Draft Revised Policy: Do Not Implement

Avelumab (Bavencio®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

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. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Documentation of laboratory report confirming microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumor status, where applicable.

III. EXCLUSIONS

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

IV. 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.

V. 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.

Medication Quantity Limits

Drug Name	Diagnosis	Maximum Dosing Regimen
Avelumab (Bavencio)	Endometrial Carcinoma	Route of Administration: Intravenous 800mg every 2 weeks
Avelumab (Bavencio)	Gestational Trophoblastic Neoplasia	Route of Administration: Intravenous 800mg every 2 weeks
Avelumab (Bavencio)	Merkel Cell Carcinoma (MCC)	Route of Administration: Intravenous 800mg every 2 weeks
Avelumab (Bavencio)	Renal Cell Carcinoma (RCC)	Route of Administration: Intravenous 800mg every 2 weeks
Avelumab (Bavencio)	Urothelial Carcinoma	Route of Administration: Intravenous 800mg every 2 weeks

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Bavencio [package insert]. Rockland, MA: EMD Serono, Inc.; March 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 6, 2024.

BlueCross BlueShield of Tennessee

Policy

Medical Policy Manual

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EFFECTIVE DATE

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