Reference number(s)
2130-A

Standard Medicare Part B Management Bavencio

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Bavencio	avelumab

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[1]

Metastatic Merkel Cell Carcinoma (MCC)

Treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma.

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 (UC) that has not progressed with first-line platinum-containing chemotherapy.

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.

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Advanced Renal Cell Carcinoma (RCC)

First-line treatment of patients with advanced renal cell carcinoma in combination with axitinib.

Compendial Uses[2]

- Urothelial carcinoma
  - Bladder cancer
  - Primary carcinoma of the urethra
  - Upper genitourinary (GU) tract tumor
  - Urothelial carcinoma of the prostate
- Merkel cell carcinoma
- Renal cell carcinoma
- Gestational trophoblastic neoplasia
- Endometrial carcinoma
- Salivary gland tumors adenoid cystic carcinoma
- Thymic carcinoma
- Extranodal natural killer (NK)/T-cell lymphoma

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

Documentation

The following documentation must be available, upon request, for all submissions:

Documentation of laboratory report confirming microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) 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[1,2]

Authorization of 12 months may be granted as a single agent for the treatment of Merkel cell carcinoma in members with locally advanced, recurrent, or metastatic disease.

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Urothelial Carcinoma – Bladder Cancer[1,2]

Authorization of 12 months may be granted for the treatment of bladder cancer as a single agent when either of the following criteria is met:

- The requested medication will be used as maintenance therapy if there is no progression on first-line platinum-containing chemotherapy.
- The requested medication will be used as subsequent therapy.

Urothelial Carcinoma – Primary Carcinoma of the Urethra[1,2]

Authorization of 12 months may be granted for the treatment of primary carcinoma of the urethra as a single agent when either of the following criteria is met:

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

Urothelial Carcinoma – Upper Genitourinary (GU) Tract Tumors or Urothelial Carcinoma of the Prostate[1,2]

Authorization of 12 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:

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

Renal Cell Carcinoma[1,2]

Authorization of 12 months may be granted for the treatment of advanced, relapsed, or stage IV renal cell carcinoma with clear cell histology when Bavencio is given in combination with axitinib as first-line treatment for the disease.

Gestational Trophoblastic Neoplasia[2]

Authorization of 12 months may be granted as a single agent for the treatment of gestational trophoblastic neoplasia for multiagent chemotherapy-resistant disease 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.

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Endometrial Carcinoma[2]

Authorization of 12 months may be granted as a single agent for subsequent treatment of recurrent microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors.

Salivary Gland Tumors Adenoid Cystic Carcinoma[2]

Authorization of 12 months may be granted in combination with axitinib for treatment of recurrent, unresectable, or metastatic adenoid cystic carcinoma.

Thymic Carcinoma[2]

Authorization of 12 months may be granted for the 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.

Extranodal Natural Killer (NK)/T-Cell Lymphoma[2]

Authorization of 12 months may be granted for the treatment of extranodal natural killer (NK)/T-cell lymphoma in members with relapsed or refractory disease.

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:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication listed in the coverage criteria.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen and
    - No evidence of disease progression while on the current regimen.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Bavencio.
- The available compendium

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    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Gestational trophoblastic neoplasia
- NCCN Guideline: Merkel cell carcinoma
- NCCN Guideline: Kidney cancer
- NCCN Guideline: Bladder cancer
- NCCN Guideline: Uterine neoplasms
- NCCN Guideline: Salivary gland tumors
- NCCN Guideline: Thymomas and thymic carcinomas
- NCCN Guideline: T-cell lymphomas

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Bavencio are covered in addition to the following:

- Urothelial carcinoma
    - Bladder cancer
    - Primary carcinoma of the urethra
    - Upper genitourinary (GU) tract tumor
    - Urothelial carcinoma of the prostate
- Merkel cell carcinoma
- Renal cell carcinoma
- Gestational trophoblastic neoplasia
- Endometrial carcinoma
- Salivary gland tumors- adenoid cystic carcinoma
- Thymic carcinoma
- Extranodal natural killer (NK)/T-cell lymphoma

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for urothelial carcinoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for Merkel cell carcinoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

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Support for renal cell carcinoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for gestational trophoblastic neoplasia can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for endometrial carcinoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for salivary gland tumors- adenoid cystic carcinoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for thymic carcinoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for extranodal natural killer/t-cell lymphoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Bavencio [package insert]. Boston, MA: EMD Serono, Inc.; November 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 14, 2025.

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