Bavencio (avelumab)

Background
Bavencio (avelumab) binds PD-L1 and blocks the interaction between PD-L1 and B7.1. This interaction releases the inhibitory effects of PD-L1 on the immune response resulting in the restoration of immune responses, including anti-tumor immune responses. Bavencio has also been shown to induce antibody-dependent cell-mediated cytotoxicity (ADCC) in vitro (1).

Regulatory Status
FDA-approved indication: Bavencio is a programmed death ligand-1 (PD-L1) blocking antibody indicated for the treatment of:

1. Adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC)
2. Locally advanced or metastatic urothelial carcinoma who:
   a. Have disease progression during or following platinum-containing chemotherapy
   b. Have experienced disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
3. Advanced renal cell carcinoma (RCC) in combination with axitinib, as first-line treatment

Bavencio can cause immune-mediated pneumonitis, hepatitis, colitis, and nephritis. Monitor patients for signs and symptoms of these adverse reactions and evaluate patients suspected of them. Discontinue Bavencio if the immune-mediated reactions become life-threatening (1).
Bavencio can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should use effective contraception while taking Bavencio and for one month after completion or discontinuation of therapy (1).

Bavencio in combination with axitinib can cause hepatotoxicity with higher than expected frequencies of Grade 3 and 4 ALT and AST elevation. More frequent monitoring of liver enzymes should be considered. Bavencio with axitinib can also cause severe and fatal cardiovascular events. Baseline and periodic evaluations of left ventricular ejection fraction (LVEF) should be considered, as well as monitoring for signs and symptoms of cardiovascular events (1).

The safety and effectiveness of Bavencio have been established in patients age 12 years and older (1).

**Related policies**
Imfinzi, Keytruda, Opdivo, Tecentriq

**Policy**

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Bavencio may be considered medically necessary in patients that are 12 years of age and older for the treatment of metastatic Merkel cell carcinoma (MCC), locally advanced or metastatic urothelial carcinoma, or advanced renal cell carcinoma and if the conditions indicated below are met.

Bavencio is considered investigational in patients who are less than 12 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**
12 years of age or older

**Diagnoses**

Patient must have **ONE** of the following:

1. Metastatic Merkel cell carcinoma (MCC)
2. Locally advanced or metastatic urothelial carcinoma with **ONE** of the following:
   a. Disease progression during or following platinum-containing chemotherapy
   b. Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

3. Advanced renal cell carcinoma (RCC)
   a. Used in combination with Inlyta (axitinib)
   b. First-line treatment
   c. Liver enzymes will be monitored
   d. Patient will be monitored for cardiovascular events

**AND ALL** of the following:
   a. Prescriber agrees to monitor for all immune-mediated adverse reactions and discontinue therapy if necessary
   b. If patient is of child bearing potential, the patient has been or will be instructed to practice effective contraception during therapy and for at least 1 month after stopping therapy

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**Prior – Approval Renewal Requirements**

**Age**

12 years of age or older

**Diagnoses**

Patient must have **ONE** of the following:

1. Metastatic Merkel cell carcinoma (MCC)
2. Locally advanced or metastatic urothelial carcinoma
3. Advanced renal cell carcinoma (RCC)
   a. Used in combination with Inlyta (axitinib)
   b. Liver enzymes will be monitored
   c. Patient will be monitored for cardiovascular events

**AND ALL** of the following:
   a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor for all immune-mediated adverse reactions and discontinue therapy if necessary.

c. If patient is of child bearing potential, the patient has been or will be instructed to practice effective contraception during therapy and for at least 1 month after stopping therapy.

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Duration 12 months

Prior – Approval Renewal Limits

Duration 12 months

Rationale

Summary
Bavencio (avelumab) binds PD-L1 and blocks the interaction between PD-L1 and B7.1. This interaction releases the inhibitory effects of PD-L1 on the immune response resulting in the restoration of immune responses, including anti-tumor immune responses. Bavencio has also been shown to induce antibody-dependent cell-mediated cytotoxicity (ADCC) in vitro. The safety and effectiveness of Bavencio have been established in patients age 12 years and older (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Bavencio while maintaining optimal therapeutic outcomes.

References

Policy History

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<td>April 2017</td>
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### Section: Prescription Drugs  
**Effective Date:** July 1, 2019

### Subsection: Antineoplastic Agents  
**Original Policy Date:** April 7, 2017

### Subject: Bavencio  
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### Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.