Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 216.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Trodelvy (sacituzumab govitecan-hziy)

I. Policy:
Trodelvy (sacituzumab govitecan-hziy)

II. Purpose/Objective:
To provide a policy of coverage regarding Trodelvy (sacituzumab govitecan-hziy)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Trodelvy (sacituzumab govitecan-hziy) is an antibody drug conjugate that consists of a humanized antitrophoblast cell-surface antigen 2 (Trop-2) monoclonal antibody coupled to the topoisomerase 1 inhibitor SN-38 via a cleavable linker (Bardia 2019). Trop-2 is overexpressed in many epithelial cancers and is associated with cancer cell growth; it has been detected in breast cancer cells (including triple-negative breast cancer cells). Sacituzumab govitecan binds to Trop-2 and is internalized; SN-38 is released in tumors both intracellularly and in the tumor microenvironment, leading to DNA damage, apoptosis, and cell death.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Trodelvy (sacituzumab govitecan-hziy) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

Unresectable Locally Advanced or Metastatic Triple-Negative Breast Cancer
- Medical record documentation that Trodelvy is written by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of unresectable locally advanced or metastatic triple-negative breast cancer* **AND**
- Medical record documentation of trial of at least two previous lines of systemic therapy, of which at least one was for metastatic disease

***Note:** Triple negative breast cancer lacks expression of estrogen receptor (ER-negative), progesterone receptor (PR-negative) and human epidermal growth factor receptor 2 (HER2-negative).

Unresectable Locally Advanced or Metastatic HR Positive, HER2 Negative Breast Cancer
- Medical record documentation that Trodelvy is written by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of unresectable locally advanced or metastatic hormone receptor (HR)positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer **AND**
- Medical record documentation of previously receiving endocrine-based therapy **AND**
- Medical record documentation of previously receiving at least two additional systemic therapies in the metastatic setting

Urothelial Cancer
- Medical record documentation that Trodelvy is written by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of locally advanced or metastatic urothelial cancer **AND**
- Medical record documentation of progression on platinum-containing chemotherapy **AND**
- Medical record documentation of progression on a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PDL1) inhibitor

AUTHORIZATION DURATION: Initial approval will be for **6 months.** Subsequent approvals will be for an additional **6 months** and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Trodelvy [prescribing information]. Foster City, CA: Gilead Sciences Inc; February 2023.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 7/21/20

Revised: 6/18/21 (Urothelial Cancer), 7/9/21 (Breast updates - advanced/unresectable, at least one metastatic treatment), 6/14/22 (Medicaid PARP statement), 4/25/23 (Medicaid business segment, Medicare carve out, add HR+/NER2- BC), 12/28/23 (references added)

Reviewed: 4/11/24

MA UM Committee approval: 12/31/23