Drug Policy:

Padcev™ (enfortumab vedotin-ejfv)

POLICY NUMBER UM ONC_1381	**SUBJECT** Padcev™ (enfortumab vedotin-ejfv)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 2**
DATES COMMITTEE REVIEWED 02/12/20, 12/09/20, 08/11/21	**APPROVAL DATE** August 11, 2021	**EFFECTIVE DATE** August 27, 2021	**COMMITTEE APPROVAL DATES** 02/12/20, 12/09/20, 08/11/21	
PRIMARY BUSINESS OWNER: UM		**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 Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. 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
2. 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

3. 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 AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When available, generic alternatives are preferred over brand-name drugs.

B. Urothelial Cancer

1. The member has locally advanced or metastatic urothelial carcinoma and Padcev (enfortumab vedotin-ejfv) is being used as a single agent in members who:
   a. Have previously received Check Point Inhibitor therapy (PD-1 or PD-L1 inhibitors) and a platinum-containing chemotherapy regimen in the neoadjuvant/adjuvant, locally advanced, or metastatic setting, OR
   b. Have previously received Immune Checkpoint Inhibitor therapy and are ineligible for platinum-based therapy

III. EXCLUSION CRITERIA

A. Padcev (enfortumab vedotin-ejfv) is being used after disease progression with the same regimen.

B. Concurrent use with other chemotherapy and targeted therapies.

C. Dosing exceeds single dose limit of Padcev (enfortumab vedotin-ejfv) 1.25 mg/kg (maximum 125 mg).

D. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Powles et al. N Eng J Med 2021;384:1125—1135. DOI: 10.1056/NEJMoa2035807

B. Padcev prescribing information. Seattle Genetics, Inc. Bothell, WA 2021.

C. Clinical Pharmacology Elsevier Gold Standard 2021.

D. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.

E. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2021.

F. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2021.