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
2. Being used in combination with Keytruda and patient is not eligible for cisplatin-containing chemotherapy

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.

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
- 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