Clinical Policy: Sacituzumab Govitecan-hziy (Trodelvy)
Reference Number: CP.PHAR.475
Effective Date: 04.22.20
Last Review Date: 08.20
Line of Business: Commercial, HIM, Medicaid

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.PHAR.21 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.PHAR.21 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.PHAR.21 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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>paclitaxel</td>
<td>Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>Abraxane® (albumin-bound paclitaxel)</td>
<td>Varies</td>
<td>Varies</td>
</tr>
</tbody>
</table>
Drug Name | Dosing Regimen | Dose Limit/Maximum Dose
--- | --- | ---
docetaxel (Taxotere®) | Varies | Varies
doxorubicin | Varies | Varies
Liposomal doxorubicin (Doxil®) | 50 mg/m² IV day 1, cycled every 28 days | Varies
capcitabine (Xeloda®) | 1,000-1,250 mg/m² PO BID on days 1-14, cycled every 21 days | Varies
gemcitabine (Gemzar®) | 800-1,200 mg/m² IV on days 1,8 and 15, cycled every 28 days | Varies
vinorelbine | Varies | Varies
Halaven® (eribulin) | 1.4 mg/m² 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/m² 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/m² IV on day 1, cycled every 21 days | Varies
Ixempra® (ixabepilone) | 40 mg/m² IV on day 1, cycled every 21 days | 40 mg/m²

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/mm³ 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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triple-negative breast cancer</td>
<td>10 mg/kg on days 1 and 8 of each 21-day cycle</td>
<td>10 mg/kg</td>
</tr>
</tbody>
</table>

VI. Product Availability

Vial: 180 mg lyophilized powder for reconstitution
VII. References

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.

<table>
<thead>
<tr>
<th>HCPSC Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>Pending</td>
<td>Injection, sacituzumab govitecan-hziy, 10 mg</td>
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</table>

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th></th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>Policy created pre-emptively.</td>
<td>03.03.20</td>
<td>05.20</td>
</tr>
<tr>
<td>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.</td>
<td>05.10.20</td>
<td>08.20</td>
</tr>
</tbody>
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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, and plan documents).
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.

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