Trodelvy (sacituzumab govitecan-hziy)
PAM – 029

Iowa Medicaid Program	Prior Authorization	**Effective Date**	07/01/2021
Revision Number	8	**Last Reviewed**	10/16/2026
Reviewed By	Medicaid Medical Director	**Next Review**	10/15/2027
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	12/23/2020

Overview

Medication: [1]	sacituzumab govitecan-hziy
Brand Name:	Trodelvy®
Pharmacologic Category:	Antineoplastic; Trop-2-directed antibody and topoisomerase inhibitor conjugate

FDA-Approved Indication(s):

Locally Advanced or Metastatic Triple-Negative Breast Cancer

First Line

1. As a single agent, for the first-line treatment of adult patients with unresectable locally advanced or metastatic triple negative breast cancer (TNBC) who are not candidates for PD-1 or PD-L1 inhibitor based therapy.
   - **NEW** indication: FDA-approved 6/24/2026
2. In combination with pembrolizumab (Keytruda) or pembrolizumab and berahyaluronidase alfa-pmph (Keytruda Qlex), for the first-line treatment of adult patients with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 [Combined Positive Score (CPS ≥ 10)] as determined by an FDA-authorized test.
   - Information on FDA-authorized tests for patient selection is available at: www.fda.gov/CompanionDiagnostics
   - **NEW** indication: FDA-approved 6/24/2026

Second Line or Later

3. Unresectable locally advanced or metastatic TNBC in adults who have received two or more prior systemic therapies, at least one of them for metastatic disease.

Locally Advanced or Metastatic HR-positive, HER2-negative Breast Cancer

4. 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.

How Supplied:	Single-dose vial, 180 mg of lyophilized powder

Dosage and Administration: Intravenous (IV) infusion

- When administered as a single agent or in combination with pembrolizumab, 10 mg/kg once weekly on Days 1 and 8 of a 21-day treatment cycle. Continue treatment until disease progression or unacceptable toxicity.
- When administered in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, discontinue pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph after approximately 24 months.

Benefit Category:	Medical

BOXED WARNING: NEUTROPENIA AND DIARRHEA

- Trodelvy® can cause severe, life-threatening, or fatal neutropenia. Withhold Trodelvy® for absolute neutrophil count below 1500/mm^3 or neutropenic fever. Monitor blood cell counts periodically during treatment. Primary prophylaxis with G-CSF is recommended for all patients at increased risk of febrile neutropenia. Initiate anti-infective treatment in patient with febrile neutropenia without delay.
- Trodelvy® can cause severe diarrhea. Monitor patients with diarrhea and give fluid and 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.

Descriptive Narrative

Triple-negative breast cancer (TNBC) describes a set of cancers that lack expression of the estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2). Unlike other subtypes (i.e., ER-positive, HER2-positive subtypes), there are no approved targeted treatments available. However, for a subset of TNBC, immunotherapy (in combination with chemotherapy) is available for those with advanced TNBC that expresses programmed cell death ligand 1 (PD-L1).

TNBC accounts for approximately 15 percent of breast cancers diagnosed worldwide, which amounts to almost 200,000 cases each year. Compared with hormone receptor-positive breast cancer, TNBC is more commonly diagnosed in women younger than 40 years of age, who are African-American, who have a BRCA1 mutation, or who have premenopausal status.[2]

Abbreviations

- **BRCA1:** breast cancer susceptibility gene 1. Pathogenic variants in BRCA1 and BRCA2 are the strongest hereditary risk factors for the development of breast and ovarian cancer.[3]
- **TNBC:** triple-negative breast cancer, defined as breast cancers that have less than 1 percent expression of the estrogen receptor (ER) and the progesterone receptor (PR) as determined by immunohistochemistry (IHC), and that are, for HER2, either 0 to 1+ by IHC, or IHC 2+ and fluorescence in situ hybridization negative (not amplified), according to American Society of Clinical Oncology/College of American Pathologists guidelines.
- **mTNBC:** metastatic triple-negative breast cancer
- **PD-1:** programmed cell death protein 1; protein found on T cells that helps keep the body's immune responses in check. PD-1 is an inhibitor of both adaptive and innate immune responses.

