RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Bavencio is used to treat adults and pediatric patients with metastatic Merkel cell carcinoma (MCC), including those who have not received prior chemotherapy, and locally advanced or metastatic urothelial carcinoma. Metastatic MCC is a rare aggressive form of skin cancer. Bavencio targets the PD-1/PD-L1 pathway which are proteins found on the body’s immune cells and some cancer cells. By blocking these interactions, Bavencio may help the body’s immune system attack cancer cells (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 either had 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

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).

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

Summary
Bavencio is a programmed death ligand-1 (PD-L1) blocking antibody that targets the PD-1/PD-L1
pathway which are proteins found on the body's immune cells and some cancer cells. By blocking these interactions, Bavencio may help the body's immune system attack cancer cells. Patients taking Bavencio should be monitored for all immune-mediated adverse reactions. This drug can cause fetal harm and women of reproductive age should use contraception. 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