POLICY: Oncology – Trodelvy™ (sacituzumab govitecan-hziy injection for intravenous use – Immunomedics, Inc.)

DATE REVIEWED: 04/23/2020

OVERVIEW

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.[1] 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.

Guidelines

Trodelvy is not addressed in the guidelines. According to the National Comprehensive Cancer Network (NCCN) breast cancer guidelines (version 3.2020 – March 6, 2020), systemic therapy options for metastatic disease include a variety of chemotherapy agents such as carboplatin or cisplatin (specified for TNBC and germline BRCA 1/2 mutation), Tecentriq (atezolizumab for injection) + Abraxane (albumin-bound paclitaxel for injection) [for programmed death ligand-1 {PD-L1} expression ≥ 1%], paclitaxel, cyclophosphamide, doxorubicin, Doxil (liposomal doxorubicin for injection), capecitabine, gemcitabine, docetaxel, epirubicin, vinorelbine, eribulin.2 Single agents are preferred; however, chemotherapy combinations may be used in patients with high tumor burden, rapidly progressing disease, and visceral crisis.

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Trodelvy. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the criteria and dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below.

Because of the of the specialized skills required for evaluation and diagnosis of patients treated with Trodelvy, as well as the monitoring required for adverse events and long-term efficacy, approval requires Trodelvy to be prescribed by or in consultation with a physician who specializes in the condition being treated.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Trodelvy is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Breast Cancer**. Approve for 1 year if the patient meets ALL of the criteria (A, B, C, and D):
   - **A)** The patient is ≥ 18 years of age; 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); AND
   - **D)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve if each dose does not exceed 10 mg/kg, administered intravenously (IV) once weekly on Days 1 and 8 of each 3-week treatment cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Trodelvy has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Trodelvy™ injection for intravenous use [prescribing information]. Morris Plains, NJ: Immunomedics, Inc.; April 2020.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (Version 3.2020 – March 6, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 22, 2020.

HISTORY

Type of Revision	Summary of Changes*	Date Reviewed
New policy	New criteria	04/23/2020