

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.

###### A. FDA-Approved Indications

1. **Metastatic Merkel Cell Carcinoma (MCC)**  
Treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma.
2. **Locally Advanced or Metastatic Urothelial Carcinoma (UC): *First-line maintenance treatment of urothelial carcinoma***  
Maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma that has not progressed with first-line platinum-containing chemotherapy.
3. **Locally Advanced or Metastatic Urothelial Carcinoma (UC): *Previously-treated 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.
4. **Advanced Renal Cell Carcinoma (RCC)**  
First-line treatment of patients with advanced renal cell carcinoma in combination with axitinib.

###### B. Compendial Indications

1. Urothelial carcinoma
  - a. Bladder cancer
  - b. Primary carcinoma of the urethra
  - c. Upper genitourinary (GU) tract tumors
  - d. Urothelial carcinoma of the prostate
2. Merkel cell carcinoma
3. Renal cell carcinoma
4. Gestational trophoblastic neoplasia
5. Endometrial carcinoma

All other indications are considered experimental/investigational and not medically necessary.

##### II. EXCLUSIONS

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

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### III. CRITERIA FOR INITIAL APPROVAL

#### A. Merkel Cell Carcinoma

Authorization of 6 months may be granted as a single agent for the treatment of Merkel cell carcinoma in members with locally advanced, recurrent, or metastatic disease.

#### B. Urothelial Carcinoma – Bladder Cancer

Authorization of 6 months may be granted for treatment of bladder cancer as a single agent when either of the following criteria is met:

1. Used as subsequent therapy.
2. Used as maintenance therapy if there is no progression on first-line platinum-containing chemotherapy.

#### 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 when either of the following criteria is met:

1. Used as subsequent systemic therapy for recurrent, locally advanced, or metastatic disease
2. Used as maintenance therapy if there is no progression on first-line platinum-containing chemotherapy.

#### D. Urothelial Carcinoma – Upper Genitourinary (GU) Tract Tumors or Urothelial Carcinoma of the Prostate

Authorization of 6 months may be granted for the treatment of upper genitourinary (GU) tract tumors or urothelial carcinoma of the prostate as a single agent when either of the following criteria is met:

1. Used as subsequent therapy for locally advanced or metastatic disease.
2. Used as maintenance therapy if there is no progression on first-line platinum-containing chemotherapy.

#### E. Renal Cell Carcinoma

Authorization of 6 months may be granted for treatment of advanced, relapsed, or stage IV renal cell carcinoma with clear cell histology when given in combination with axitinib as first-line treatment for the disease.

#### F. Gestational Trophoblastic Neoplasia

Authorization of 6 months may be granted as a single agent for treatment of gestational trophoblastic neoplasia for multiagent chemotherapy-resistant disease when either of the following criteria is met:

1. Member has recurrent or progressive intermediate trophoblastic tumor (placental site trophoblastic tumor or epithelioid trophoblastic tumor) following treatment with a platinum-based regimen.
2. Member has high-risk disease.

#### G. Endometrial Carcinoma

Authorization of 6 months may be granted as a single agent for subsequent treatment of recurrent or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors.

### 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 when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

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## V. REFERENCES

1. Bavencio [package insert]. Rockland, MA: EMD Serono, Inc.; September 2023.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed December 15, 2023