SmartHealth Ascension

Sacituzumab Govitecan-Hziy

(Trodelvy®) J9317 (2.5 mg)

Covered with prior authorization

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

- Individual has recurrent or metastatic, histologically confirmed triple-negative Breast Cancer (lack of estrogen- and progesterone-receptor expression and no overexpression of HER2); **AND**
- Individual has confirmation of disease progression after two prior lines of therapies; **AND**
- Trodelvy® (sacituzumab govitecan-hziy) is used as single agent therapy.

OR

- Individual has HR+/HER2- advanced breast cancer; **AND**
- Prior treatment including endocrine, a CDK4/6 inhibitor and at least two lines of chemotherapy.

OR

- Individual has locally advanced or metastatic Urothelial Cancer; **AND**
- Individual has confirmation of disease progression after platinum-containing chemotherapy (e.g., avelumab, nivolumab, atezolizumab, durvalumab, etc.) and either an anti-PD-1 or anti-PDL1 agent; **AND**
- Trodelvy® (sacituzumab govitecan-hziy) is used as a single agent.

Requests for Trodelvy® (sacituzumab govitecan-hziy) may **not** be approved if the above criteria are not met and for all other indications not included above.

Initial and renewal authorizations are for up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Exclusion criteria:

- Trodelvy® (sacituzumab govitecan-hziy) is not considered medically necessary when any of the following selection criteria is met:
    - Individual is using in combination with an irinotecan-containing regimen or its SN-38 metabolite; **OR**
    - When the above criteria are not met and for all other indications.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage. Trodelvy® is a Trop-2-directed antibody and topoisomerase inhibitor conjugate primarily used to treat breast cancer. The FDA approved indication 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.

Key References Accessed 8/2022:
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. Bardia A, Hurvitz S, Tolaney SM et al. Sacituzumab Govitecan in Metastatic Triple-Negative Breast Cancer. N Engl J Med. 2021;384:1529-1541
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
4. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.

5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
7. 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.
    a. Breast Cancer. V2.2022. Revised December 20, 2021.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.