

Padcev (enfortumab vedotin)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Padcev (enfortumab vedotin)

APPROVAL CRITERIA

Requests for Padcev (enfortumab vedotin) may be approved if the following criteria are met (Label, NCCN 1, 2A):

I. Individual is under 19 years of age;

OR

II. Individual has a diagnosis of locally advanced or metastatic urothelial cancer; **AND**

A. Individual is using in one of the following ways:

1. In combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph as first-line systemic therapy; **OR**
2. Individual is using as a single agent for subsequent therapy after progression in one of the following ways:
 - a. Anti-PD-1 or anti-PD-L1 agent and platinum-containing chemotherapy; **OR**
 - b. Individual is ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy;

OR

III. Individual has a diagnosis of muscle invasive bladder cancer (MIBC) (Label); **AND**

- A. Individual is using in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph as either neoadjuvant or adjuvant treatment; **AND**
- B. Individual is ineligible for cisplatin-containing chemotherapy.

Padcev (enfortumab vedotin) may not be approved for the following:

- I. Individuals with moderate or severe hepatic impairment (Child-Pugh B or C); **OR**
- II. When the above criteria are not met and for all other indications.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.

4. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 17, 2025.
 - a. Bladder Cancer. V6.2024. Revised January 17, 2025.
5. Powles T, Rosenberg JE, Sonpavde GP, et al. Enfortumab vedotin in previously treated advanced urothelial carcinoma. *N Engl J Med* 2021;384:1125-1135
6. Yu EY, Petrylak DP, O'Donnell PH, et al. Enfortumab vedotin after PD-1 or PD-L1 inhibitors in cisplatin-ineligible patients with advanced urothelial carcinoma (EV-201): a multicentre, single-arm, phase 2 trial. *Lancet Oncol* 2021; 22:872-882.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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