Generic Name: sacituzumab govitecan-hziy

Therapeutic Class or Brand Name: Trodelvy

Applicable Drugs: Trodelvy (sacituzumab govitecan-hziy)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 8/4/2026

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

I. Documentation of the following FDA-approved diagnosis AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Breast Cancer

i. Documentation of unresectable locally advanced or metastatic disease and meets criteria a or b:

a) Documentation of Triple Negative Breast Cancer (TNBC): hormone receptor (HR)-negative [or estrogen receptor (ER)-negative and progesterone receptor (PR)-negative], and human epidermal growth factor receptor 2 (HER2)-negative and meets one of the following i or ii:

i. Trodelvy will be used as monotherapy.

ii. Trodelvy will be used first-line with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab berahyaluronidase alfa-pmph) for tumors that express programmed death-ligand 1 (PD-L1) (combined positive score [CPS] greater than or equal to 10) as determined by an FDA-authorized test.

b) Documentation of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer

i. Documentation of disease progression following endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.

Other Uses With Supportive Evidence

B. Bladder Cancer

C. Breast Cancer

II. Age requirement: 18 years old and older.

III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

Exclusion Criteria

- N/A

Other Criteria

- N/A

Quantity / Days Supply Restrictions

Trodelvy is available as a 180 mg IV solution vial.

- The recommended dosage is 10 mg/kg on Days 1 and 8 of 21-day cycles until disease progression or unacceptable toxicity.
- Quantity limit: two 10 mg/kg doses per 21-day cycle.

Approval Length

- **Authorization:** 1 year
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

Appendix

N/A

References

1. Trodelvy. Prescribing Information. Gilead Sciences, Inc.; 2026. Accessed August 4, 2026.
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Breast Cancer. Version 6.2026. Updated *July 29, 2026*. Accessed *August 4, 2026.*
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Bladder Cancer. Version 2.2026. Updated *June 22, 2026*. Accessed *August 4, 2026.*

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.