BlueCross BlueShield Federal Employee Program

BAVENCIO (avelumab)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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.