Clinical Policy: Sacituzumab Govitecan-hziy (Trodelvy)

Reference Number: CP.PHAR.475
Effective Date: 04.22.20
Last Review Date: 05.21
Line of Business: Commercial, HIM, Medicaid

Coding Implications
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 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 Centene Corporation® 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. Failure of two prior regimens 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:
HIM/Medicaid – 6 months
Commercial – 6 months or to the member's renewal date

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit, 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:
HIM/Medicaid – 12 months
Commercial – 6 months or to the member's renewal date

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, 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
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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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
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

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.gilead.com/-/media/files/pdfs/medicines/oncology/trodelvy/trodelvy_pi.pdf. Accessed February 2, 2021.
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.

5. Sacituzumab govitecan. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 2, 2021.

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
J9317	Injection, sacituzumab govitecan-hziy, 2.5 mg

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: no significant changes; updated JCode; references for HIM line of business off-label use revised from HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	02.02.21	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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.