JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP071
		Effective Date	06/01/2022
		Review Date	04/20/2022
	Subject **Trodelvy**	*Revision Date*	04/20/2022
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: trodelvy

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I. POLICY

A. Trodelvy (sacituzumab govitecan-hziy) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Trodelvy may be approved for patients who meet the following:
   1. Breast cancer
      a. Documentation has been submitted showing the following:
         I. Patient has been diagnosed with recurrent, unresectable locally advanced, or metastatic triple-negative breast cancer (mTNBC)
         II. Diagnosis of triple-negative breast cancer has been confirmed by the cancer cells testing showing negative results for all of the following receptors:
            - Human epidermal growth factor receptor 2 (HER2)
            - Estrogen
            - Progesterone
         III. Patient has received at least two prior therapies, at least one of them for metastatic disease
   2. Urothelial cancer (UC)
      a. Documentation has been submitting showing the following:
         I. Patient has been diagnosed with locally advanced or metastatic urothelial cancer (mUC)
         II. Patient has received a platinum-containing chemotherapy and one of the following:
            - a programmed death receptor-1 (PD-1) inhibitor
            - a programmed death-ligand 1 (PD-L1) inhibitor

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy

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B. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient is continuing to tolerate the regimen and there has not been disease progression while on treatment

IV. EXCLUSIONS

A. Trodelvy will not be covered for the following:
   1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSAGE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

VI. CODES

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Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, sacituzumab govitecan-hziy, 2.5 mg	J9317

VII. REFERENCES

1. Trodelvy [prescribing information]. Morris Plains, NJ: Immunomedics; April 2021.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 25, 2022.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2022	Policy Creation

Review Date/s: 04/20/2022

Revision Date/s:

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