OVERVIEW
Bavencio is a human immunoglobulin G1 (IgG1) lambda monoclonal antibody that binds to programmed cell death ligand-1 (PD-L1). By binding, it blocks the interaction of PD-L1 with PD-1 and B7.1 receptors, thereby releasing the inhibition of immune responses, including anti-tumor immune responses. Bavencio has been shown to induce antibody dependent cell-mediated cytotoxicity in vitro.

Bavencio is indicated for the treatment of adults and pediatric patients ≥ 12 years of age with metastatic Merkel cell carcinoma. It is also indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma 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. In combination with Inlyta (axitinib tablets), Bavencio is indicated for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

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 RCC indication, Bavencio is used in combination with Inlyta 5 mg taken orally twice daily.

Bavencio is available as 200 mg/10 mL (20 mg/mL) clear, colorless to slightly yellow solution in a single-dose vial.

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). It is recommended after progression on platinum-based chemotherapy or for disease that has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. Bavencio can be used regardless of PD-L1 expression levels. The NCCN Compendium 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 2.2019 – January 18, 2019) recommends Bavencio as one of the options for disseminated disease (category 2A). 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]. For patients with contraindications to immunotherapy, cisplatin ± etoposide, carboplatin ± etoposide, topotecan, and the combination regimen of cyclophosphamide, doxorubicin (or epirubicin), and vincristine are the recommended therapies.

The NCCN guidelines for kidney cancer (version 1.2020 – June 7, 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 RCC 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

1. Merkel Cell Carcinoma. Approve for 1 year if the patient meets the following criteria (A, B, and C):
   A) Bavencio is prescribed by or in consultation with an oncologist; AND
   B) The patient has metastatic (disseminated) Merkel cell carcinoma; AND
   C) The patient is 12 years of age or older.

   **Dosing.** Approve up to 800 mg administered as an intravenous infusion once every 2 weeks.¹

2. Urothelial Carcinoma. Approve for 1 year if the patient meets the following criteria (A, B, and C):
   A) Bavencio is prescribed by or in consultation with an oncologist; AND
   B) The patient has locally advanced or metastatic urothelial carcinoma; AND
   C) The patient has tried platinum-containing chemotherapy (cisplatin or carboplatin).

   **Dosing.** Approve up to 800 mg administered as an intravenous infusion once every 2 weeks.¹

3. Renal Cell Carcinoma (RCC). Approve for 1 year if the patient meets the following criteria (A, B, and C):
   A) Bavencio is prescribed by or in consultation with an oncologist; AND
   B) The patient has relapsed or Stage IV clear cell RCC; AND
   C) Bavencio will be used in combination with Inlyta (axitinib tablets) for first-line treatment.

   **Dosing.** Approve up to 800 mg administered as an intravenous infusion once every 2 weeks.
CONDITIONS NOT RECOMMENDED FOR APPROVAL

1. **Other Indications (Non-Cancer).** Coverage is not recommended for circumstances not listed in the Authorization Criteria (FDA-approved indications and Other Uses with Supportive Evidence). Criteria will be updated as new published data are available.

REFERENCES


HISTORY

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<thead>
<tr>
<th>Type of Revision</th>
<th>Summary of Changes*</th>
<th>Approval Date</th>
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<tbody>
<tr>
<td>New policy</td>
<td>New criteria</td>
<td>05/23/2018</td>
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| 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 |