VENTURA COUNTY HEALTH CARE PLAN

Utilization Review Policy

POLICY: Oncology – Padcev™cc
(enfortumab vedotin – ejfv injection for intravenous use – Astellas Pharma and Seattle Genetics)

DATE REVIEWED: 12/20/2019

OVERVIEW

Padcev is an antibody-drug conjugate which contains the fully human anti-Nectin-4 monoclonal antibody conjugated to the microtubule disrupting agent, monomethyl auristatin E.[1]

Padcev, an antibody-drug conjugate, 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 in the neoadjuvant/adjuvant, locally advanced or metastatic setting.[1]

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(s). 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.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Urothelial Carcinoma.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
   - **A)** The patient is ≥ 18 years of age; AND
   - **B)** The patient has locally advanced or metastatic disease; AND
   - **C)** The patient has previously received a programmed death receptor-1 or programmed death-ligand 1 inhibitor.
     Note: Programmed death receptor-1 and programmed death-ligand 1 inhibitors include: Opdivo® (nivolumab injection), Keytruda® (pembrolizumab injection), Tecentriq® (atezolizumab injection), Bavencio® (avelumab injection), and Imfimzi® (durvalumab injection); AND
   - **D)** The patient has previously received platinum-containing chemotherapy.
     Note: Examples include cisplatin, carboplatin, and oxaliplatin; AND
   - **E)** Padcev is prescribed by or in consultation with an oncologist.

Dosing. Approve the following dosing regimen: Each individual dose must not exceed 125 mg administered intravenously no more frequently than three times in each 28-day cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Padcev has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

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™ for injection for intravenous use [prescribing information]. Northbrook, IL: Astellas Pharma; December 2019.

HISTORY

Type of Revision	Summary of Changes	Date Reviewed
New Policy	--	12/20/2019