- **PD-L1:** programmed cell death ligand 1; protein found on the surface of multiple tissue types, including many tumor cells. It is expressed by some tumor cells as an “adaptive immune mechanism” to escape anti-tumor responses. Immune checkpoint inhibitors like Trodelvy® bind to PD-L1 and block its binding to PD-1, leaving the T cells free to kill cancer cells.
- **PD-1/PD-L1 pathway:** controls the induction and maintenance of immune tolerance within the tumor microenvironment. The activity of PD-1 and its ligands PD-L1 or PD-L2 are responsible for T cell activation, proliferation, and cytotoxic secretion in cancer to degenerating anti-tumor immune responses.

Guidelines

The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology document evidence-based, consensus-driven management to ensure that all patients receive preventive, diagnostic, treatment, and supportive services that are most likely to lead to optimal outcomes. The guidelines are developed and updated by 63 individual panels, comprising over 1,900 clinicians and oncology researchers from the 33 NCCN Member Institutions. The categories for recommendations are based on both the level of clinical evidence available and the degree of consensus within the NCCN Guidelines Panel.

The library of NCCN Guidelines® currently apply to more than 97 percent of people living with cancer or anyone at risk for a diagnosis of cancer in the United States. The guidelines incorporate real-time updates in keeping with the rapid advancements in the field of cancer research and management and are intended to assist all individuals who impact decision-making in cancer care, including physicians, nurses, pharmacists, payers, patients and their families, and others.

The NCCN Guidelines provide recommendations based on the best evidence available at the time they are derived. Because new data are published continuously, it is essential that the NCCN Guidelines also be continuously updated and revised* to reflect new data and clinical information that may add to or alter current clinical practice standards.[4,5]

The information referenced at the time of this policy writing/revision (note version number and effective date) is from the NCCN Guidelines® for:[6]

- Breast Cancer (v.6.2026 – July 29, 2026)

* To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

Criteria

Prior authorization is required.

Triple-Negative Breast Cancer

Trodelvy® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of triple-negative breast cancer (TNBC); **AND**
2. Disease is unresectable locally advanced or metastatic; **AND**
3. Member is 18 years of age or older; **AND**
4. Request meets **ONE** of the following options (a, b, or c);
    a. Member is not a candidate for PD-1 or PD-L1 inhibitor-based therapy, and Trodelvy® is prescribed as a single agent for first-line therapy; **OR**
    b. Member's tumors express PD-L1 (as determined by an FDA-authorized test), and:
        i. Combined Positive Score (CPS) is ≥ 10; and,
        ii. Trodelvy® is prescribed in combination with pembrolizumab (Keytruda®) or pembrolizumab and berahyaluronidase alfa-pmph (Keytruda Qlex®) for first-line therapy; **OR**
    c. Member has received two or more prior systemic therapies, at least one of them for metastatic disease, and Trodelvy® is prescribed as a second-line or later therapy; **AND**
5. Will not be prescribed in combination with irinotecan or its active metabolite SN-38; **AND**
6. Prescribed by, or in consultation with, an oncologist; **AND**
7. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 10 mg/kg once weekly on Days 1 and 8 of a 21-day treatment cycle; or,
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

HR-positive, HER2-negative Breast Cancer

Trodelvy® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of unresectable locally advanced or metastatic breast cancer, which is (both a and b):
    a. Hormone receptor (HR)-positive; **AND**
    b. Human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+, or IHC 2+/ISH-); **AND**
2. Member is 18 years of age or older; **AND**
3. Member has received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting; **AND**
4. Will not be prescribed in combination with irinotecan or its active metabolite SN-38; **AND**
5. Prescribed by, or in consultation with, an oncologist; **AND**
6. Request meets one of the following (a b):
    a. Regimen prescribed does not exceed 10 mg/kg once weekly on Days 1 and 8 of a 21-day treatment cycle; or,
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Continuation Therapy

Trodelvy® is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy, as demonstrated by tumor response or lack of disease progression, and an acceptable toxicity profile; **AND**
3. Prescribed by, or in consultation with, an oncologist; **AND**
4. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 10 mg/kg once weekly (on Days 1 and 8 of a 21-day treatment cycle) until disease progression or unacceptable toxicity*; or,
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

* When Trodelvy is administered in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph), the Keytruda or Keytruda Qlex should be discontinued after approximately 24 months. Refer to the Prescribing Information for these products for the recommended dosing information.

