

SPECIALTY GUIDELINE MANAGEMENT

BAVENCIO (avelumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Metastatic Merkel Cell Carcinoma
Treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma
2. Locally Advanced or Metastatic Urothelial Carcinoma
Treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
3. Advanced Renal Cell Carcinoma
First-line treatment of patients with advanced renal cell carcinoma in combination with axitinib

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Merkel Cell Carcinoma

Authorization of 12 months may be granted for the treatment of metastatic Merkel cell carcinoma.

B. Urothelial Carcinoma

Authorization of 12 months may be granted for treatment of locally advanced or metastatic urothelial carcinoma when either of the following criteria are met:

1. Member experienced disease progression during or following platinum-containing chemotherapy.
2. Member experienced disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

C. Renal Cell Carcinoma

Authorization of 12 months may be granted for treatment of advanced renal cell carcinoma when Bavencio is given in combination with axitinib as first-line treatment for the disease.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Bavencio [package insert]. New York, NY: Pfizer Inc.; May 2019.