POLICY: Oncology – Bavencio® (avelumab injection for intravenous use – EMD Serono, Inc.)

EFFECTIVE DATE: 1/1/2020
LAST REVISION DATE: 07/19/2023

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Bavencio, a programmed cell death ligand-1 (PD-L1) blocking antibody, is indicated for the treatment of the following uses:[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 **a)** disease progression during or following platinum-containing chemotherapy; or **b)** disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; and for **c)** maintenance treatment of locally advanced or metastatic disease that has not progressed with first-line platinum-containing chemotherapy.

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

Bavencio is addressed in National Comprehensive Cancer Network (NCCN) guidelines:

- **Bladder Cancer:** Guidelines (version 3.2023 – May 25, 2023) recommend Bavencio as an alternative "Preferred" regimen for second-line therapy (category 2A) for locally advanced or metastatic disease (Stage IV).[2,3] Guidelines also recommend Bavencio as maintenance therapy following platinum-based chemotherapy (category 1). The NCCN Compendium recommends Bavencio, as a single agent, for urothelial carcinoma of the bladder; for upper genitourinary tract tumors (metastatic disease); urothelial carcinoma of the prostate (metastatic disease); and for primary carcinoma of the urethra (recurrent or metastatic disease) as second-line or maintenance therapy.[3]
- **Gestational Trophoblastic Neoplasm:** Guidelines (version 1.2023 – December 20, 2022) recommend Bavencio as a single agent for multidrug resistant high-risk disease, and recurrent or progressive intermediate trophoblastic tumor following a platinum-containing regimen.[3,6]
- **Kidney Cancer:** Guidelines (version 1.2024 – June 21, 2023) recommend Bavencio in combination with Inlyta for first-line treatment for relapsed or Stage IV clear cell disease (category 2A).[3,5] For subsequent therapy, Bavencio + Inlyta is a category 3 recommendation.
- **Merkel Cell Carcinoma:** Guidelines (version 1.2023 – April 10, 2023) recommend Bavencio as one of the options for disseminated disease (category 2A).[3,4] Clinical trial is "Preferred" in this setting; other PD-1/PD-L1 inhibitor options for disseminated disease include Keytruda®

(pembrolizumab intravenous infusion) and Opdivo® (nivolumab intravenous infusion) [all category 2A].

- **Uterine Neoplasms:** Guidelines (version 2.2023 – April 28, 2023) recommend Bavencio, as a single agent, for the treatment of recurrent or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors.[3,7]

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

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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 has metastatic (disseminated) Merkel cell carcinoma; 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.

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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.

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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

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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. 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 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; July 2021.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 3.2023 – May 25, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 10, 2023.
3. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 10, 2023. Search term: avelumab.
4. The NCCN Merkel Cell Carcinoma Clinical Practice Guidelines in Oncology (version 1.2023 – April 10, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 10, 2023.
5. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 1.2024 – June 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 10, 2023.

6. The NCCN Gestational Trophoblastic Neoplasia Clinical Practice Guidelines in Oncology (version 1.2023 – December 20, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 10, 2023.
7. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2023 – April 28, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 10, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Merkel Cell Carcinoma:** Removed descriptor "up to" from the dosing regimen. **Renal Cell Carcinoma:** Added requirement that the patient is ≥ 18 years of age. Removed descriptor "up to" from the dosing regimen. **Urothelial Carcinoma:** Added requirement that the patient is ≥ 18 years of age. Removed descriptor "up to" from the dosing regimen. **Endometrial Carcinoma:** Added new condition of approval. **Gestational Trophoblastic Neoplasm:** Added requirement that the patient is ≥ 18 years of age. Removed descriptor "up to" from the dosing regimen and changed approved dose from 800 mg to 10 mg/kg.	07/20/2022
Annual Revision	No criteria changes.	07/19/2023