

Enfortumab vedotin-ejfv (Padcev®)

Place of Service

Office Administration

Outpatient Facility Infusion Administration

Infusion Center Administration

HCPCS: J9177 per 0.25 mg

Condition(s) listed in policy (see criteria for details)

- [Urothelial cancer](#)

AHFS therapeutic class: antineoplastic agent

Mechanism of action: Nectin-4 directed antibody–drug conjugate

**(1) Special Instructions and Pertinent Information**

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

**(2) Prior Authorization/Medical Review is required for the following condition(s)**

All requests for enfortumab vedotin-ejfv (Padcev®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

**Urothelial cancer**

1. Disease is locally advanced, recurrent, or metastatic, **AND**
2. Either of the following:
  - a. Being used as a single agent, and one of the following:
    - i. For second line: Patient is ineligible for cisplatin-containing chemotherapy, and has previously received one of more prior lines of therapy, OR
    - ii. For third line and after: Patient has received PD-1 or PD-L1 inhibitor, and a platinum-containing chemotherapy
  - OR
  - b. Being used in combination with Keytruda

**Covered Doses**

Up to 125 mg on Days 1, 8, and 15 of a 28-day cycle

**Coverage Period**

Indefinite

**ICD-10:**

C61, C65.1, C65.2, C65.9, C66.1, C66.2, C66.9, C67.0-C67.9, C68.0, D09.0, Z85.51, Z85.59

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**

All requests for enfortumab vedotin-ejfv (Padcev®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

**(4) This Medication is NOT medically necessary for the following condition(s):**

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Commercial

Enfortumab vedotin-ejfv (Padcev®)

Please refer to the Provider Manual and User Guide for more information.

#### **(5) Additional Information**

How supplied:

- 20 mg, 30 mg (single-dose vials)

#### **(6) References**

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- National Comprehensive Cancer Network. Bladder Cancer (Version 2.2022). Available at: [www.nccn.org](http://www.nccn.org)
- Padcev® (enfortumab vedotin-ejfv) [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; 4/2023.

#### **(7) Policy Update**

Date of last revision: 1Q2024

Date of next review: 3Q2024

Changes from previous policy version:

- Section (2): Urothelial carcinoma - Removed requirement for cisplatin-ineligibility from coverage of combination treatment with Keytruda. *Rationale: In December 2023, FDA expanded the indication of combination Padcev + Keytruda for treatment of adult patients with locally advanced or metastatic urothelial cancer to include cisplatin-eligible patients.*

*BSC Drug Coverage Criteria to Determine Medical Necessity  
Reviewed by P&T Committee*