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 disease progression after at least one prior line 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 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.

Note:
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.

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.: 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.