

## Corporate Medical Policy

### Sacituzumab govitecan-hziy (Trodelvy™)

<b>File Name:</b>	sacituzumab_govitecan_trodelvy
<b>Origination:</b>	6/2020
<b>Last CAP Review:</b>	n/a
<b>Next CAP Review:</b>	3/2021
<b>Last Review:</b>	6/2020

#### Description of Procedure or Service

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Sacituzumab govitecan-hziy (Trodelvy™) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adults with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease.

Triple negative breast cancer (TNBC) is defined by a lack of tumor cell expression of the estrogen receptor, progesterone receptor, and human epidermal growth factor receptor 2 (HER2). This type of breast cancer is correlated with more aggressive tumor behavior, as well as a poor prognosis. Unlike other breast cancer types with positive hormone and HER2 receptor expression, there are no approved targeted treatments available for TNBC. Treatment of mTNBC depends on prior treatment history, programmed cell death ligand 1 (PD-L1) expression, and germline *BRCA* mutation status. In the metastatic setting, single-agent sequential cytotoxic chemotherapy has remained the standard of care. Combination chemotherapy may be appropriate for patients with extensive or rapidly progressive visceral disease, where chance of treatment response may outweigh high risk of toxicity. Sacituzumab govitecan represents a new targeted therapy option for patients with mTNBC who have already tried at least two prior therapies in the metastatic setting.

Sacituzumab govitecan-hziy (Trodelvy) is an antibody-drug conjugate (ADC) composed of a humanized Trop-2 directed monoclonal antibody, a topoisomerase inhibitor, and a cleavable linker. It was approved by the U.S. Food and Drug Administration (FDA) in April 2020 for the treatment of metastatic triple-negative breast cancer. Sacituzumab govitecan binds to Trop-2-expressing cancer cells, then is internalized and intracellular linker cleavage occurs. Upon release, the topoisomerase inhibitor causes DNA damage and apoptotic cell death.

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

#### Policy

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**BCBSNC will provide coverage for sacituzumab govitecan-hziy (Trodelvy™) when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.**

#### Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit

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design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## **When Sacituzumab govitecan-hziy (Trodelvy) is covered**

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### **Initial Therapy**

Sacituzumab govitecan-hziy (Trodelvy) may be considered medically necessary for the treatment of adult patients with breast cancer when the following criteria are met:

1. The patient has metastatic triple-negative disease; **and**
2. The patient has received prior treatment with at least two systemic chemotherapies in the metastatic setting; **and**
3. Sacituzumab govitecan-hziy will be used as a single agent.

Initial authorization: 12 months

### **Continuation Therapy**

Continuation of treatment with sacituzumab govitecan-hziy (Trodelvy) beyond 12 months after initiation of therapy, and every 12 months thereafter, may be considered medically necessary for the treatment of metastatic triple-negative breast cancer when the following criteria are met:

1. The patient is currently receiving sacituzumab govitecan and continues to meet initial criteria; **and**
2. The patient has continued clinical benefit on sacituzumab govitecan therapy as demonstrated by tumor response or lack of disease progression, and an acceptable toxicity profile.

Use of sacituzumab govitecan-hziy (Trodelvy) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either:

- In accordance with FDA label (when clinical benefit has been established, (see Policy Guidelines); **OR**
- In accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached.

## **When Sacituzumab govitecan-hziy (Trodelvy) is not covered**

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Sacituzumab govitecan-hziy (Trodelvy) is considered **investigational** and therefore not covered when the above criteria are not met.

Sacituzumab govitecan-hziy (Trodelvy) is considered investigational when used for:

1. Non-cancer indications; **OR**

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2. When criteria are not met regarding FDA labeling **OR** strong endorsement/support by nationally recognized compendia, as stated under “When Sacituzumab govitecan-hziy (Trodelvy) is covered.”

## Policy Guidelines

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Triple negative breast cancer is defined by a lack of tumor cell expression for estrogen receptor and progesterone receptor, and human epidermal growth factor receptor 2 (HER2).

### Dosing and Administration

The recommended dose of Trodelvy is 10 mg/kg administered as an intravenous infusion once weekly on days 1 and 8 of continuous 21-day treatment cycles until disease progression or unacceptable toxicity. Doses greater than 10 mg/kg are not recommended. Trodelvy is not to be substituted for or used with other drugs containing irinotecan or its active metabolite SN-38.

### Clinical Trial Evidence

The efficacy of sacituzumab govitecan was evaluated in a multicenter, single-arm, clinical trial (NCT01631552) assessing 108 patients with metastatic triple-negative breast cancer (mTNBC) who had received at least two prior therapies for metastatic disease. Patients were included with treated brain metastases not on high dose steroids (>20 mg prednisone or equivalent) for at least 4 weeks. Patients were excluded who had bulky disease (>7cm), or who had known Gilbert’s disease. In the trial, patients received sacituzumab govitecan 10 mg/kg intravenously on days 1 and 8 of 21-day treatment cycles until disease progression or treatment intolerance. The median number of prior systemic therapies received in the metastatic setting was three (range: 2-10). The primary efficacy endpoint included overall response rate (ORR), which was 33% (95% CI, 24.6% to 43.1%) including CR in 2.8% of patients receiving third-line or higher treatment for mTNBC. The median duration of response was 7.7 months (95% CI, 4.9 to 10.8). Median progression-free survival was 5.5 months (95% CI, 4.1 to 6.3), and overall survival was 13.0 months (95% CI, 11.2 to 13.7). Sacituzumab govitecan resulted in a modest ORR in this small trial of patients with heavily pretreated mTNBC. Myelosuppression and diarrhea were the primary adverse events and there was a low rate of treatment discontinuation.

Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy (CMP), “Investigational (Experimental) Services.”

Please refer to CMP “Investigational (Experimental) Services” for a summary of evidence standards from nationally recognized compendia.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: J9317, S0353, S0354*

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BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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Immunomedics, Inc. Trodelvy (sacituzumab govitecan-hziy) for injection, for intravenous use. Highlights of prescribing information. April 2020. Available at: <https://www.trodelvy.com/pdf/PrescribingInformation.pdf>. Last accessed June 2020.

U.S. Food and Drug Administration. FDA approves new therapy for triple negative breast cancer that has spread, not responded to other treatments. April 22, 2020. Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-new-therapy-triple-negative-breast-cancer-has-spread-not-responded-other-treatments>. Last accessed June 2020.

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):741-51.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer, version 4.2020. Revised May 8, 2020. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/breast.pdf](https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf). Last accessed June 2020.

Medical Director review 6/2020

## Policy Implementation/Update Information

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- 6/30/20 New policy developed. Trodelvy is considered medically necessary for the treatment of adult patients with mTNBC when specified medical criteria and guidelines are met. Added HCPCS codes C9399, J3490, J3590, J9999, S0353, and S0354 to Billing/Coding section. References added. Medical Director review 6/2020. (krc)
- 10/1/20 Added HCPCS code C9066 to Billing/Coding section effective 10/1/2020. (krc)
- 12/31/20 Added HCPCS code J9317 to Billing/Coding section effective 1/1/2021 and deleted codes C9066, C9399, J3490, J3590, and J9999 termed 12/31/2020. (krc)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.