As second-line systemic therapy as a single agent when there has been previous chemotherapy and immunotherapy, and there has been no previous enfortumab vedotin-ejfv; OR - As subsequent-line systemic therapy as a single agent when the individual has already received platinum and a checkpoint inhibitor, if eligible, and there has been previous chemotherapy, immunotherapy, and enfortumab vedotin-ejfv;
OR	
iv.	Individual has a diagnosis of primary carcinoma of the urethra with urothelial carcinoma histology (NCCN 2A); AND A. Individual has recurrent or metastatic disease; AND B. Individual is using Trodelvy in one of the following ways: As second-line systemic therapy as a single agent when there has been previous chemotherapy and immunotherapy, and there has been no previous enfortumab vedotin-ejfv; OR

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2. As subsequent-line systemic therapy as a single agent when the individual has already received platinum and a checkpoint inhibitor, if eligible, and there has been previous chemotherapy, immunotherapy, and enfortumab vedotin-ejfv.

B. Criteria For Continuation of Therapy

- i. MMM considers continuation of Trodelvy® (sacituzumab govitecan) therapy medically necessary in members requesting reauthorization for an indication listed in Section A Above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen, and the recommended duration of therapy has not been exceeded. The following information should be submitted for reauthorization:
 - A. A current oncology note documenting the patient's response to treatment showing no progression of disease.
 - B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results (every six months).

C. Authorization Duration

- i. Initial Approval Duration: Up to 6 months
- ii. Reauthorization Approval Duration: Up to 6 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

- i. Individual is using in combination with irinotecan or another regimen containing its active metabolite SN-38; **OR**
- ii. When the above criteria (Section A: Criteria for Initial Approval) are not met and for all other indications.

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Trodelvy injection 180 mg single-dose vial

FDA Approved Indication	Recommended Dose	Duration of Therapy
Locally Advanced or Metastatic Breast Cancer	10 mg/kg IV once weekly on Days 1 and 8 of continuous 21-day treatment cycles	Until disease progression or unacceptable toxicity.
Bladder Cancer	Max Dose: 10 mg/kg	
Exceptions		
Primary prophylaxis with G-CSF is recommended starting in the first cycle in all patients at increased risk of febrile neutropenia.		

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

ICD-10 Diagnostic Codes:

Codes	Description
C50.011-C50.929	Malignant neoplasm of breast
C50.A0-C50.A2	Malignant inflammatory neoplasm of breast
C61	Malignant neoplasm of prostate
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C66.1	Malignant neoplasm of right ureter
C66.2	Malignant neoplasm of left ureter
C66.9	Malignant neoplasm of unspecified ureter
C67.0-C67.9	Malignant neoplasm of bladder
C68.0-C68.9	Malignant neoplasm of overlapping sites of urinary organs
C79.81-C79.89	Secondary malignant neoplasm of other and unspecified sites
D05.00-D05.92	Carcinoma in situ of breast
D09.0	Carcinoma in situ of bladder
Z85.3	Personal history of malignant neoplasm of breast
Z85.51	Personal history of malignant neoplasm of bladder
Z85.59	Personal history of malignant neoplasm of other urinary tract organ
Z17.1	Estrogen receptor negative status [ER-]

HCPCS Codes:

Codes	Description
J9317	Injection, sacituzumab govitecan-hziy, 2.5 mg [Trodelvy]

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Reference Information:

1. Bardia A, Mayer IA, Vahdat LT, et al. Sacituzumab Govitecan-hziy in Refractory Metastatic Triple-Negative Breast Cancer. N Engl J Med. 2019; 380(8): 741-751. Available at <https://www.nejm.org/doi/pdf/10.1056/NEJMoa1814213?articleTools=true>.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 6, 2023.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Gilead Sciences, Inc. (2026). TRODELVY® (sacituzumab govitecan-hziy) for injection, for intravenous use: Prescribing information. Revised June 2026. Accessed July 10, 2026.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2026; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2026 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>.
 - a. Bladder Cancer. V1.2026. Revised March 16, 2026.
 - b. Breast Cancer. V5.2026. Revised July 7, 2026.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Updated Background Information to align with the current Trodelvy prescribing information and current NCCN recommendations, including breast cancer and select urothelial carcinoma uses. Removed the former FDA indication for locally advanced or metastatic urothelial cancer. Updated Initial Approval criteria to incorporate current FDA-labeled breast cancer indications and NCCN-supported criteria for breast cancer, bladder cancer, upper GU tract tumors, urothelial carcinoma of the prostate, and primary carcinoma of the urethra. Updated Conditions Not Covered to clarify that Trodelvy should not be used with irinotecan or SN-38-containing regimens. Added available dosage forms and updated supportive care language to include consideration of prophylaxis with G-CSF starting in the first cycle for appropriate patients. Coding reviewed: added ICD-10-CM C50.A0-C50.A2, C61, C65.1, C65.2, C65.9, C66.1, C66.2, C66.9, D09.0, Z85.51, and Z85.59. Updated reference information and incorporated new policy template. Updated background information and clinical criteria to add the new FDA-approved first-line indications for adult patients with unresectable locally advanced or metastatic triple-negative breast cancer, including use as a single agent for patients who are not candidates for PD-1/PD-L1 inhibitor-based therapy and use in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for PD-L1 positive disease with CPS $\geq$ 10. Coding reviewed: no changes. Updated reference information.	8/14/2026	8/19/2026
Annual Review 8/28/2025	Minimal changes; word formatting. Coding reviewed: No changes.	9/5/2025	9/16/2025
Annual Review 09/23/2024	Update breast cancer criteria for triple negative disease after one line of therapy, update breast cancer for metastatic disease and subsequent therapy, update breast cancer after failure to preoperative therapy (NCCN 1), update urothelial cancer for recurrent therapy, wording update. Coding reviewed: No changes.	11/18/2024	12/17/2024
Select Review	Update statement for criteria for initial approval: Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met all approval criteria.	3/25/2024	5/9/2024
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023