Reference number(s)
4477-A

STANDARD MEDICARE PART B 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
1. Breast cancer
2. Urothelial carcinoma
   i. Bladder cancer
   ii. Primary carcinoma of the urethra
   iii. Upper genitourinary tract tumors
   iv. Urothelial carcinoma of the prostate

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions 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 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 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) for advanced disease (e.g., paclitaxel, doxorubicin, gemcitabine)

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

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization of 12 months may be granted when all of the following criteria are met.

A. The member is currently receiving therapy with Trodelvy
B. Trodelvy is being used to treat an indication enumerated in Section III
C. The member is receiving benefit from therapy. Benefit is defined as:
    1. No evidence of unacceptable toxicity while on the current regimen AND
    2. No evidence of disease progression while on the current regimen

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Trodelvy.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. NCCN Guideline: Breast cancer
4. NCCN Guideline: Bladder cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Trodelvy are covered in addition to the following:

1. Breast cancer
2. Urothelial carcinoma
    i. Bladder cancer
    ii. Primary carcinoma of the urethra
    iii. Upper genitourinary tract tumors
    iv. Urothelial carcinoma of the prostate

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Trodelvy to treat breast cancer can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for using Trodelvy to treat urothelial carcinoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

VII. REFERENCES

1. Trodelvy [package insert]. Foster City, CA: Gilead Sciences, Inc; December2022.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed December 7, 2022.