

Drug Policy:

Trodelvy™ (sacituzumab govitecan-hziy)

POLICY NUMBER UM ONC_1407	SUBJECT Trodelvy™ (sacituzumab govitecan-hziy)	DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 06/10/20, 06/09/21, 07/14/21	APPROVAL DATE July 14, 2021	EFFECTIVE DATE July 30, 2021	COMMITTEE APPROVAL DATES 06/10/20, 06/09/21, 07/14/21
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee	
URAC STANDARDS HUM 1	NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS	APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Trodelvy (sacituzumab govitecan-hziy) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)
2. When health plan Exchange coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)

3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the [Preferred Drug Guidelines shall follow NCH L1 Pathways](#) when applicable, otherwise shall follow NCH drug policies **AND**
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision **AND**
5. When applicable, generic alternatives are preferred over brand-name drugs.

B. Breast Cancer

1. **NOTE: Per NCH Policy and NCH Pathway, Trodelvy (sacituzumab govitecan-hzly) is the recommended agent for subsequent line (2nd line and beyond) therapy of metastatic, triple negative breast cancer.**
 - a. Trodelvy use, as a single agent, is supported when **ALL** of the following criteria are met:
 - i. Member has recurrent/metastatic triple negative (ER/PR/HER-2 negative) breast cancer **AND**
 - ii. Member has experienced disease progression on one or more lines of therapy for metastatic triple negative breast cancer
2. **NOTE: Risk of Febrile Neutropenia is 5% which does not require the use of myeloid growth factors as primary prophylaxis.**

C. Urothelial Cancer

1. Trodelvy (sacituzumab govitecan-hzly) will be use as monotherapy in members with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.

III. EXCLUSION CRITERIA

- A. Disease progression while receiving Trodelvy (sacituzumab govitecan-hzly).
- B. Concurrent use with other anti-cancer therapy.
- C. Member with HER-2 positive and/or ER/PR positive breast cancer.
- D. Dosing exceeds single dose limit of Trodelvy (sacituzumab govitecan-hzly) 10 mg/kg.
- E. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

- A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

- A. None

VII. REFERENCES

- A. Tagawa ST, et al. ROPHY-U-01: A Phase II Open-Label Study of Sacituzumab Govitecan in Patients With Metastatic Urothelial Carcinoma Progressing After Platinum-Based Chemotherapy and Checkpoint Inhibitors. J Clin Oncol. 2021 Apr 30;JCO2003489.
- B. Bardia et al. ASCENT trial. N Engl J Med 2021;384: 1529-41. DOI: 10.1056/NEJMoa2028485.
- C. Trodelvy PI prescribing information. Immunomedics, Inc Morris Plains, NJ 2021.
- D. Clinical Pharmacology Elsevier Gold Standard 2021.
- E. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.
- F. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2021.
- G. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2021.