

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Padcev Prior Authorization Policy

- Padcev™ (enfortumab vedotin-ejfv intravenous infusion – Astellas and Seagen)

REVIEW DATE: 12/21/2022

OVERVIEW

Padcev, an antibody-drug conjugate, is indicated for the treatment of adult patients with locally advanced or metastatic **urothelial cancer** who:¹

- Have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and platinum-containing chemotherapy.
- Are ineligible for cisplatin-containing chemotherapy and have previously received \geq one prior line of therapy.

Guidelines

The National Comprehensive Cancer Network (NCCN) **bladder cancer** clinical practice guidelines (version 2.2022 – May 20, 2022) recommend Padcev for the subsequent treatment of locally advanced or metastatic urothelial carcinoma of the bladder, upper genitourinary tract, prostate, and urethra.^{2,3} Patients should have previously received platinum-containing chemotherapy, a checkpoint inhibitor, platinum-containing chemotherapy plus a checkpoint inhibitor, or first-line therapy with agents other than platinum or a checkpoint inhibitor.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Padcev. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Padcev as well as the monitoring required for adverse events and long-term efficacy, approval requires Padcev to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Padcev is recommended in those who meet the following criteria:

FDA-Approved Indication

- 1. Urothelial Carcinoma.** Approve for 1 year if the patient meets ALL of the following criteria (A, B, C, and D):
 - A) Patient is \geq 18 years of age; AND
 - B) Patient has locally advanced or metastatic disease; AND
 - C) Patient has tried at least one other systemic therapy; AND
 - D) Padcev is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

12/21/2022

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Coverage of Padcev is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Padcev™ intravenous infusion [prescribing information]. Northbrook, IL: Astellas Pharma; October 2022.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – May 20, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 19, 2022.
3. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 19, 2022. Search term: enfortumab.