Reference number(s)
3818-A

SPECIALTY GUIDELINE MANAGEMENT

TRODELVY (sacituzumab govitecan-hziy)

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 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 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.

V. REFERENCES

1. Trodelvy [package insert]. Foster City, CA: Gilead Sciences, Inc; February 2023.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed December4, 2023.