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

AND
III. Individual as a current ECOG performance status of 0-2.

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. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 20, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 20, 2022.
   a. Bladder Cancer. V6.2021. Revised December 6, 2021.
6. Powles T, Rosenberg JE, Sonpavde GP, et al. Enfortumab vedotin in previously treated advanced urothelial carcinoma. N Engl J Med 2021;384:1125-1135
7. 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.