

Subject: Trodelvy (sacituzumab govitecan)
Document #: ING-CC-0165 **Publish Date:** 06/26/2020
Status: New **Last Review Date:** 06/08/2020

Table of Contents

[Overview](#) [Coding](#) [References](#)
[Clinical criteria](#) [Document history](#)

Overview

This document addresses the use of Trodelvy (sacituzumab govitecan). Trodelvy is a Trop-2-directed antibody and topoisomerase inhibitor conjugate primarily used to treat breast cancer.

The FDA approved indications 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. 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 accounts for about 15% of invasive breast cancer. TNBC refers to breast cancer that does not express estrogen receptor, progesterone receptor, 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 was approved under accelerated approval and its continued approval is contingent upon verifications and description of clinical benefit in a confirmatory trial.

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.

Definitions and Measures

Disease Progression: Cancer that continues to grow or spread.

Metastasis: The spread of cancer from one part of the body to another. A metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Trodelvy (sacituzumab govitecan)

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.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

<u>J9999</u>	<u>Not otherwise classified, antineoplastic drugs (when specified as [Trodelvy])</u>
<u>J3590</u>	<u>Unclassified Biologicals (when specified as [Trodelvy])</u>
<u>J3490</u>	<u>Unclassified drugs (when specified as [Trodelvy])</u>
<u>C9399</u>	<u>Unclassified drugs or biologics (Hospital Outpatient Only) (when specified as [Trodelvy])</u>

ICD-10 Diagnosis

ALL DIAGNOSIS

Document History

New: 06/08/2020

Document History:

- 06/08/2020 – Annual Review: Add new clinical criteria document for Trodelvy (sacituzumab govitecan). Coding Reviewed: Added HCPCS J9999, J3590, J3490, C9399, ALL DX pend

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.: 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.

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.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

© CPT Only – American Medical Association