DeanHealthPlan
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# Padcev® (enfortumab vedotin-ejfv)
## (Intravenous)

Document Number: IC-0521

**Last Review Date: 07/20/2022**
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**Dates Reviewed: 01/2020, 07/2020, 07/2021, 07/2022**
**Effective Date: 01/01/2023**

## I. Length of Authorization

Coverage will be provided for six months and may be renewed.

## II. Dosing Limits

**A. Quantity Limit (max daily dose) [NDC Unit]:**

- Padcev 20 mg single-dose vial: 15 vials of each 28-day cycle
- Padcev 30 mg single-dose vial: 15 vials of each 28-day cycle

**B. Max Units (per dose and over time) [HCPCS Unit]:**

- 500 billable units on days 1, 8 and 15 of every 28-day cycle

## III. Initial Approval Criteria [1-3,10]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

**Universal Criteria**

- Used as single agent therapy; **AND**

**Urothelial Carcinoma (Bladder Cancer) †**

- Patient has one of the following diagnoses:
  - Locally advanced or metastatic urothelial carcinoma †; **OR**
  - Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder ‡; **OR**
  - Local or metastatic bladder cancer recurrence post-cystectomy ‡; **OR**
  - Primary carcinoma of the urethra ‡; **AND**
    - Used for recurrent *(excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes)* or metastatic disease; **OR**

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- Metastatic upper genitourinary (GU) tract tumors ‡; **OR**
- Metastatic urothelial carcinoma of the prostate ‡; **AND**

- Used in one of the following treatment settings:
  - Patient previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor (i.e., nivolumab, pembrolizumab, atezolizumab, avelumab, etc.); **AND**
    - Patient previously received platinum-containing chemotherapy (i.e., carboplatin, cisplatin, etc.); **OR**
  - Used as subsequent therapy in patients ineligible for cisplatin-containing chemotherapy*

| ***Note:*** [11] |
|---|
| – *Cisplatin-ineligible comorbidities may include the following: CrCl < 60 mL/min, PS ≥ 2, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, grade ≥ 2 peripheral neuropathy, or NYHA class ≥ 3. Carboplatin may be substituted for cisplatin particularly in those patients with a CrCl <60 mL/min or a PS of 2.* |

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

## IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and indication-specific relevant criteria as identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hyperglycemia or diabetic ketoacidosis, severe pneumonitis, severe peripheral neuropathy, ocular disorders including vision changes, severe skin reactions (e.g., Steven Johnson syndrome, toxic epidermal necrolysis, etc.), infusion site extravasation, etc.

## V. Dosage/Administration [1]

| Indication | Dose |
|---|---|
| Urothelial Carcinoma (Bladder Cancer) | Administer 1.25 mg/kg (up to a maximum of 125 mg for patients ≥100 kg) administered as an intravenous infusion over 30 minutes on Days 1, 8 and 15 of a 28-day cycle until disease progression or unacceptable toxicity. |

## VI. Billing Code/Availability Information

<u>HCPCS Code:</u>


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- J9177 – Injection, enfortumab vedotin-ejfv, 0.25 mg: 1 billable unit = 0.25 mg

NDC:

- Padcev 20 mg single-dose vial: 51144-0020-xx
- Padcev 30 mg single-dose vial: 51144-0030-xx

## VII. References


1. Padcev [package insert]. Northbrook, IL; Astellas Pharma US, Inc; May 2022. Accessed May 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for enfortumab vedotin. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2022.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 2.2022. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2022.
4. Rosenberg JE, O'Donnell PH, Balar AV, et al. Pivotal Trial of Enfortumab Vedotin in Urothelial Carcinoma After Platinum and Anti-Programmed Death 1/Programmed Death Ligand 1 Therapy. J Clin Oncol. 2019 Oct 10;37(29):2592-2600.
5. Gupta S, Sonpavde G, Grivas P, et al. Defining "platinum-ineligible" patients with metastatic urothelial cancer (mUC). J Clin Oncol. 2019 Mar 1;37(7_suppl):451.
6. Fahrenbruch R, Kintzel P, Bott AM, et al. Dose Rounding of Biologic and Cytotoxic Anticancer Agents: A Position Statement of the Hematology/Oncology Pharmacy Association. J Oncol Pract. 2018 Mar;14(3):e130-e136.
7. Hematology/Oncology Pharmacy Association (2019). Intravenous Cancer Drug Waste Issue Brief. Retrieved from http://www.hoparx.org/images/hopa/advocacy/Issue-Briefs/Drug_Waste_2019.pdf
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9. Powles T, Rosenberg JE, Sonpavde GP, et al. Enfortumab Vedotin in Previously Treated Advanced Urothelial Carcinoma. N Engl J Med. 2021 Mar 25;384(12):1125-1135. doi: 10.1056/NEJMoa2035807. Epub 2021 Feb 12.




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10. Balar AV, McGregor BA, Rosenberg JE, et al. EV-201 Cohort 2: Enfortumab vedotin in cisplatin-ineligible patients with locally advanced or metastatic urothelial cancer who received prior PD-1/PD-L1 inhibitors. DOI: 10.1200/JCO.2021.39.6_suppl.394 Journal of Clinical Oncology 39, no. 6_suppl (February 20, 2021) 394-394.
11. Gupta S, Sonpavde G, Grivas P, et al. Defining "platinum-ineligible" patients with metastatic urothelial cancer (mUC). J Clin Oncol. 2019 Mar 1;37(7_suppl):451.

## Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|---|---|
| C61 | Malignant neoplasm of prostate |
| C65.1 | Malignant neoplasm of right renal pelvis |
| C65.2 | Malignant neoplasm of left renal pelvis |
| C65.9 | Malignant neoplasm of unspecified renal pelvis |
| C66.1 | Malignant neoplasm of right ureter |
| C66.2 | Malignant neoplasm of left ureter |
| C66.9 | Malignant neoplasm of unspecified ureter |
| C67.0 | Malignant neoplasm of trigone of bladder |
| C67.1 | Malignant neoplasm of dome of bladder |
| C67.2 | Malignant neoplasm of lateral wall of bladder |
| C67.3 | Malignant neoplasm of anterior wall of bladder |
| C67.4 | Malignant neoplasm of posterior wall of bladder |
| C67.5 | Malignant neoplasm of bladder neck |
| C67.6 | Malignant neoplasm of ureteric orifice |
| C67.7 | Malignant neoplasm of urachus |
| C67.8 | Malignant neoplasm of overlapping sites of bladder |
| C67.9 | Malignant neoplasm of bladder, unspecified |
| C68.0 | Malignant neoplasm of urethra |
| D09.0 | Carcinoma in situ of bladder |
| Z85.51 | Personal history of malignant neoplasm of bladder |
| Z85.59 | Personal history of malignant neoplasm of other urinary tract organ |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found


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at:http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| **Jurisdiction** | **Applicable State/US Territory** | **Contractor** |
| E (1) | CA, HI, NV, AS, GU, CNMI | Noridian Healthcare Solutions, LLC |
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |
| 5 | KS, NE, IA, MO | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6 | MN, WI, IL | National Government Services, Inc. (NGS) |
| H (4 & 7) | LA, AR, MS, TX, OK, CO, NM | Novitas Solutions, Inc. |
| 8 | MI, IN | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9) | FL, PR, VI | First Coast Service Options, Inc. |
| J (10) | TN, GA, AL | Palmetto GBA, LLC |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA, LLC |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |
| 15 | KY, OH | CGS Administrators, LLC |


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