Clinical Policy: Sacituzumab Govitecan-hziy (Trodelvy)

Reference Number: ERX.SPA.385
Effective Date: 04.22.20
Last Review Date: 05.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Sacituzumab govitecan-hziy (Trodelvy™) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate.

FDA Approved Indication(s)
Trodelvy is indicated for the treatment of adult patients with

- Unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received at least two or more prior systemic therapies, at least one of them for metastatic disease
- Locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PDL1) inhibitor*

**This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.*

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Trodelvy is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (must meet all)**:**

1. Diagnosis of unresectable or locally advanced metastatic breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Documentation of triple negative (i.e., estrogen receptor-, progesterone receptor-, and human epidermal growth factor receptor 2 [HER2]-negative) disease;
5. Failure of both of the following (a and b):
   a. Two or more prior regimens (*see Appendix B*);
   b. At least one of the prior regimens administered for metastatic disease (*see Appendix B*);
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 10 mg/kg on days 1 and 8 of each 21-day cycle;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Urothelial Cancer (must meet all)**:**

1. Diagnosis of locally advanced or metastatic urothelial cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Failure of both of the following (a and b):

a. Platinum-containing chemotherapy (*see Appendix B*);
b. Programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor (*see Appendix B*);

5. Request meets one of the following (a or b):*
   a. Dose does not exceed 10 mg/kg on days 1 and 8 of each 21-day cycle;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Trodelvy for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 10 mg/kg on days 1 and 8 of each 21-day cycle;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2
PD-1: programmed death receptor-1
PD-L1: programmed death-ligand

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Examples of systemic therapies for recurrent unresectable or metastatic breast cancer		
paclitaxel	Varies	Varies
Abraxane® (albumin-bound paclitaxel)	Varies	Varies
docetaxel (Taxotere®)	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
doxorubicin	Varies	Varies
Liposomal doxorubicin (Doxil®)	50 mg/m^2 IV day 1, cycled every 28 days	Varies
capecitabine (Xeloda®)	1,000-1,250 mg/m^2 PO BID on days 1-14, cycled every 21 days	Varies
gemcitabine (Gemzar®)	800-1,200 mg/m^2 IV on days 1, 8 and 15, cycled every 28 days	Varies
vinorelbine	Varies	Varies
Halaven® (eribulin)	1.4 mg/m^2 IV on days 1 and 8, cycled every 21 days	Varies
carboplatin	AUC 6 IV on day 1, cycled every 21-28 days	Varies
cisplatin	75 mg/m^2 IV on day 1, cycled every 21 days	Varies
cyclophosphamide	50 mg PO QD on days 1-21, cycled every 28 days	Varies
epirubicin (Ellence®)	60-90 mg/m^2 IV on day 1, cycled every 21 days	Varies
Ixempra® (ixabepilone)	40 mg/m^2 IV on day 1, cycled every 21 days	40 mg/m^2
Examples of platinum-containing regimens for urothelial cancer		
DDMVAC (dose-dense methotrexate, vinblastine, doxorubicin, and cisplatin)	Varies	Varies
gemcitabine with either cisplatin or carboplatin	Varies	Varies
Examples of PD-1 and PD-L1 inhibitors for urothelial cancer		
Keytruda® (pembrolizumab)	Varies	Varies
Tecentriq® (atezolizumab)	Varies	Varies
Opdivo® (nivolumab)	Varies	Varies
Bavencio® (avelumab)	800 mg IV infusion once every 2 weeks	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): severe hypersensitivity reaction to Trodelvy
- Boxed warning(s): neutropenia and diarrhea

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Triple-negative breast cancer, urothelial cancer	10 mg/ kg on days 1 and 8 of each 21-day cycle	10 mg/kg

VI. Product Availability
Single-dose vial: 180 mg lyophilized powder for reconstitution

VII. References
1. Trodelvy Prescribing Information. Morris Plains, NJ: Immunomedics, Inc.; April 2021. Available at: Available at: https://www.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi.pdf. Accessed April 18, 2021.
2. Bardia A, Mayer IA, Vahdat LT, et al. Sacituzumab govitecan-hziy in refractory metastatic triple-negative breast cancer. N Engl J Med 2019 Feb 21;380(8):741-51.
3. Sacituzumab govitecan. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed April 18, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively.	03.03.20	05.20
Drug is now FDA-approved - criteria updated per FDA-labeling: removed requirement for previous taxane-based regimen as this is neither in the PI nor required by NCCN.	05.10.20	08.20
2Q 2021 annual review: RT4: added criteria for new metastatic urothelial carcinoma indication; updated breast cancer criteria to add unresectable locally advanced option and clarified that of the two or more prior regimens, at least one of them be for metastatic disease, based on updated FDA-labeling; references reviewed and updated.	04.19.21	05.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.