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HEALTHCARE YOU CAN FEEL GOOD ABOUT

CENTRAL HEALTH MEDICARE PLAN

Medical Policy

Padcev™ (enfortumab vedotin-ejfv)	
MEDICAL POLICY NUMBER	MED_Clin_Ops_089
POLICY OWNER	A. Bartley Bryt, MD, Chief Medical Officer
ORIGINAL EFFECTIVE DATE	1/1/2022
CURRENT VERSION NUMBER	2
CURRENT VERSION EFFECTIVE DATE	1/01/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

***IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY**: These services may or may not be covered by all Brand New Day/Central Health Medicare Plan Plans. Please refer to the member's plan document for specific coverage information.*

Brand New Day/Central Health Medicare Plan may use tools developed by third parties, such as MCG™ Care Guidelines and the ASAM Criteria™ to assist in administering health benefits. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Care Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan.

Before using this policy, please check the member benefit plan document and any federal or state mandates, if applicable. Brand New Day/Central Health Medicare Plan policies and practices are compliant with all federal and state requirements, including mental health parity laws.

PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Padcev™ (enfortumab vedotin-ejfv) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Padcev will be provided for 12 months and may be renewed.

A. Patient is 18 years of age or older; **AND**
B. **Patient has a diagnosis of** with locally advanced or metastatic urothelial cancer (mUC); **AND**
C. Patient has previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy; **OR**
D. Patient is ineligible for cisplatin-containing chemotherapy and has previously received one or more prior lines of therapy.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

BACKGROUND

Padcev is an antibody-drug conjugate (ADC). The antibody is a human IgG1 directed against Nectin-4, an adhesion protein located on the surface of cells. The small molecule, MMAE, is a microtubule-disrupting agent, attached to the antibody via a protease-cleavable linker. Nonclinical data suggest that the anticancer activity of enfortumab vedotin-ejfv is due to the binding of the ADC to Nectin-4-expressing cells, followed by internalization of the ADC-Nectin-4 complex, and the release of MMAE via proteolytic cleavage. Release of MMAE disrupts the microtubule network within the cell, subsequently inducing cell cycle arrest and apoptotic cell death.

DEFINITIONS

1. PADCEV (enfortumab vedotin-ejfv) for injection, for intravenous use. Initial U.S. Approval: 2019
    a. PADCEV (enfortumab vedotin-ejfv) 20 mg and 30 mg are supplied as a sterile, preservative-free, white to off-white lyophilized powder in single-dose vials.

CODING

Applicable NDC Codes	
51144-0030-01	PADCEV, enfortumab vedotin-ejfv injection vial of 30 mg
51144-0020-01	PADCEV, enfortumab vedotin-ejfv injection vial of 20 mg

Applicable Procedure Code	
J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg (Padcev).

Applicable Diagnosis Codes	
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C66.1	Malignant neoplasm of right ureter
C66.2	Malignant neoplasm of left ureter
C66.9	Malignant neoplasm of unspecified ureter
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder

C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified
C68.0	Malignant neoplasm of urethra

EVIDENCE BASED REFERENCES

1. Product Information: NULOJIX(R) intravenous injection, belatacept intravenous injection. Bristol-Myers Squibb Company (per FDA), Princeton, NJ, 2021.

POLICY HISTORY

Original Effective Date	1/1/2022
Revised Date	1/01/2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)
P&T Committee Endorsement	11/1/2021

DISCLAIMER

Medical Policy

Approved by Pharmacy and Therapeutics Committee

A Bartley Bryt MD MPH

By: _____
A Bartley Bryt, MD, MPH Chief Medical Officer

Date: 11/19/2021