Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Sacituzumab govitecan (Trodelvy®)	MP-RX-FP-94-23	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B DRUG

Service Description

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

Background Information

Trodelvy is a Trop-2-directed antibody and topoisomerase inhibitor conjugate primarily used to treat breast cancer.

The FDA approved indications for Trodelvy is the treatment of adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease. Trodelvy (sacituzumab govitecan) is also FDA approved for the treatment of adults with locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.

The National Comprehensive Cancer Network® (NCCN) also provides an additional recommendation with a category 2A level of evidence for the use of Trodelvy in recurrent, triple-negative breast cancer.

Breast cancer is one of the most common forms of cancer in the United States. Metastatic 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 the first Trop-2-directed antibody-drug conjugate, and the first targeted therapy approved for TNBC. 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.

Trodelvy has a black box 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.

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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

FDA Approved Indication
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. • 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.
Locally Advanced or Metastatic Urothelial Cancer Locally advanced or metastatic urothelial cancer (mUC) 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.

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Other Uses

See Background section above.

Applicable Codes

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.

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

ICD-10	Description
C50.011-C50.929	Malignant neoplasm of breast
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
Z85.3	Personal history of malignant neoplasm of breast
Z17.1	Estrogen receptor negative status [ER-]

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.

Sacituzumab govitecan (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.)*
   i. Individual has recurrent or metastatic, histologically confirmed triple-negative Breast Cancer (lack of estrogen- and progesterone-receptor expression and no overexpression of HER2); **AND**
   ii. Individual has confirmation of disease progression after two prior lines of therapies;

OR

iii. Individual has unresectable, locally advanced or metastatic, histologically confirmed hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2)- negative breast cancer; **AND**
iv. Individual has received endocrine based therapy; **AND**
v. Individual has confirmation of disease progression after two prior lines of therapies;

OR

vi. Individual has no response to preoperative systemic therapy or recurrent unresectable breast cancer (NCCN 1); **AND**
vii. Individual is using as second-line;

OR

viii. Individual has locally advanced or metastatic Urothelial Cancer; AND
ix. Individual has confirmation of disease progression after platinum-containing chemotherapy *and* either an anti-PD-1 or anti-PD- L1 agent.

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 an irinotecan-containing regimen or its SN-38 metabolite; **OR**
ii. When the above criteria (Section A: Criteria for Initial Approval) are not met and for all other indications.

Limits or Restrictions

A. Quantity Limitations

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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.

FDA Approved Indication	Recommended Dose	Duration of Therapy
Locally Advanced or Metastatic Breast Cancer	10 mg/kg once weekly on Days 1 and 8 of continuous 21-day treatment cycles Max Dose: 10 mg/kg	Until disease progression or unacceptable toxicity.
Locally Advanced or Metastatic Urothelial Cancer		
Exceptions		
None		

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. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 203; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 17, 2023.
    a. Bladder Cancer. V1.2023. Revised February 9, 2023.
    b. Breast Cancer. V3.2023. Revised March 3, 2023

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

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023
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

Revised: 10/12/2023