

## Clinical Policy: Enfortumab Vedotin-ejfv (Padcev)

Reference Number: PA.CP.PHAR.455

Effective Date: 10/2020

Last Review Date: 01/2023

[Coding Implications](#)

[Revision Log](#)

### Description

Enfortumab vedotin-ejfv (Padcev™) is a Nectin-4-directed antibody and microtubule inhibitor conjugate.

### FDA Approved Indication(s)

Padcev 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
- Are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy

This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health & Wellness® that Padcev is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Urothelial Carcinoma (must meet all):

1. Diagnosis of one of recurrent, locally advanced or metastatic (stage IV) urothelial carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. One of the following (a or b):
  - a. Failure of both of the following (i and ii):
    - i. Platinum-containing chemotherapy (*see Appendix B*);
    - ii. Programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor (*see Appendix B*);
  - b. Ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy (*see Appendix B*);
2. Request meets one of the following (a or b):\*
  - a. Dose does not exceed 125 mg on Days 1, 8, and 15 of a 28-day cycle;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months**

**B. Other diagnoses/indications**

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

**II. Continued Therapy**

**A. Urothelial Carcinoma (must meet all):**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):\*
  - a. New dose does not exceed 125 mg on Days 1, 8 and 15 of a 28-day cycle;
  - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 12 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

**Approval duration: Duration of request or 6 months (whichever is less); or**

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

PD-1: programmed death receptor-1

PD-L1: programmed death-ligand

NCCN: National Comprehensive Cancer Network

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<b>Examples of platinum-containing regimens</b>		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
DDMVAC (dose-dense methotrexate, vinblastine, doxorubicin, and cisplatin)	Varies	Varies
gemcitabine with either cisplatin or carboplatin	Varies	Varies
<b>Examples of PD-1 inhibitors</b>		
Keytruda® (pembrolizumab)	Varies	Varies
Opdivo® (nivolumab)	Varies	Varies
<b>Examples of PD-L1 inhibitors</b>		
Tecentriq® (atezolizumab)	Varies	Varies
Imfinzi® (durvalumab)	10 mg/kg IV infusion every 2 weeks	Varies
Bavencio® (avelumab)	800 mg IV infusion once every 2 weeks	Varies

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

#### Appendix C: Contraindications/Boxed Warnings

Contraindication(s): None reported

Boxed warning(s): Serious skin reactions

### V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Urothelial cancer	1.25 mg/kg (up to a maximum dose of 125 mg) given as an intravenous infusion over 30 minutes on Days 1, 8 and 15 of a 28-day cycle until disease progression or unacceptable toxicity	125 mg for patients ≥ 100 kg) on Days 1, 8 and 15 of a 28-day cycle

### VI. Product Availability

Single-dose vial for injection: 20 mg, 30 mg

### VII. References

1. Padcev Prescribing Information. Northbrook, IL: Astellas Pharma US, Inc; October 2022. Available at: <https://www.padcev.com>. Accessed November 15, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). Accessed November 15, 2022.
3. National Comprehensive Cancer Network. Bladder Cancer Version 2.2022. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/bladder.pdf](https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf). Accessed November 15, 2022.
4. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed November 15, 2022.

### Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-

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date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

<b>HCPCS Codes</b>	<b>Description</b>
J9177	Injection, enfortumab vedotin-ejfv, 0.25mg

<b>Reviews, Revisions, and Approvals</b>	<b>Date</b>
Policy created.	10/2020
1Q 2021 annual review: recurrent UC added and trial settings (e.g., neoadjuvant) removed to encompass NCCN recommended uses; references reviewed and updated.	01/2021
1Q 2022 annual review: updated HCPCS codes for Padcev and Appendix C with new boxed warning; references reviewed and updated.	01/2022
1Q 2023 annual review: no significant changes; references reviewed and updated.	01/2023