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, 11/10/21, 05/11/22	**APPROVAL DATE** May 11, 2022	**EFFECTIVE DATE** May 27, 2022	**COMMITTEE APPROVAL DATES** 06/10/20, 06/09/21, 07/14/21, 11/10/21, 05/11/22	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	**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

(http://pathways.newcenturyhealth.com/) 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 AND
6. When there is a documented drug shortage, disease progression, contraindication, or confirmed intolerance to a Preferred drug/regimen, per NCH Policy and Pathway, the available alternative product may be used if deemed medically appropriate and the indication is listed in a standard reference compendia or accepted peer review literature. For a list of current drug shortages, please refer to FDA drug shortage website in the reference section.

B. Breast Cancer

1. NOTE: Per NCH Policy and NCH Pathway, Trodelvy (sacituzumab govitecan-hzly) is the recommended agent for subsequent line (third 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 two or more lines of therapy and at least one of the therapies is 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-hziy) 10 mg/kg.

E. Investigational use of Trodelvy (sacituzumab govitecan-hziy) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those

recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.

4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

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.

H. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

I. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

J. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.