Sacituzumab Govitecan-hziy (Trodelvy®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- Trodelvy is indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.
- Trodelvy is indicated for the treatment of adult patients with unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received endocrine based therapy and at least two additional systemic therapies in the metastatic setting.

Compendial Uses

- Breast Cancer
- Urothelial Carcinoma
  - Bladder Cancer
  - Primary Carcinoma of the Urethra
  - Upper Genitourinary Tract Tumors
  - Urothelial Carcinoma of the Prostate

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review, where applicable: Test results confirming status of the following:

- Human epidermal growth factor receptor 2 (HER2)
- Hormone receptor (HR)
- Programmed death-ligand 1 (PD-L1)

COVERAGE CRITERIA

Breast Cancer

Authorization of 12 months may be granted for treatment of HER2-negative recurrent unresectable or metastatic breast cancer or disease with no response to preoperative systemic therapy when either of the following criteria are met:

- The disease is HR-positive and all of the following criteria are met:
  - The member has received prior treatment including all of the following:
    - Endocrine therapy (e.g., anastrozole, letrozole, fulvestrant)
    - A CDK4/6 inhibitor (e.g., abemaciclib, palbociclib, ribociclib)
    - At least two lines of chemotherapy (including a taxane) at least one of which was in the metastatic setting
  - Member is not a candidate for fam-trastuzumab deruxtecan-nxki (Enhertu)
  - The requested medication will be used as a single agent as subsequent therapy
- The disease is HR-negative and either of the following criteria are met:
  - The requested medication will be used as first-line therapy in combination with pembrolizumab [Keytruda] for PD-L1 positive disease
  - The requested medication will be used as a single agent

Urothelial Carcinoma – Bladder Cancer

Authorization of 12 months may be granted as a single agent for subsequent treatment of stage II or III, recurrent, persistent, or metastatic bladder cancer in members who have received a platinum-containing chemotherapy and either a programmed death receptor-1 (PD-1) or a programmed death-ligand 1 (PD-L1) inhibitor.

Urothelial Carcinoma – Primary Carcinoma of the Urethra

Authorization of 12 months may be granted as a single agent for subsequent treatment of recurrent or metastatic primary carcinoma of the urethra in members who have received a platinum-containing chemotherapy and either a programmed death receptor-1 (PD-1) or a programmed death-ligand 1 (PD-L1) inhibitor.

Urothelial Carcinoma – Upper Genitourinary Tract Tumors or Urothelial Carcinoma of the Prostate

Authorization of 12 months may be granted as a single agent for subsequent treatment of metastatic upper genitourinary tract tumors or urothelial carcinoma of the prostate in members who have received a platinum-containing chemotherapy and either a programmed death receptor-1 (PD-1) or a programmed death-ligand 1 (PD-L1) inhibitor.

CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Trodelvy (Sacituzumab Govitecan-hziy)	Breast Cancer, Urothelial Carcinoma: Bladder Cancer, Primary Carcinoma	Route of Administration: Intravenous 10mg/kg on Days 1 and 8 of a 21-day cycle

	of the Urethra, Upper Genitourinary Tract Tumors, Urothelial Carcinoma of the Prostate	

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Trodelvy [package insert]. Foster City, CA: Gilead Sciences, Inc; March 2025.
2. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 26, 2026.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 5.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed December 8, 2025.

EFFECTIVE DATE 9/30/2026

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