sacituzumab govitecan-hziy (Trodelvy®)	Place of Service Office Administration Infusion Center Administration Home Infusion Administration Outpatient Facility Administration HCPCS: **J9317** per 2.5 mg

Condition listed in policy (*see criteria for details*)

- Breast cancer
- Urothelial cancer

AHFS therapeutic class: Antineoplastic agent

Mechanism of action: Trop-2-directed antibody and topoisomerase inhibitor conjugate

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for sacituzumab govitecan-hziy (Trodelvy®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Breast cancer

1. Meets one of the following:
    a. Patient has a diagnosis of inflammatory breast cancer which has had no response to preoperative systemic therapy
    OR
    b. Patient has a diagnosis of recurrent unresectable (locally advanced or regional) or metastatic breast cancer

AND

2. Attestation of HER2-negativity, **AND**
3. Either of the following:
    a. Attestation of HR (ER and PR) negativity, **and** Patient has received at least two prior systemic therapies,
    OR
    b. Attestation of HR (ER and PR) positivity, **and** Patient has received prior treatment with endocrine therapy, a CDK4/6 inhibitor, and at least two lines of chemotherapy (including a taxane)

Covered Dose
Up to 10 mg/kg IV once weekly on Days 1 and 8 of continuous 21-day treatment cycles

Coverage Period
Indefinite

ICD-10:
C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519,

C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, Z85.3

Urothelial cancer

1. Disease is locally advanced, recurrent, or metastatic, **AND**
2. Being used as a single agent, **AND**
3. Patient has previously received both of the following in the advanced setting:
    a. Platinum-containing therapy, and
    b. PD-1 or PD-L1 inhibitor

Covered Dose
Up to 10 mg/kg IV once weekly on Days 1 and 8 of continuous 21-day treatment cycles

Coverage Period
Indefinite

ICD-10:
C61, C65.1, C65.2, C65.9, C66.1, C66.2, C66.9, C67.0-C67.9, C68.0, D09.0, Z85.51, Z85.59

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for sacituzumab govitecan-hziy (Trodelvy®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
180 mg lyophilized powder in a single-dose vial

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network. Bladder cancer (Volume 2.2022). Available by subscription at: www.nccn.org.
- National Comprehensive Cancer Network. Breast cancer (Version 3.2022). Available at www.nccn.org.
- Trodelvy® (sacituzumab govitecan-hziy) [Prescribing information]. Morris Plains, NJ: Immunomedics, Inc.; 06/2022.

(7) Policy Update

Date of last revision: 1Q2023
Date of next review: 3Q2023
Changes from previous policy version:

- Section (2) Breast cancer - Added coverage for previously treated hormone receptor-positive (HR+)/HER2-negative breast cancer

Rationale: NCCN category 2A support

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee