Draft Revised Policy: Do Not Implement

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.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:
POLICY

I. 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.

A. FDA-Approved Indications
   1. 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.
   2. 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.
   3. Trodelvy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either a programmed death receptor-1 (PD-1) or a programmed death-ligand 1 (PD-L1) inhibitor.

B. Compendial Uses
   1. Breast cancer
   2. Urothelial carcinoma
      a. Bladder cancer
      b. Primary carcinoma of the urethra
      c. Upper genitourinary tract tumors
      d. Urothelial carcinoma of the prostate

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review, where applicable: Test results confirming status of the following receptors:
A. Human epidermal growth factor receptor 2 (HER2)
B. Estrogen
C. Progesterone

III. CRITERIA FOR INITIAL APPROVAL

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

1. The disease is recurrent unresectable, metastatic, or the member had no response to preoperative systemic therapy and all of the following criteria are met:
   i. The diagnosis of triple-negative breast cancer is confirmed by the cancer cells testing negative for all of the following receptors:
      a. Human epidermal growth factor receptor 2 (HER2)
      b. Estrogen
      c. Progesterone
   ii. The member has received at least one prior regimen, ~~two prior therapies,~~ with at least one line for metastatic disease.
2. 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:
   i. The cancer cells are hormone receptor positive and human epidermal growth factor receptor 2 (HER2)-negative.
   ii. The member has received prior treatment including all of the following:
      a. Endocrine therapy (e.g., anastrozole, letrozole, fulvestrant)
      b. A CDK4/6 inhibitor (e.g., abemaciclib, palbociclib, ribociclib)
      c. At least two lines of chemotherapy (including a taxane) at least one of which was in the metastatic setting.
   iii. Member is not a candidate for fam-trastuzumab deruxtecan-nxki (Enhertu).

B. Urothelial Carcinoma – Bladder Cancer
Authorization of 12 months may be granted as a single agent for subsequent treatment of stage II, locally advanced, 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.

C. Urothelial Carcinoma – Primary Carcinoma of the Urethra
Authorization of 12 months may be granted as a single agent for subsequent treatment of locally advanced, 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.

D. 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 locally advanced or 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.

IV. CONTINUATION OF THERAPY

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

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

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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; April 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 13, 2024.

EFFECTIVE DATE	7/31/2020	(7/14/20 - Approved by P&T Corporate Subcommittee)
	11/2/2021	(8/10/21 - Approved by P&T Corporate Subcommittee)
	9/30/2022	(7/12/22 - Approved by P&T Corporate Subcommittee)
	6/30/2023	(4/11/23 - Approved by P&T Corporate Subcommittee)
	1/1/2024	(10/10/23 - CHS - Approved by P&T Corporate Subcommittee)
	5/31/2024	(3/12/24 - Approved by P&T Corporate Subcommittee)
	10/1/2024	(7/9/24 - Approved by P&T Corporate Subcommittee)

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