



Medical Policy Manual **Approved Rev: Do Not Implement until 3/4/25**

Enfortumab Vedotin-ejfv (Padcev®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Padcev (enfortumab vedotin-ejfv), as a single agent, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy or are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy.
2. Padcev, in combination with pembrolizumab, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC)

B. Compendial Uses

Urothelial carcinoma

1. Bladder cancer
2. Primary carcinoma of the urethra
3. Upper genitourinary (GU) tract tumors
4. Urothelial carcinoma of the prostate

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Urothelial Carcinoma

- A. Authorization of 12 months may be granted for treatment of urothelial carcinoma as a single agent when used as subsequent therapy following platinum-containing chemotherapy and prior treatment with a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor or when used as subsequent therapy for members who are ineligible for cisplatin-containing chemotherapy for any of the following subtypes:
 1. Urothelial carcinoma of the bladder in any of the following settings:
 - a. Stage II, locally advanced or metastatic disease
 - b. Metastatic or local recurrence post-cystectomy
 - c. Muscle invasive local recurrence or persistent disease in a preserved bladder
 2. Primary carcinoma of the urethra with locally advanced, recurrent or metastatic disease.



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3. Urothelial carcinoma of the upper genitourinary tract or urothelial carcinoma of the prostate with locally advanced or metastatic disease.
 - B. Authorization of 12 months may be granted for **first-line** treatment of urothelial carcinoma in combination with pembrolizumab for any of the following subtypes:
 1. Urothelial carcinoma of the bladder in any of the following settings:
 - a. Stage II, locally advanced or metastatic disease
 - b. Metastatic or local recurrence post-cystectomy
 - c. Muscle invasive local recurrence or persistent disease in a preserved bladder
 2. Primary carcinoma of the urethra with locally advanced or metastatic disease.
 3. Urothelial carcinoma of the upper genitourinary tract or urothelial carcinoma of the prostate with locally advanced or metastatic disease.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Padcev [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; **December 2024**.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed **June 12, 2024**.

EFFECTIVE DATE

3/4/2025

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