Medical Drug Clinical Criteria

Subject:	Trodelvy (sacituzumab govitecan)		
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Overview

This document addresses the use of Trodelvy (sacituzumab govitecan). 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/mm^3 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.

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).

Clinical Criteria

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.

Trodelvy (sacituzumab govitecan)

Requests for Trodelvy (sacituzumab govitecan) may be approved if the following criteria are met (Label, NCCN 2A):

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 disease progression after at least one prior lines of therapy (NCCN 1);

OR

III. Individual has unresectable, locally advanced or metastatic, 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 of disease progression after two prior lines of therapies;

OR

VI. Individual has no response to preoperative systemic therapy, metastatic, or recurrent unresectable breast cancer (NCCN 1, 2A); **AND**
VII. Individual is using as second-line or subsequent therapy;

OR

VIII. Individual has locally advanced, recurrent, or metastatic Urothelial Cancer; **AND**
IX. Individual has disease progression after platinum-containing chemotherapy *and* either an anti-PD-1 or anti-PD-L1 agent.

Trodelvy (sacituzumab govitecan) may not be approved for the following:

I. Individual is using in combination with an irinotecan-containing regimen or its SN-38 metabolite; **OR**
II. When the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

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

ICD-10 Diagnosis

C50.011-C50.929	Malignant neoplasm of breast
C67.0-C67.9	Malignant neoplasm of the bladder [Urothelial Carcinoma]
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-]

Document History

Revised: 05/17/2024
Document History:

- 05/17/2024: Annual Review: Update breast cancer criteria for triple negative disease after one line of therapy, update breast cancer for metastatic disease and subsequent therapy, update urothelial cancer for recurrent therapy, wording update. Coding reviewed: No changes.

- 08/18/2023: Select Review: Update second-line therapy criteria for breast cancer 05/19/2023 – Annual Review: Add HER2 negative HR positive breast cancer criteria. Coding Reviewed: No changes.
- 05/19/2023 – Annual Review: No Change. Coding Reviewed: No changes.
- 02/24/2023 – Select Review: Add new FDA indication for HER2 negative, HR positive breast cancer. Coding Reviewed: Added ICD-10-CM Z17.1.
- 05/20/2022 – Annual Review: Update criteria in triple negative breast cancer to clarify therapies vs lines of therapies. Coding Reviewed: No changes.
- 05/21/2021 – Annual Review: Update criteria to add new indication for urothelial cancer per label. Coding Reviewed: Added ICD-10-CM C68.8.0-C68.9. Added C67.0-C67.9. Extended code range to C50.011-C50.929.
- 06/08/2020 – Annual Review: Add new clinical criteria document for Trodelvy (sacituzumab govitecan). Coding Reviewed: Added HCPCS J9999, J3590, J3490, C9399, ALL DX pend. Effective 10/1/2020 Added HCPCS C9066, Delete HCPCS C9399 (9/30/2020), Added ICD-10-CM: C50.011-C50.329, C79.81-C79.89, D05.00-D05.92, Z85.3. Effective 1/1/2021 Added J9317, Deleted 12/31/2020: J9999, J3590, J3490, C9066.

References

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2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. 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. Updated periodically.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: Accessed: March 4, 2024.
    a. Bladder Cancer. V1.2024. Revised January 30, 2024.
    b. Breast Cancer. V1.2024. Revised January 25, 2024.

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.