

Trodelvy (sacituzumab govitecan)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Trodelvy (sacituzumab govitecan)

APPROVAL CRITERIA

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 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.

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.

Note:

Trodely 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:

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 policies may take precedence over the application of this clinical criteria.

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