VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Padcev Utilization Management Medical Policy
- Padcev™ (enfortumab vedotin ejfv intravenous infusion – Astellas and Seagen)

REVIEW DATE: 12/15/2021

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 ≥ one prior line of therapy.

Guidelines

The National Comprehensive Cancer Network (NCCN) **bladder cancer** clinical practice guidelines (version 6.2021 – December 6, 2021) 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 medical benefit coverage of Padcev. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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 the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 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.

Dosing. Approve up to 125 mg administered intravenously no more frequently than three times in each 28-day cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

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; July 2021.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 6.2021 – December 6, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 13, 2021.
3. The NCCN Drugs and Biologics Compendium. © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 13, 2021. Search term: enfortumab.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/16/2020
Selected Revision	**Urothelial Carcinoma:** Removed criteria that patient has received a checkpoint inhibitor and platinum containing chemotherapy. Added criterion that patient has tried at least one systemic therapy.	08/18/2021
Annual Revision	No criteria changes.	12/15/2021