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.

POLICY

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

Metastatic Merkel Cell Carcinoma (MCC)
Treatment of adults and pediatric patients 12 years and older with metastatic MCC

Locally Advanced or Metastatic Urothelial Carcinoma (UC)
First-line maintenance treatment of urothelial carcinoma
Maintenance treatment of patients with locally advanced or metastatic UC that has not progressed with first-line platinum-containing chemotherapy.
Previously-treated urothelial carcinoma
Treatment of patients with locally advanced or metastatic UC 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

Advanced Renal Cell Carcinoma (RCC)
First-line treatment of patients with advanced RCC in combination with axitinib

Compendial Uses

- Locally advanced and recurrent Merkel cell carcinoma
- Urothelial carcinoma
  - Bladder cancer
  - Primary carcinoma of the urethra
  - Upper genitourinary (GU) tract tumors
  - Urothelial carcinoma of the prostate
- Relapsed and stage IV renal cell carcinoma
- Colorectal adenocarcinoma
  - Endometrial carcinoma
  - Extranodal natural killer (NK)/T-cell lymphoma
  - Gestational trophoblastic neoplasia
  - Small bowel adenocarcinoma

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- Thymic carcinoma

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

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- Documentation of laboratory report confirming microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) with ultra-hypermutated tumor mutational burden [TMB] (greater than 50 mutations/megabase [mut/Mb]) tumor status, where applicable.
- Documentation of laboratory report confirming mismatch repair proficient (pMMR) tumor status, where applicable.

EXCLUSIONS

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

COVERAGE CRITERIA

Merkel Cell Carcinoma

Authorization of 6 months may be granted for treatment of locally advanced, regional, recurrent, or metastatic Merkel cell carcinoma as a single agent.

Urothelial Carcinoma

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

- The requested medication will be used as subsequent therapy for locally advanced or metastatic disease.
- The requested medication will be used as maintenance therapy if there is no progression on first-line platinum-containing chemotherapy.

Renal Cell Carcinoma

Authorization of 6 months may be granted for first-line treatment of advanced, relapsed, or stage IV renal cell carcinoma with clear cell histology in combination with axitinib (Inlyta).

Colorectal Adenocarcinoma

Authorization of 6 months may be granted for treatment of resectable, locally unresectable, medically inoperable, or metastatic colorectal adenocarcinoma when all of the following criteria are met:

- The tumor is mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (TMB > 50 mut/Mb).
- The requested medication will be used as a single agent.

Authorization of up to 6 months may be granted for neoadjuvant treatment of mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (TMB > 50 mut/Mb) positive colorectal adenocarcinoma as a single agent.

Endometrial Carcinoma

Authorization of 6 months may be granted for subsequent treatment of recurrent endometrial carcinoma when either of the following criteria is met:

- The tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) and the requested medication will be used as a single agent.
- The tumor is mismatch repair proficient (pMMR) and the requested medication will be used in combination with axitinib (Inlyta).

Extranodal Natural Killer (NK)/T-Cell Lymphoma

Authorization of 6 months may be granted for treatment of relapsed or refractory extranodal natural killer (NK)/T-cell lymphoma.

Gestational Trophoblastic Neoplasia

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

- Member has recurrent or progressive intermediate trophoblastic tumor (placental site trophoblastic tumor or epithelioid trophoblastic tumor).
- Member has high-risk disease.

Small Bowel Adenocarcinoma

Authorization of 6 months may be granted for treatment of resectable, locally unresectable, medically inoperable, advanced, or metastatic small bowel adenocarcinoma when all of the following criteria are met:

- The tumor is mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (TMB > 50 mut/Mb).
- The requested medication will be used as a single agent.

Authorization of up to 6 months may be granted for neoadjuvant treatment of mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (TMB > 50 mut/Mb) positive small bowel adenocarcinoma as a single agent.

Thymic Carcinoma

Authorization of 6 months may be granted for treatment of thymic carcinoma when both of the following criteria are met:

- The requested medication will be used as subsequent therapy or in members who cannot tolerate first-line combination regimens.
- The requested medication will be used in combination with axitinib (Inlyta).

CONTINUATION OF THERAPY

Colorectal Adenocarcinoma, Small Bowel Adenocarcinoma

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for treatment of resectable, locally unresectable, medically inoperable, advanced, or metastatic colorectal adenocarcinoma or small bowel adenocarcinoma when there is no evidence of disease progression or unacceptable toxicity while on the current regimen.

Authorization of up to 6 months total may be granted for continued treatment in members requesting reauthorization for neoadjuvant treatment of colorectal adenocarcinoma or small bowel adenocarcinoma when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

All Other Indications
Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria when there is no evidence of disease progression or unacceptable toxicity while on the current regimen.

Medication Quantity Limits

Drug Name	Diagnosis	Maximum Dosing Regimen
Bavencio (Avelumab)	Endometrial Carcinoma	Route of Administration: Intravenous 800mg every 2 weeks
Bavencio (Avelumab)	Extranodal NK/T-Cell Lymphomas	Route of Administration: Intravenous 800mg every 2 weeks
Bavencio (Avelumab)	Gestational Trophoblastic Neoplasia	Route of Administration: Intravenous 800mg every 2 weeks
Bavencio (Avelumab)	Merkel Cell Carcinoma (MCC)	Route of Administration: Intravenous 800mg every 2 weeks
Bavencio (Avelumab)	Renal Cell Carcinoma (RCC)	Route of Administration: Intravenous 800mg every 2 weeks
Bavencio (Avelumab)	Thymic Carcinoma	Route of Administration: Intravenous 800mg every 2 weeks
Bavencio (Avelumab)	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]. Boston, MA: EMD Serono, Inc.; June 2025.
2. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 4, 2026.

EFFECTIVE DATE 1/30/2027

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