| Reference number(s) |
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| 4473-A |

# STANDARD MEDICARE PART B MANAGEMENT

## PADCEV (enfortumab vedotin-ejfv)

### 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) who are not eligible for cisplatin-containing chemotherapy.

B. Compendial Indications
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 will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

### 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 disease if tumor is present following reassessment of tumor status 2-3 months after primary treatment with concurrent bladder preserving chemoradiotherapy and maximal transurethral resection of bladder tumor (TURBT)

b. Locally advanced or metastatic disease
c. Metastatic or local recurrence post-cystectomy
d. Muscle invasive local recurrence or persistent disease in a preserved bladder
2. Primary carcinoma of the urethra with locally advanced, recurrent or metastatic disease.
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 treatment of urothelial carcinoma in combination with pembrolizumab 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 disease if tumor is present following reassessment of tumor status 2-3 months after primary treatment with concurrent bladder preserving chemoradiotherapy, and maximal transurethral resection of bladder tumor (TURBT)
   b. Locally advanced or metastatic disease
   c. Metastatic or local recurrence post-cystectomy
   d. Muscle invasive local recurrence or persistent disease in a preserved bladder
2. Primary carcinoma of the urethra with locally advanced, recurrent 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

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:
A. The member is currently receiving therapy with the requested medication
B. The requested medication is being used to treat an indication enumerated in Section II
C. The member is receiving benefit from therapy. Benefit is defined as:
   1. No evidence of unacceptable toxicity while on the current regimen and
   2. No evidence of disease progression while on the current regimen

## IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Padcev.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology
3. 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:
1. Bladder cancer
2. Primary carcinoma of the urethra

3. Upper genitourinary (GU) tract tumors
4. Urothelial carcinoma of the prostate

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

## VI. REFERENCES

1. Padcev [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; April 2023.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed August 2, 2023.