VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION REVIEW MEDICAL POLICY

POLICY: Oncology (Injectable) – Bavencio Utilization Review Medical Policy
- Bavencio® (avelumab injection for intravenous use – EMD Serono, Inc.)

REVIEW DATE: 07/15/2020

OVERVIEW

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

- **Merkel cell carcinoma**, in adults and pediatric patients ≥ 12 years of age with metastatic disease.
- **Renal cell carcinoma**, in combination with Inlyta (axitinib tablets), for the first-line treatment of patients with 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)** have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; and for **c)** first-line 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. 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 (IV) infusion over 60 minutes once every 2 weeks until disease progression or unacceptable toxicity. For renal cell carcinoma indication, Bavencio is used in combination with Inlyta 5 mg taken orally twice daily.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on bladder cancer (version 3.2019 – April 23, 2019) recommends Bavencio as one of the "alternative preferred regimens" for subsequent therapy (category 2A) for locally advanced or metastatic disease (Stage IV, post-platinum).[2] It is recommended as second-line therapy for locally advanced or metastatic disease (stage IV) [post-platinum]. Bavencio can be used regardless of PD-L1 expression levels. The new indication in the maintenance setting after platinum therapy is not yet addressed in the guidelines. The NCCN Compendium[3] recommends Bavencio 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).

The NCCN guidelines on Merkel cell carcinoma (version 1.2020 – October 2, 2019) recommends Bavencio as one of the options for disseminated disease (category 2A).[4] Clinical trial is preferred in this setting; but other PD-1/PD-L1 inhibitor options for disseminated disease include Keytruda® (pembrolizumab for injection) and Opdivo® (nivolumab for injection) [all category 2A].

The NCCN guidelines for kidney cancer (version 2.2020 – August 5, 2019) recommends Bavencio in combination with Inlyta for first-line treatment in all risk group patients (favorable and poor/intermediate) for relapsed or Stage IV disease. It is one of the "other recommended regimens" for clear cell histology renal cell carcinoma with a category 2A recommendation. For subsequent therapy, Bavencio + Inlyta is a category 3 recommendation.

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.

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 the following criteria (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 up to 800 mg administered as an intravenous infusion not more frequently than once every 2 weeks.[1]

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2. Renal Cell Carcinoma. Approve for 1 year if the patient meets the following criteria (A, B, and C):
- **A)** Patient has relapsed or Stage IV clear cell disease; 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 up to 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 the following criteria (A, B, and C):
- **A)** Patient has locally advanced or metastatic urothelial carcinoma; AND
- **B)** Patient has tried platinum-containing chemotherapy (cisplatin or carboplatin); AND
- **C)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 800 mg administered as an intravenous infusion not more frequently than once every 2 weeks.[1]

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® injection for intravenous use [prescribing information]. Rockland, MA: EMD Serono, Inc.; June 2020.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (Version 5.2020 – May 12, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 13, 2020.
3. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on June 12, 2020. Search term: avelumab.
4. The NCCN Merkel Cell Carcinoma Clinical Practice Guidelines in Oncology (Version 1.2020 – October 2, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 13, 2020.
5. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (Version 2.2020 – August 5, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 13, 2020.

HISTORY

Type of Revision	Summary of Changes	Review Date
New policy	New criteria	05/23/2018
Annual revision	• For all approved conditions, deleted Initial and Extended approval, Labs/Diagnostics, and Duration of Therapy sections. Also deleted Waste Management, Other Cancer Indications, and Patient has been Started on Bavencio sections. • Merkel Cell Carcinoma: Added approval duration of 1 year. Deleted criteria "Bavencio will be used as a single agent," and modified weight-based dosing to state "Approve up to 800 mg" Bavencio administered "once" every 2 weeks. The new dose is as noted in the prescribing information. Deleted infusion time (60 minutes) from dosing. • Urothelial Carcinoma: Added approval duration of 1 year. Deleted criteria "Bavencio will be used as a single agent," and modified weight-based dosing to state: "Approve up to 800 mg" administered "once" every 2 weeks. Deleted infusion time (60 minutes) from dosing. Re-worded to state patient "has tried" platinum-containing chemotherapy; previously it stated patient "has disease progression during or after trying" chemotherapy. • Renal Cell Carcinoma: Added new approval condition and criteria based on new indication and guideline support.	06/18/2019
Annual revision	• For all dosing criteria, added "not more frequently than" for dosing intervals. • Instead of specifying "Bavencio", used "The medication" wherever applicable. • **Merkel Cell Carcinoma:** Instead of "12 years of age or older" used "≥". • **Renal Cell Carcinoma:** Deleted criteria referencing "for first-line treatment". • **Conditions Not Recommended For Approval**. Deleted "Other Indications (Non-Cancer)".	07/15/2020