Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 08/01/2020**
Policy Number: PA.CP.PHAR.475	**Effective Date: 07/15//2020** **Revision Date: 07/15/2020**
Policy Name: Sacituzumab Govitecan-hziy (Trodelvy)	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

New Policy Created

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Sacituzumab Govitecan-hziy (Trodelvy)

Reference Number: PA.CP.PHAR.475
Effective Date: 07/2020
Last Review Date: 07/2020

Coding Implications
Revision Log

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 metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease.

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.

It is the policy of health plans affiliated with PA Health & Wellness® that Trodelvy is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of 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. Member has received at least two prior therapies 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*).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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*).

Approval duration: 12 months

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2
mTNBC: metastatic triple-negative breast cancer

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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
paclitaxel	Varies	Varies
Abraxane® (albumin-bound paclitaxel)	Varies	Varies
docetaxel (Taxotere®)	Varies	Varies
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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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

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 to Trodelvy
- Boxed warning(s): neutropenia and diarrhea
  - Severe neutropenia may occur. Withhold Trodelvy for absolute neutrophil count below 1.500/mm^3 or neutropenic fever. Monitor blood cell counts periodically during treatment. Consider granulocyte colony stimulating factor (G-CSF) for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.
  - Severe diarrhea may occur. Monitor patients with diarrhea and give fluid and electrolytes as needed. Administer atropine, if not contraindicated, for early diarrhea of any severity. At the onset of late 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.

V. Dosage and Administration

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

VI. Product Availability

Vial: 180 mg lyophilized powder for reconstitution

VII. References

1. Trodelvy Prescribing Information. Morris Plains, NJ: Immunomedics, Inc.; April 2020. Available at: https://www.trodelvy.com/. Accessed May 10, 2020.
2. ClinicalTrials.gov. ASCENT-Study of sacituzumab govitecan in refractory/relapsed triple-negative breast cancer. Available at: https://clinicaltrials.gov/ct2/show/NCT02574455. Accessed February 24, 2020.
3. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT01631552. Phase I/II Study of IMMU-132 in Patients with Epithelial Cancers. Accessed February 24, 2020.
4. 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.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-

date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
Pending	Injection, sacituzumab govitecan-hziy, 10 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New Policy Created	07/2020	