

Specialty Guideline Management

Trodelvy

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Trodelvy	sacituzumab govitecan-hziy

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 Indications¹

- 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 Uses²

- 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 receptors:

- Human epidermal growth factor receptor 2 (HER2)
- Estrogen
- Progesterone

Coverage Criteria

Breast cancer^{1,2}

Authorization of 12 months may be granted as a single agent for treatment of breast cancer when either of the following criteria are met:

- The disease is recurrent unresectable, metastatic, or the member had no response to preoperative systemic therapy and all of the following criteria are met:
 - The diagnosis of triple-negative breast cancer is confirmed by the cancer cells testing negative for all of the following receptors:
 - Human epidermal growth factor receptor 2 (HER2)
 - Estrogen
 - Progesterone
 - The member has received at least one prior regimen, with at least one line for metastatic disease.
- The disease is recurrent unresectable or metastatic, or the member had no response to preoperative systemic therapy and all of the following criteria are met:
 - The cancer cells are hormone receptor positive and human epidermal growth factor receptor 2 (HER2)-negative.
 - 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).

Urothelial Carcinoma – Bladder Cancer²

Authorization of 12 months may be granted as a single agent for subsequent treatment of stage II, 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 Urethra²

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 Prostate²

Authorization of 12 months may be granted as a single agent for subsequent treatment of metastatic upper genitourinary tract tumors or urothelial carcinoma (UC) 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.

References

1. Trodelvy [package insert]. Foster City, CA: Gilead Sciences, Inc; November 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed December 13, 2024.