ATRIO HEALTH PLANS

Trodelvy - Complement Inhibitors

Trodelvy (pegcetacoplan) J9317

Prior Authorization Request

Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Continuation"**

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

THIS AUTHORIZATION DOES NOT GUARANTEE PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

For questions or assistance, please contact Customer Service at 1-877-672-8620, daily, 8am – 8pm (PST) (TTY users should call 1-800-735-2900).

Prior Authorization Group – Trodelvy PA

Drug Name(s):

TRODELVY **SACITUZUMAB GOVITECAN-HZIY**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. **Drug meets the following utilization management criteria:**
    a. For treatment of **breast cancer** when either of the following criteria are met:
        i. The disease is recurrent, unresectable, metastatic, or the member had no response to preoperative systemic therapy and ALL of the following criteria are met:
            1. The diagnosis of triple-negative breast cancer is confirmed by the cancer cells testing negative for all of the following receptors:
                a. Human epidermal growth factor receptor 2 (HER2); AND
                b. Estrogen; AND
                c. Progesterone;
            2. The member has received at least two prior therapies, with at least one line for metastatic disease; or
        ii. The disease is recurrent unresectable or metastatic disease and ALL the following criteria are met:
            1. The cancer cells are hormone receptor positive and human epidermal growth factor receptor 2 (HER2)-negative; and
            2. The member has received prior treatment including all of the following:
                a. Endocrine therapy (e.g., anastrozole, letrozole, fulvestrant); AND
                b. A CDK4/6 inhibitor (e.g., abemaciclib, palbociclib, ribociclib); AND
                c. At least two lines of chemotherapy (including a taxane) for advanced disease (e.g., paclitaxel, doxorubicin, gemcitabine)
    b. For treatment of **Bladder cancer, Carcinoma of the Urethra or Upper Genitourinary Tract tumors**:
        i. Used as a single agent for subsequent treatment of locally advanced, recurrent, persistent, or metastatic cancer
        ii. The member has received prior treatment including all of the following:
            1. Platinum-containing chemotherapy AND
            2. A programmed death receptor-1 (PD-1) OR
            3. A programmed death-ligand 1 (PD-L1) inhibitor.
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
    - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
    - Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

- **N/A**

Prescriber Restrictions:

- Oncology or related specialty

Coverage Duration:

Approval will be for 6 months

FDA Indications:

- Breast cancer, Unresectable locally advanced or metastatic, HR-positive and HER2-negative (IHC 0, IHC 1+, or IHC 2+/ISH-) disease, after endocrine-based and at least 2 additional systemic therapies in metastatic setting
- Triple-negative breast cancer, Unresectable locally advanced or metastatic, after at least 2 prior systemic therapies
- Urothelial carcinoma, Metastatic or locally advanced, after platinum-containing chemotherapy and either PD-1 or PD-L1 inhibitor

Off-Label Uses:

- N/A

Age Restrictions:

- Safety and effectiveness have not been established in pediatric patients

Other Clinical Consideration:

- Increased risk of neutropenia, febrile neutropenia, anemia, and potentially other adverse reactions in patients who are homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele; monitoring is required for patients with reduced UGT1A1 activity and interruption or discontinuation of therapy may be necessary

Resouces:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/B511AE/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/D134B0/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=932911&contentSetId=100&title=Sacituzumab+Govitecan-hziy&servicesTitle=Sacituzumab+Govitecan-hziy&brandName=Trodelvy&UserMdxSearchTerm=trodelvy&=null#