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 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
   Recurrent unresectable or stage IV (M1) triple-negative breast cancer in patients who have received at least two prior therapies for metastatic disease

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 that the cancer cells are negative for 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 for treatment of recurrent, unresectable locally advanced, or metastatic triple-negative breast cancer (mTNBC) when all of the following criteria are met:
1. The diagnosis of triple-negative breast cancer is confirmed by the cancer cells testing negative for all of the following receptors:
   i. Human epidermal growth factor receptor 2 (HER2)
   ii. Estrogen
   iii. Progesterone
2. The member has received at least two prior therapies, at least one of them for metastatic disease

B. Urothelial cancer (UC)

Authorization of 12 months may be granted for treatment of locally advanced or metastatic urothelial cancer (mUC) when the member has 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]. Morris Plains, NJ: Immunomedics; April 2021.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 12, 2021.