

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Programmed Death-Ligand 1) – Bavencio Utilization Management Medical Policy

- Bavencio® (avelumab intravenous infusion – EMD Serono)

REVIEW DATE: 07/01/2026

OVERVIEW

Bavencio, a programmed cell death ligand-1 (PD-L1) blocking antibody, is indicated for the treatment of the following:¹

- **Merkel cell carcinoma**, in patients ≥ 12 years of age with metastatic disease.
- **Renal cell carcinoma**, in combination with Inlyta® (axitinib tablets), for the first-line treatment of advanced disease.
- **Urothelial carcinoma**, in patients with locally advanced or metastatic disease who have:
 - Disease progression during or following platinum-containing chemotherapy.
 - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
 - Maintenance treatment of locally advanced or metastatic disease that has not progressed with first-line platinum-containing chemotherapy.

Dosing Information

Premedication with an antihistamine and acetaminophen is recommended with the first four infusions of Bavencio.¹ For subsequent Bavencio infusions, premedication is recommended based on clinical judgement and presence/severity of prior infusion reactions. The recommended dose of Bavencio is 800 mg administered as an intravenous infusion over 60 minutes once every 2 weeks until disease progression or unacceptable toxicity. For renal cell carcinoma, Bavencio is used in combination with Inlyta 5 mg taken orally twice daily.

Guidelines

The use of Bavencio is recommended across multiple National Comprehensive Cancer Network (NCCN) guidelines and the NCCN Compendium.^{2-9,12-16} Recommendations with a category of evidence of 2B or higher support the approval criteria outlined below.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Bavencio. Approval is recommended for those who meet the conditions of coverage in the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Bavencio, as well as the monitoring required for adverse events and long-term efficacy, approval requires Bavencio to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Bavencio is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Merkel Cell Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
 - A) Patient is ≥ 12 years of age; AND
 - B) Patient meets ONE of the following (i, ii, iii, or iv):
 - i. Patient has primary or recurrent locally advanced disease, if according to the prescriber curative surgery and curative radiation therapy are not feasible; OR
 - ii. Patient has primary or recurrent regional disease, if according to the prescriber curative surgery and curative radiation therapy are not feasible; OR
 - iii. Patient has metastatic (disseminated) disease; OR
 - iv. Patient has in-transit regional disease; AND
 - C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 800 mg administered as an intravenous infusion not more frequently than once every 2 weeks.

2. **Renal Cell Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has relapsed or Stage IV clear cell disease; AND
 - C) The medication will be used in combination with Inlyta (axitinib tablets); AND
 - D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 800 mg administered as an intravenous infusion not more frequently than once every 2 weeks.

3. **Urothelial Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has locally advanced or metastatic disease; AND
 - C) Patient has tried platinum-containing chemotherapy (cisplatin or carboplatin); AND
 - D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 800 mg administered as an intravenous infusion not more frequently than once every 2 weeks.

Other Uses with Supportive Evidence

4. **Colon and Rectal Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C)
 - A) The patient is ≥ 18 years of age; AND
 - B) Patient meets ONE of the following (i or ii):

- i. The disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); OR
- ii. The disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype; AND

Note: Ultra-hypermutated phenotype is defined as tumor mutational burden > 50 mutations/megabase.

C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 800 mg administered as an intravenous infusion not more frequently than once every 2 weeks.

5. Endometrial Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Patient has recurrent or metastatic disease; AND

C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 10 mg/kg administered as an intravenous infusion not more frequently than once every 2 weeks.

6. Extranodal NK/T-Cell Lymphoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Patient has received an asparaginase-based chemotherapy regimen; AND

Note: Examples of asparaginase-based chemotherapy are dexamethasone, ifosfamide, pegaspargase, etoposide; and gemcitabine, pegaspargase, oxaliplatin.

C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 10 mg/kg administered as an intravenous infusion not more frequently than once every 2 weeks.

7. Gestational Trophoblastic Neoplasia. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Patient has multi-agent chemotherapy resistant disease; AND

C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve ONE of the following dosing regimens (A or B):

A) 10 mg/kg administered as an intravenous infusion not more frequently than once every 2 weeks;
OR

B) 800 mg administered as an intravenous infusion not more frequently than once every 2 weeks.

8. Salivary Gland Tumor. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

A) Patient is ≥ 18 years of age; AND

- B) Patient has recurrent, unresectable, or metastatic disease; AND
- C) The medication will be used in combination with Inlyta (axitinib tablets); AND
- D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 10 mg/kg administered as an intravenous infusion not more frequently than once every 2 weeks.

9. Small Bowel Adenocarcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

- A) Patient is ≥ 18 years of age; AND
- B) Patient meets ONE of the following (i or ii):
 - i. Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease; OR
 - ii. The disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype; AND

Note: Ultra-hypermutated phenotype is defined as tumor mutational burden > 50 mutations/megabase.
- C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 800 mg administered as an intravenous infusion not more frequently than once every 2 weeks.

10. Thymic Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

- A) Patient is ≥ 18 years of age; AND
- B) The medication will be used in combination with Inlyta (axitinib tablets); AND
- C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 10 mg/kg administered as an intravenous infusion not more frequently than once every 2 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Bavencio is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

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15. The NCCN Small Bowel Adenocarcinoma Clinical Practice Guidelines in Oncology (version 2.2026 – April 7, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 29, 2026.
16. The NCCN Head and Neck Cancers Clinical Practice Guidelines in Oncology (version 2.2026 – May 12, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 29, 2026.
17. Ferrarotto R, Sousa LG, Feng L, et al. Phase II clinical trial of axitinib and avelumab in patients with recurrent/metastatic adenoid cystic carcinoma. *J Clin Oncol*. 2023;41(15):2843-2851.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Merkel Cell Carcinoma: Added patient has locally advanced disease and patient has recurrent regional disease as additional options for approval. Gestational Trophoblastic Neoplasia: Added 800 mg administered as an intravenous infusion not more frequently than once every 2 weeks as an additional dosing regimen.	07/24/2024
Annual Revision	Merkel Cell Carcinoma: For locally advanced disease, “primary or recurrent” was added as a qualifier; a requirement that “if according to the prescriber, curative surgery and curative radiation therapy are not feasible” was added. For regional disease, “primary” was added as a qualifier; a requirement that “if according to the prescriber, curative surgery and curative radiation therapy are not feasible” was added. Extranodal NK/T-Cell Lymphoma: This was added as a new condition of approval. Thymic Carcinoma: This was added as a new condition of approval.	07/16/2025
Early Annual Revision	Merkel Cell Carcinoma: The patient has in-transit regional disease was added as an option for approval. Thymic Carcinoma: The requirement that the patient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors was removed.	01/14/2026
Early Annual Revision	Colon and Rectal Cancer: This was added as a new condition of approval to “Other Uses with Supportive Evidence”. Endometrial Carcinoma: The requirement that the medication will be used as a single agent was removed. Gestational Trophoblastic Neoplasia: The requirement that the medication will be used as a single agent was removed. Salivary Gland Tumor: This was added as a new condition for approval to “Other Uses with Supportive Evidence”. Small Bowel Adenocarcinoma: This was added as a new condition for approval to “Other Uses with Supportive Evidence”. Thymic Carcinoma: The requirement that the patient has tried at least one chemotherapy regimen and the corresponding Note was removed.	07/01/2026

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