

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

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:

- I. Individual has a diagnosis of locally advanced or metastatic urothelial cancer; **AND**
- II. Individual is using as subsequent therapy after progression with *both* of the following:
 - a. Anti-PD-1 or anti-PD-L1 agent; **AND**
 - b. Platinum-containing chemotherapy (or be ineligible for platinum-based chemotherapy); **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.: 2019. 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: December 30, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 14, 2020.
 - a. Bladder Cancer. V2.2020. Revised January 7, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.