Padcev® (enfortumab vedotin-ejfv)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be provided for 6 months (180 days) thereafter, unless otherwise specified.
  - Muscle invasive bladder cancer (MIBC) neoadjuvant treatment then continued after cystectomy as adjuvant treatment: Prior authorization validity may be provided for a maximum of nine 21-day cycles.

II. Dosing Limits

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

- 4680 billable units every 84 days

III. Initial Approval Criteria [1]

Prior authorization is provided in the following conditions:

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

Urothelial Carcinoma (Bladder Cancer) † ‡ [1-3]

- Used in combination with pembrolizumab**; **AND**
  - Member has one of the following diagnoses:
    - Locally advanced or metastatic urothelial carcinoma † ‡; **OR**
    - Primary carcinoma of the urethra ‡; **AND**
      - Used as first-line therapy for metastatic disease; **OR**
      - Used as second-line therapy for recurrent or metastatic disease *(excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes)*; **OR**
    - Metastatic upper genitourinary (GU) tract tumors ‡; **OR**
    - Metastatic urothelial carcinoma of the prostate ‡; **OR**
    - Muscle invasive bladder cancer (MIBC); **AND**
      - Used for local recurrence or persistent disease in a preserved bladder treated with curative intent ‡; **OR**

        - ➢ Used as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment *(Note: cisplatin eligibility/ineligibility* must be assessed to determine neoadjuvant/adjuvant treatment dosing schedules)* **†**; **OR**
      - Metastatic or local bladder cancer recurrence post-cystectomy treated with curative intent **‡**; **OR**
- Used as a single agent; **AND**
  - Member has one of the following diagnoses:
    - Locally advanced or metastatic urothelial carcinoma **† ‡**; **OR**
    - Muscle invasive bladder cancer local recurrence or persistent disease in a preserved bladder treated with curative intent **‡**; **OR**
    - Metastatic or local bladder cancer recurrence post-cystectomy treated with curative intent **‡**; **OR**
    - Primary carcinoma of the urethra **‡**; **AND**
      - ➢ Used for recurrent or metastatic disease *(excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes)*; **OR**
    - Metastatic upper genitourinary (GU) tract tumors **‡**; **OR**
    - Metastatic urothelial carcinoma of the prostate **‡**; **AND**
  - Used in one of the following treatment settings:
    - Member was previously treated with platinum-containing chemotherapy***** and programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1); **OR**
    - Used as subsequent therapy in members ineligible for cisplatin-containing chemotherapy*****; **OR**
    - Used as second-line therapy**

***Note:** [3,11,12]

- *Cisplatin-ineligible comorbidities may include the following: CrCl < 60 mL/min, ECOG PS ≥ 2 or KPS ≤ 70%, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, grade ≥ 2 peripheral neuropathy, or NYHA Heart Failure class ≥ 3. Carboplatin may be substituted for cisplatin in the metastatic setting for cisplatin-ineligible members such as those with a GFR less than 60 mL/min.*
- *Platinum-ineligible comorbidities may include the following: CrCl < 30 mL/min, ECOG PS ≥ 3, grade ≥ 2 peripheral neuropathy, or NYHA Heart Failure class > 3, etc.*

*** When used as second line therapy, previous treatment with immunotherapy or chemotherapy is allowable (if no prior enfortumab vedotin use)* [2,3]

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

IV. Renewal Criteria [1]

Prior authorization validity may be renewed based upon the following criteria:

- Member continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, as identified in section III; **AND**
- Duration of authorization had not been exceeded *(refer to Section I)*; **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/interstitial lung disease (ILD), 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 [1,3]

Indication	Dose
Urothelial Carcinoma (Bladder Cancer)	**Single Agent** Administer 1.25 mg/kg (up to a maximum of 125 mg for members ≥100 kg) as an intravenous infusion over 30 minutes on Days 1, 8 and 15 of a 28-day cycle until disease progression or unacceptable toxicity. **In combination with pembrolizumab** – MIBC neoadjuvant treatment then continued after cystectomy as adjuvant treatment ○ **Cisplatin eligible:** Administer 1.25 mg/kg (up to a maximum of 125 mg for members ≥100 kg) as an intravenous infusion on Days 1 and 8 of each 21-day cycle for 4 cycles or until disease progression that precludes curative intent cystectomy or unacceptable toxicity, followed by adjuvant treatment on Days 1 and 8 of each 21-day cycle for 5 cycles or until disease recurrence or unacceptable toxicity ○ **Cisplatin ineligible:** Administer 1.25 mg/kg (up to a maximum of 125 mg for members ≥100 kg) as an intravenous infusion on Days 1 and 8 of each 21-day cycle for 3 cycles or until disease progression that precludes curative intent cystectomy or unacceptable toxicity, followed by adjuvant treatment on Days 1 and 8 of each 21-day cycle for 6 cycles or until disease recurrence or unacceptable toxicity – All other treatment settings: Administer 1.25 mg/kg (up to a maximum of 125 mg for members ≥100 kg) as an intravenous infusion over 30 minutes on Days 1 and 8 of a 21-day cycle until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC(s):

- 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.; July 2026. Accessed July 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for enfortumab vedotin-ejfv. National Comprehensive Cancer Network, 2026. 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 July 2026.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 2.2026. National Comprehensive Cancer Network, 2026. 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 July 2026.
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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used

to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied 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		
Jurisdictio	**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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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