

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

## 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 therapies.

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<sup>3</sup> 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>.

CRX-ALL-0570-20

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New Program Date 07/10/2020

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. 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: May 20, 2020.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on May 20, 2020.
  - a. Breast Cancer. V4.2020. Revised May 8, 2020.

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