Reference number(s)
3469-A

Specialty Guideline Management
Padcev

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Padcev	enfortumab vedotin-ejfv

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.

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.
- Padcev, in combination with pembrolizumab, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC).

Compendial Uses[2]

Urothelial carcinoma

- Bladder cancer
- Primary carcinoma of the urethra

- Upper genitourinary (GU) tract tumors
- Urothelial carcinoma of the prostate

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

Coverage Criteria

Urothelial Carcinoma[1-3]

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:

- Urothelial carcinoma of the bladder in any of the following settings:
    - Stage II, locally advanced or metastatic disease
    - Metastatic or local recurrence post-cystectomy
    - Muscle invasive local recurrence or persistent disease in a preserved bladder
- Primary carcinoma of the urethra with locally advanced, recurrent or metastatic disease.
- Urothelial carcinoma of the upper genitourinary tract or urothelial carcinoma of the prostate with locally advanced or metastatic disease.

Authorization of 12 months may be granted for treatment of urothelial carcinoma in combination with pembrolizumab for any of the following subtypes:

- Urothelial carcinoma of the bladder and requested medication will be used as subsequent therapy in any of the following settings:
    - Stage II, locally advanced or metastatic disease
    - Metastatic or local recurrence post-cystectomy
    - Muscle invasive local recurrence or persistent disease in a preserved bladder
- Primary carcinoma of the urethra and either of the following criteria is met:
    - Requested medication will be used first-line and disease is locally advanced or metastatic
    - Requested medication will be used as subsequent therapy and either of the following criteria is met:
        - Disease is locally advanced or metastatic
        - Disease is recurrent with T2 clinical staging
- Urothelial carcinoma of the upper genitourinary tract or urothelial carcinoma of the prostate with locally advanced or metastatic disease

Continuation of Therapy

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

References

1. Padcev [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; February 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 20, 2025.
3. NCCN Clinical Practice Guidelines in Oncology® Bladder Cancer (Version 1.2025). © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed May 21, 2025.