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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	May 22, 2020
Subject:	Trodelvy	**Page:**	1 of 5

Last Review Date: March 7, 2025

Trodelvy

Description

Trodelvy (sacituzumab govitecan-hziy)

Background
Trodelvy (sacituzumab govitecan-hziy) is an antibody drug conjugate that consists of a humanized antitrophoblast cell-surface antigen 2 (Trop-2) monoclonal antibody coupled to the topoisomerase 1 inhibitor SN-38 via a cleavable linker. Trop-2 is overexpressed in many epithelial cancers and is associated with cancer cell growth. Pharmacology data suggests that Trodelvy binds to Trop-2-expressing cancer cells and is internalized with the subsequent release of SN-38 via hydrolysis of the linker. SN-38 interacts with topoisomerase I and prevents re-litigation of topoisomerase I-induced single strand breaks. The resulting DNA damage leads to apoptosis and cell death (1-2).

Regulatory Status
FDA-approved indications: Trodelvy is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with: (2)

- Locally Advanced or Metastatic Breast Cancer
    - 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.
    - 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.

Trodelvy has a boxed warning for neutropenia and diarrhea: (2)

- Severe neutropenia may occur. Trodelvy should be withheld for absolute neutrophil count below 1500/mm^3 or neutropenic fever. Monitor blood cell counts periodically during treatment. Consider G-CSF for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.
- Severe diarrhea may occur. Patients with diarrhea should be monitored and given fluid or electrolytes as needed. At the onset of diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold Trodelvy until resolved to ≤ Grade 1 and reduce subsequent doses.

Trodelvy can cause fetal harm when administered to a pregnant woman. Female patients of reproductive potential should be advised to use effective contraception during treatment with Trodelvy and for 6 months after the last dose. Male patients with female partners of reproductive potential should be advised to use effective contraception during treatment with Trodelvy and for 3 months after the last dose (2).

The recommended dose of Trodelvy is 10 mg/kg once weekly on Days 1 and 8 of continuous 21-day treatment cycles until disease progression or unacceptable toxicity (2).

The safety and effectiveness of Trodelvy in pediatric patients less than 18 years of age have not been established (2).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Trodelvy may be considered **medically necessary** if the conditions indicated below are met.

Trodelvy may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Unresectable locally advanced or metastatic breast cancer **AND ONE** of the following:
    a. Triple-negative breast cancer (mTNBC)
        i. Patient has had at least two prior systemic therapies, at least one of them for metastatic disease
    b. HR-positive, HER2-negative (IHC 0, IHC 1+, or IHC 2+/ISH-) breast cancer
        i. Patient has received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting

AND ALL of the following:

a. Prescriber agrees to monitor blood cell counts for neutropenia
b. Prescriber agrees to monitor for diarrhea
c. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Trodelvy and for 6 months after the last dose
d. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Trodelvy and for 3 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Unresectable locally advanced or metastatic breast cancer

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor blood cell counts for neutropenia
c. Prescriber agrees to monitor for diarrhea

d. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Trodelvy and for 6 months after the last dose
e. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Trodelvy and for 3 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Trodelvy (sacituzumab govitecan-hziy) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with unresectable locally advanced or metastatic breast cancer. Trodelvy has a boxed warning for neutropenia and diarrhea. Trodelvy can cause fetal harm when administered to a pregnant woman. The safety and effectiveness of Trodelvy in pediatric patients less than 18 years of age have not been established (1-2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Trodelvy while maintaining optimal therapeutic outcomes.

References

1. Trodelvy. Drug Facts and Comparisons. eFacts [online]. Available from Wolters Kluwer Health, Inc. Accessed on 1/11/24.
2. Trodelvy [package insert]. Forest City, CA: Gilead Sciences, Inc.; November 2024.
3. NCCN Drugs & Biologics Compendium® Sacituzumab govitecan-hziy 2025. National Comprehensive Cancer Network, Inc. Accessed on January 8, 2025.

Policy History

Date	Action
May 2020	Addition to PA
June 2020	Annual review
September 2020	Annual review
May 2021	Revised indication to “unresectable locally advanced or metastatic triple-negative breast cancer who have received at least two prior systemic therapies, at least one of them for metastatic disease”. Added new indication of locally advanced or metastatic urothelial cancer
June 2021	Annual editorial review and reference update
September 2022	Annual review and reference update
February 2023	Addition of indication: unresectable locally advanced or metastatic HR-positive, HER2-negative breast cancer
June 2023	Annual review and reference update
March 2024	Annual review and reference update
June 2024	Annual review and reference update
December 2024	Per PI update, removed indication of urothelial cancer
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.