Reference number(s)
2130-A

STANDARD MEDICARE PART B 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
   i. Maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy
   ii. 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

B. Compendial Uses
1. Urothelial carcinoma - bladder cancer: second-line systemic therapy post-platinum for:
   i. muscle invasive local recurrence or persistent disease in a preserved bladder
   ii. metastatic or local recurrence post cystectomy
2. Urothelial carcinoma - primary carcinoma of the urethra, recurrent, as second-line systemic therapy post-platinum
3. Kidney cancer, in combination with axitinib as first-line therapy for relapse or stage IV disease

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

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 urothelial carcinoma when any of the following criteria are met:
1. The requested drug will be used as maintenance therapy if there is no progression on first-line platinum-containing chemotherapy.
2. The requested drug will be used as subsequent therapy post-platinum for any of the following:
   i. locally advanced or metastatic urothelial carcinoma

ii. urothelial carcinoma of the bladder with muscle invasive local recurrence or persistent disease in a preserved bladder
iii. urothelial carcinoma of the bladder with metastatic or local recurrence post cystectomy
iv. recurrent primary carcinoma of the urethra.

3. Member has a clinical reason to avoid therapy with platinum-containing chemotherapy.

C. Kidney Cancer

Authorization of 12 months may be granted for treatment of advanced (including stage IV) or relapsed kidney cancer 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 be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

A. The member is currently receiving therapy with Bavencio.
B. Bavencio is being used to treat an indication enumerated in Section II.
C. The member is receiving benefit from therapy.

IV. REFERENCES

1. Bavencio [package insert]. New York, NY: Pfizer Inc.; June 2020.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 16, 2020.