Reference number(s)
1675-A

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.

FDA-Approved Indications

A. Metastatic Merkel Cell Carcinoma
   Treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma
B. 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
C. Advanced Renal Cell Carcinoma
   First-line treatment of patients with advanced renal cell carcinoma in combination with axitinib

Compendial Indications

A. Bladder cancer as subsequent systemic therapy post-platinum as a single agent
B. Metastatic upper GU tract tumors as a single agent for subsequent systemic therapy post platinum
C. Metastatic carcinoma of the prostate as a single agent for subsequent therapy post platinum
D. Metastatic carcinoma of the urethra as a single agent for subsequent systemic therapy post platinum
E. Kidney cancer used in combination with axitinib as first-line therapy for relapse or stage IV disease and clear cell histology

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

II. EXCLUSIONS

Coverage will not be provided for members who have experienced disease progression while on PD-1 or PD-L1 inhibitor therapy.

III. CRITERIA FOR INITIAL APPROVAL

A. Merkel Cell Carcinoma
Authorization of 6 months may be granted for the treatment of metastatic Merkel cell carcinoma.

B. Urothelial Carcinoma – Bladder Cancer
Authorization of 6 months may be granted as a single agent for treatment of bladder cancer when any of the following criteria is met:

1. As subsequent therapy following platinum-containing chemotherapy as a single agent for locally advanced or metastatic disease.
2. Member has metastatic or local recurrence post-cystectomy.

C. Urothelial Carcinoma – Primary Carcinoma of the Urethra
Authorization of 6 months may be granted for treatment of primary carcinoma of the urethra as a single agent for recurrent, locally advanced, or metastatic disease as subsequent systemic therapy following platinum-containing chemotherapy.

D. Urothelial Carcinoma – Upper Genitourinary Tract Tumors or Urothelial Carcinoma of the Prostate
Authorization of 6 months may be granted as a single agent for the treatment of locally advanced or metastatic upper genitourinary (GU) tract tumors or urothelial carcinoma of the prostate as subsequent therapy following platinum-containing chemotherapy.

E. Kidney cancer
Authorization of 6 months may be granted for treatment of advanced, relapsed, or stage IV kidney cancer including renal cell carcinoma when Bavencio is given in combination with axitinib as first-line treatment for the disease.

IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III who have not experienced disease progression or an unacceptable toxicity.

V. REFERENCES

1. Bavencio [package insert]. New York, NY: Pfizer Inc.; May 2019.
2. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 17, 2019.