**Trodelvy™ (sacituzumab govitecan-hziy)**

**Last Review Date:** September 11, 2020  
**Number:** MG.MM.PH.218

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**Definition**

Trodelvy, a Trop-2-directed antibody and topoisomerase inhibitor conjugate, 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. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication maybe contingent upon verification and description of clinical benefit in trials.

**Length of Authorization**

Coverage will be provided for 12 months and may be renewed.

**Dosing Limits**

Max Units (per dose and over time) [Medical Benefit]:

- 10mg/kg once weekly on days 1 and 8 of 21-day treatment cycles

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**TRODELVY™ (SACITUZUMAB GOVITECAN-HZIY) DOSING**

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**I. INITIAL APPROVAL CRITERIA**

*Trodelvy may be considered medically necessary if one of the below conditions are met AND use is consistent with the medical necessity criteria that follows:*

**Breast Cancer**

A. The medication must be prescribed by or in consultation with an oncologist; **AND**

B. The patient has metastatic triple-negative breast cancer; **AND**

C. The patient has been previously treated with at least two systemic therapy regimens for
metastatic disease.

Note: Examples are cisplatin, carboplatin, doxorubicin, cyclophosphamide, paclitaxel, docetaxel, capecitabine, gemcitabine, ixabepilone, vinorelbine, eribulin, epirubicin, Doxil (liposomal doxorubicin for injection), Tecentriq (atezolizumab for injection) + Abraxane (albumin-bound paclitaxel for injection).

Limitations/Exclusions

Trodelvy is not considered medically necessary for when any of the following selection criteria is met:

1) The patient is less than 18 years of age
2) Disease progression while on Trodelvy
3) Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. RENEWAL CRITERIA

- Patient continues to meet INITIAL APPROVAL CRITERIA.
- Tumor response with disease stabilization or reduction of tumor size and spread.

Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tbody>
<tr>
<td>Breast Cancer</td>
<td>The recommended dose of Trodelvy is 10 mg/kg administered as an intravenous infusion once weekly on Days 1 and 8 of 21-day treatment cycles. Continue treatment until disease progression or unacceptable toxicity. Do not administer Trodelvy at doses greater than 10 mg/kg.</td>
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</tbody>
</table>

Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>C9066</td>
<td>Injection, sacituzumab govitecan-hziy, 10 mg (Trodelvy). C-Code effective date: 10/01/2020</td>
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</tbody>
</table>

Applicable NDCs

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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>55135-0132-01</td>
<td>Trodelvy™ (sacituzumab govitecan-hziy) supplied as 180 mg of sacituzumab govitecan-hziy as lyophilized powder in a single-use vial</td>
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</tbody>
</table>

Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C50.919</td>
<td>Malignant neoplasm of unspecified site of unspecified female breast</td>
</tr>
<tr>
<td>C50.929</td>
<td>Malignant neoplasm of unspecified site of unspecified male breast</td>
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</table>

Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>9/11/2020</td>
<td>Added C-Code (C9066) Injection, sacituzumab govitecan-hziy, 10 mg (Trodelvy). C-Code effective date: 10/01/2020</td>
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<tr>
<td>06/23/2020</td>
<td>New Medical Policy</td>
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References