BlueCross BlueShield Federal Employee Program

TRODELVY
(sacituzumab govitecan-hziy)

RATIONALE FOR INCLUSION IN PA PROGRAM

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.

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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).

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.