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	6 months	12 months
Quantity Limits	10 mg/kg once weekly on Days 1 and 8 of a continuous 21-day treatment cycle	

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J9317	Injection, sacituzumab govitecan-hziy, 2.5 mg

ICD-10	Description
C50.011 – C50.329	Malignant neoplasm of breast
C79.81	Secondary malignant neoplasm of breast

NDC (Strength)	Labeler	Dosage	Pkg Size	Pkg Qty	Units/ Pkg
55135-0132-01 (180 mg)	Gilead Sciences, Inc. (55135)	2.5 mg	1	EA	72

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be

safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Trodelvy® prescribing information (06/2026). Gilead Sciences, Inc.: Foster City, CA. Available online: www.trodelvyhcp.com. Accessed August 3, 2026.

[2] Anders CK, Carey LA. ER/PR negative, HER2-negative (triple-negative) breast cancer. Vora SR, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed August 3, 2026.

[3] Peshkin BN, Isaacs C. Genetic testing for hereditary breast and ovarian cancer syndromes. Vora SR, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed August 3, 2026.

[4] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

[5] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

[6] NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are continuously updated and revised to reflect new data and clinical information that may add to or alter current clinical practice standards. To view the most recent and complete version, go online to NCCN.org. NCCN Guidelines® referenced at time of this revision (note version number and effective date):

- Breast Cancer (v.6.2026 – July 29, 2026)

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

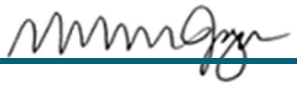
Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

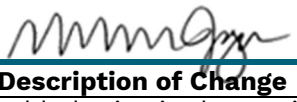
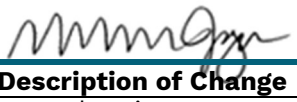
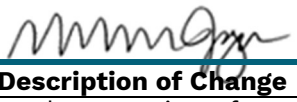
Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
10/16/2026	CAC	Annual review. Updated references. FDA approved 6/24/2026: Two new indications for first-line treatment of locally advanced or metastatic triple-negative breast cancer. Updated policy to include this information (Overview, Criteria, etc.). Policy format update: Removed current NCCN Guidelines recommendations, as guidelines may change more frequently than the review cadence of this document. Will continue to reference NCCN when writing criteria, and include the specific version referenced at the time of the policy writing/revision.	8
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
01/16/2026	CAC	Annual review. Removed indication for locally advanced or metastatic urothelial cancer – indication removed by FDA November 22, 2024. Removed criteria and other references to this indication. Updated boxed warning (previous reference to G-CSF for secondary prophylaxis of febrile neutropenia; now primary prophylaxis with G-CSF is recommended for all patients at increased risk of febrile neutropenia.	7
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
10/18/2024	CAC	Annual review. Moved from July to October review to align with other policies for breast cancer. Added boxed warning information below Overview table. Added dosing into criteria. Reviewed NCCN Guidelines; no changes. Updated references where applicable.	6
Signature William (Bill) Jagiello, DO			

Criteria Change History *(continued)*

Change Date	Changed By	Description of Change	Version
07/21/2023	CAC	Annual review. New indication for unresectable locally advanced or metastatic HR-positive, HER2-negative breast cancer approved 2/3/2023. Updated overview table and developed criteria for new indication. Updated NCCN Guidelines.	5
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
07/15/2022	CAC	Added criteria that regimen/dosing prescribed must be in alignment with FDA-approved labeling or supported in NCCN Guidelines. Updated NCCN Guidelines. Formatting.	4
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
07/16/2021	CAC	Annual review.	3
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
04/16/2021	CAC	Implementation of new formatting. Added new indications.	2
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
01/15/2021	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee