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.

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 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 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 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

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 US, Inc.; April 2023.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed February 14, 2024.