

**Policy: MBP 152.0**

**Section: Medical Benefit Pharmaceutical Policy**

**Subject: Bavencio (avelumab)**

### **I. Policy:**

Bavencio (avelumab)

### **II. Purpose/Objective:**

To provide a policy of coverage regarding Bavencio (avelumab)

### **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:**

Bavencio (avelumab) is a fully human monoclonal antibody that binds to programmed death ligand 1 (PD-L1) to selectively prevent the interaction between the programmed cell death-1 (PD-1) and B7.1 receptors, while still allowing interaction between PD-L2 and PD-1.2 PD-L1 is an immune check point protein expressed on tumor cells and tumor infiltrating cells and down regulates antitumor T-cell function by binding to PD-1 and B7.1; blocking PD-1 and B7.1 interactions restores antitumor T-cell function.

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

Bavencio (avelumab) will be considered medically necessary when ALL of the following criteria are met for each indication:

**Merkel Cell Carcinoma**

- Prescribed by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of metastatic Merkel Cell Carcinoma (MCC) **AND**
- Medical record documentation of age  $\geq 12$  years

**Urothelial Carcinoma**

- Prescribed by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma **AND**
- Medical record documentation of one of the following:
  - Documentation that Bavencio will be used as maintenance treatment with no progression following first-line platinum-containing chemotherapy **OR**
  - Disease progression during or following platinum-containing chemotherapy **OR**
  - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

**Renal Cell Carcinoma**

- Prescribed by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of advanced renal cell carcinoma (RCC) **AND**
- Medical record documentation that Bavencio will be given in combination with axitinib (Inlyta) **AND**
- Medical record documentation that Bavencio and axitinib are being used as first-line treatment

**AUTHORIZATION DURATION:** Initial approval will be for **6 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.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

**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:** 5/16/17

**Revised:** 9/19/17 (urothelial carcinoma indication), 7/16/19 (RCC), 9/15/20 (UC), 9/15/22 (Medicaid PARP statement)

**Reviewed:** 8/30/18, 7/1/20, 9/15/21