Reference number(s)
4477-A

Standard Medicare Part B 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 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.
- 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 Uses[2,3]

- Breast Cancer
- Urothelial Carcinoma
    - Bladder Cancer
    - Primary Carcinoma of the Urethra

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- Upper Genitourinary Tract Tumors
- Urothelial Carcinoma of the Prostate

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

Documentation

The following documentation must be available, upon request, for all submissions: Test results confirming status of the following:

- Human epidermal growth factor receptor 2 (HER2)
- Hormone receptor (HR)
- Programmed death-ligand 1 (PD-L1)

Coverage Criteria

Breast Cancer[1-3]

Authorization of 12 months may be granted for treatment of HER2-negative recurrent unresectable or metastatic breast cancer or disease with no response to preoperative systemic therapy when either of the following criteria are met:

- The disease is HR-positive and all of the following criteria are met:
    - 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)
    - The requested medication will be used as a single agent as subsequent therapy
- The disease is HR-negative and either of the following criteria are met:
    - The requested medication will be used as first-line therapy in combination with pembrolizumab [Keytruda] for PD-L1 positive disease
    - The requested medication will be used as a single agent

Urothelial Carcinoma – Bladder Cancer[2]

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

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Urothelial Carcinoma – Primary Carcinoma of the Urethra[2]

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 Prostate[2]

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

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:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication listed in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen, and
    - No evidence of disease progression while on the current regimen

Summary of Evidence

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

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

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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:

- Breast cancer
- Urothelial carcinoma
    - Bladder cancer
    - Primary carcinoma of the urethra
    - Upper genitourinary tract tumors
    - Urothelial carcinoma of the prostate

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).

References

1. Trodelvy [package insert]. Foster City, CA: Gilead Sciences, Inc.; March 2025.
2. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 26, 2026.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 5.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed December 8, 2025.

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