CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Programmed Death-Ligand 1) – Bavencio Utilization Management Medical Policy
- Bavencio® (avelumab intravenous infusion – EMD Serono)

REVIEW DATE: 07/16/2025

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.

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, or iii):
     - **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; 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 urothelial carcinoma; 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. **Endometrial Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent or metastatic disease; AND
   - **C)** Patient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors; AND
   - **D)** The medication will be used as a single agent; AND
   - **E)** 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.

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5. 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.

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6. Gestational Trophoblastic Neoplasia. 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 multi-agent chemotherapy resistant disease; AND
- **C)** The medication will be used as a single agent; AND
- **D)** 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.

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7. Thymic 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 tried at least one chemotherapy regimen; AND
  Note: Examples of a chemotherapy regimen include carboplatin plus paclitaxel, cisplatin, doxorubicin plus cyclophosphamide, cisplatin plus etoposide, carboplatin, paclitaxel, and Cyramza (ramucirumab intravenous infusion).
- **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.

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

1. Bavencio® intravenous infusion [prescribing information]. Rockland, MA: EMD Serono; June 2025.
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4. The NCCN Merkel Cell Carcinoma Clinical Practice Guidelines in Oncology (version 2.2025 – April 18, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 8, 2025.
5. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – January 9, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 08, 2025.
6. The NCCN Gestational Trophoblastic Neoplasia Clinical Practice Guidelines in Oncology (version 3.2025 – May 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 08, 2025.
7. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 3.2025 – March 7, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 08, 2025.
8. You B, Bolze PA, Lotz JP, et al. Avelumab in patients with gestational trophoblastic tumors with resistance to single-agent chemotherapy: Cohort A of the TROPHIMMUN Phase II trial. *J Clin Oncol*. 2020;38:3129-3137.
9. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 2.2025 – May 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 09, 2025.
10. The NCCN Thymomas and Thymic Carcinoma Clinical Practice Guidelines in Oncology (version 2.2025 – May 19, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 09, 2025.
11. Conforti F, Zucali PA, Pala L, et al. Avelumab plus axitinib in unresectable or metastatic type B3 thymomas and thymic carcinomas (CAVEATT): a single-arm, multicentre, phase 2 trial. *Lancet Oncol*. 2022;23(10):1287-1296.
12. Kim SJ, Lim JQ, Laurensia Y, et al. Avelumab for the treatment of relapsed or refractory extranodal NK/T-cell lymphoma: an open-label phase 2 study. *Blood*. 2020;136(24):2754-2763.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	07/19/2023
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