Reference number(s)
3469-A

SPECIALTY GUIDELINE 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.

FDA-Approved Indications
Padcev (enfortumab vedotin-ejfv) 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.

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 are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Urothelial Carcinoma – Bladder Cancer
Authorization of 12 months may be granted for treatment of bladder cancer 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:
1. Stage II disease if tumor is present following reassessment of tumor status 2-3 months after primary treatment with bladder preserving concurrent chemoradiotherapy
2. Locally advanced or metastatic disease
3. Metastatic or local recurrence post-cystectomy
4. Muscle invasive local recurrence or persistent disease in a preserved bladder

B. Urothelial Carcinoma – Primary Carcinoma of the Urethra
Authorization of 12 months may be granted for treatment of locally advanced, recurrent, or metastatic primary carcinoma of the urethra 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.

C. Urothelial Carcinoma – Upper Genitourinary Tract Tumors or Urothelial Carcinoma of the Prostate

Authorization of 12 months may be granted for treatment of locally advanced or metastatic upper genitourinary tract tumors or urothelial carcinoma of the prostate 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.

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.

IV. REFERENCES

1. Padcev [package insert]. Northbrook, IL: Astellas Pharma; July 2021.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 6, 2021.