Geisinger Health Plan

POLICIES AND PROCEDURE MANUAL

Policy: MBP 209.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Padcev (enfortumab vedotin-ejfv)

I. Policy:
Padcev (enfortumab vedotin-ejfv)

II. Purpose/Objective:
To provide a policy of coverage regarding Padcev (enfortumab vedotin-ejfv)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age

DESCRIPTION:
Padcev (enfortumab vedotin-ejfv) is an antibody-drug conjugate consisting of human IgG1-kappa antibody, anti-Nectin-4, attached to a microtubule disrupting agent, monomethyl auristatin E (MMAE), by a cleavable maleimidocaproyl valine-citrulline linker. The antibody-drug conjugate binds to the Nectin-4 adhesion protein found on the cell surface and the entire complex is internalized. MMAE is cleaved from the complex resulting in the disruption of the microtubule network within the cell, leading to cell cycle arrest and apoptotic cell death.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Padcev (enfortumab vedotin-ejfv) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation that prescription is written by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of locally advanced or metastatic urothelial cancer **AND**
- Medical record documentation of one of the following:
    - Medical record documentation that member has received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting **OR**
    - Medical record documentation that member has received at least one prior line of therapy and is ineligible for cisplatin-containing chemotherapy*

*Note to reviewer: In clinical trials, patients who were not considered cisplatin-eligible had one or more of the following characteristics: baseline creatinine clearance of 30 – 59 mL/min, ECOG performance status of 2, or Grade 2 or greater hearing loss.

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 3/17/20

Revised: 9/21/21 (added cisplatin ineligible UC w/ one prior therapy)

Reviewed: 1/28/21