

Reference number(s)
4473-A

Standard Medicare Part B 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 Indications¹

- 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 Uses²

Urothelial carcinoma

- Bladder cancer
- Primary carcinoma of the urethra

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

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Urothelial Carcinoma^{1,2}

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 disease is locally advanced, recurrent, or metastatic
- Urothelial carcinoma of the upper genitourinary tract or urothelial carcinoma of the prostate with locally advanced or metastatic disease.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication listed in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
 - No evidence of unacceptable toxicity while on the current regimen and
 - No evidence of disease progression while on the current regimen

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Padcev.
- The available compendium
 - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
 - Micromedex DrugDex
 - American Hospital Formulary Service- Drug Information (AHFS-DI)
 - Lexi-Drugs
 - Clinical Pharmacology
- NCCN Guideline: Bladder cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Padcev are covered in addition to the following:

- Bladder cancer
- Primary carcinoma of the urethra
- Upper genitourinary (GU) tract tumors
- Urothelial carcinoma of the prostate

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Padcev to treat urothelial carcinoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy

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Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic 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.