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| **Section:** | Prescription Drugs | **Effective Date:** | April 1, 2025 |
| **Subsection:** | Antineoplastic Agents | **Original Policy Date:** | April 7, 2017 |
| **Subject:** | Bavencio | **Page:** | 1 of 5 |

***Last Review Date:*** March 7, 2025

# Bavencio

## Description

## Bavencio (avelumab)

**Background**
Bavencio (avelumab) is a programmed death ligand-1 (PD-L1) blocking antibody. 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 indications: Bavencio is a programmed death ligand-1 (PD-L1) blocking antibody indicated for:

1. Merkel Cell Carcinoma (MCC)
    a. Adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC)
2. Urothelial Carcinoma (UC)
    a. Maintenance treatment of patients with locally advanced or metastatic UC that has not progressed with first-line platinum-containing chemotherapy
    b. Patients with locally advanced or metastatic urothelial carcinoma who:
        i. Have disease progression during or following platinum-containing chemotherapy
        ii. Have experienced disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
3. Renal Cell Carcinoma (RCC)

a. First-line treatment, in combination with axitinib, of patients with advanced renal cell carcinoma (RCC)

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 not been established in pediatric patients less than 12 years of age (1).

**Related policies**
Keytruda, Opdivo

## 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** if the conditions indicated below are met.

Bavencio may be considered **investigational** 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. **NO** disease progression with first-line platinum-containing chemotherapy
        a. Used as maintenance treatment
    b. Disease progression during or following platinum-containing chemotherapy
    c. 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. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during therapy and for at least 1 month after the last dose

## 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. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during therapy and for at least 1 month after the last dose

## Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

**Duration** 12 months

### Prior – Approval *Renewal* Limits

Same as above

## Rationale

**Summary**

Bavencio (avelumab) is a programmed death ligand-1 (PD-L1) blocking antibody. 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 not been established in pediatric patients less than 12 years of age (1).

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

**References**

1. Bavencio [package insert]. Rockland, MA: EMD Serono, Inc.; November 2024.
2. NCCN Drugs & Biologics Compendium® Avelumab 2025. National Comprehensive Cancer Network, Inc. Accessed on January 27, 2025.

## Policy History

| Date | Action |
|---|---|
| April 2017 | Addition to PA |
| June 2017 | Annual editorial review and reference update<br>Addition of new indication: Locally advanced or metastatic urothelial carcinoma |
| June 2018 | Annual editorial review and reference update |
| November 2018 | Annual review and reference update |
| May 2019 | Addition of indication: advanced renal cell carcinoma (RCC) |
| June 2019 | Annual review |
| June 2020 | Annual review |
| July 2020 | Addition of indication: maintenance treatment of locally advanced or metastatic urothelial carcinoma that has not progressed with first-line platinum-containing chemotherapy. Also revised contraception requirement |
| September 2020 | Annual review |
| March 2021 | Annual editorial review and reference update |
| September 2021 | Annual review and reference update |
| March 2022 | Annual review and reference update |
| September 2022 | Annual review and reference update |
| March 2023 | Annual review and reference update |
| September 2023 | Annual review and reference update |
| March 2024 | Annual review and reference update |
| September 2024 | Annual review and reference update |
| December 2024 | Annual review and reference update |
| March 2025 | Annual review and reference update |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.**