

POLICY NUMBER UM Onc_1381	SUBJECT Padcev™ (enfortumab vedotin-ejfv)	DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 02/12/20	APPROVAL DATE February 12, 2020	EFFECTIVE DATE March 01, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 02/12/20
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee	
URAC STANDARDS HUM 1		NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS	APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Padcev (enfortumab vedotin-ejfv) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

- When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies: <http://pathways.newcenturyhealth.com> **AND**
- Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
- When available, generic alternatives are preferred over brand-name drugs.

2. Urothelial Cancer

- The member has locally advanced or metastatic urothelial carcinoma and Padcev (enfortumab vedotin-ejfv) is being used as a single agent for **ALL** of the following:
 - As subsequent line of therapy **AND**
 - The member has contraindications, intolerance, or failure to standard therapy **AND**
 - Prior therapy included gemcitabine/platinum-based chemotherapy **AND** a PD-1/PD-L1 inhibitor (e.g. atezolizumab, avelumab, durvalumab, nivolumab, or pembrolizumab).



III. EXCLUSION CRITERIA

1. Padcev (enfortumab vedotin-ejfv) is being used after disease progression with the same regimen.
2. Concurrent use with other chemotherapy, targeted therapies, or definitive radiotherapy.
3. The member has sensory or motor neuropathy Grade ≥ 2 or active CNS metastases.
4. Dosing exceeds single dose limit of Padcev (enfortumab vedotin-ejfv) 1.25 mg/kg (maximum, 125 mg).
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Padcev PI prescribing information. Seattle Genetics, Inc. Bothell, WA 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.