# Clinical Policy: Avelumab (Bavencio)

Reference Number: LA.PHAR.333
Effective Date:
Last Review Date: 06.19.23
Line of Business: Medicaid

Coding Implications
Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

****Please note: This policy is for medical benefit****

## Description

Avelumab (Bavencio®) is a programmed death ligand-1 blocking antibody.

## FDA Approved Indication(s)

Bavencio is indicated for:

- Adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC).*
- Maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy.
- Patients with locally advanced or metastatic UC who:
  - Have disease progression during or following platinum-containing chemotherapy.
  - Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
- First-line treatment, in combination with axitinib, of patients with advanced renal cell carcinoma (RCC).

*This indication is approved under accelerated approval based on tumor response and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

## Policy/Criteria

*Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of Louisiana Healthcare Connections that Bavencio is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Merkel Cell Carcinoma** (must meet all)**:**

1. Diagnosis of metastatic or recurrent MCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 12 years;
4. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg (4 vials) every two weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

**Approval duration:** 6 months

**B. Urothelial Carcinoma** (must meet all)**:**

1. Diagnosis of recurrent, locally advanced, or metastatic UC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Member has received platinum-based chemotherapy (e.g., cisplatin, carboplatin);
5. Prescribed as a single agent;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg (4 vials) every two weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

**Approval duration:** 6 months

**C. Renal Cell Carcinoma** (must meet all)**:**

1. Diagnosis of advanced RCC (e.g., relapse, stage IV disease) with clear cell histology;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as first-line therapy in combination with Inlyta®;
   **Prior authorization may be required for Inlyta*
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg (4 vials) every two weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

**Approval duration:** 6 months

**D. Other NCCN Recommended Uses (off-label)** (must meet all)**:**

1. Diagnosis of one of the following (a or b):
   a. Gestational trophoblastic neoplasia;
   b. Endometrial carcinoma;
2. Prescribed or in consultation with an oncologist;
3. Age ≥ 18 years;
4. For gestational trophoblastic neoplasia: Prescribed as a single agent following failure of ≥ 2 systemic chemotherapeutic agents (see *Appendix B*) and member has one of the following (a or b):
   a. High-risk disease;
   b. Recurrent or progressive intermediate trophoblastic tumor (placental site trophoblastic tumor or epithelioid trophoblastic tumor) following treatment with a platinum-based regimen;
5. For endometrial carcinoma, both of the following (a and b):
   a. Prescribed as a single agent second-line treatment (see *Appendix B*);
   b. Disease is recurrent or metastatic for microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors;
6. Request meets one of the following (a or b):*

a. Dose does not exceed 800 mg (4 vials) every two weeks;
b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

**Approval duration:** 6 months

**E. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

## II. Continued Therapy

**A. All Indications in Section I** (must meet all)**:**

1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Bavencio for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 800 mg (4 vials) every two weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

**Approval duration:** 12 months

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53 for Medicaid, or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

dMMR: deficient mismatch repair
FDA: Food and Drug Administration
MCC: Merkel cell carcinoma
MSI-H: microsatellite instability-high
NCCN: National Comprehensive Cancer Network

RCC: renal cell carcinoma UC: urothelial carcinoma

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| **Gestational Trophoblastic Neoplasia** | | |
| **Examples of systemic chemotherapeutic agents:** bleomycin, carboplatin, cyclophosphamide, dactinomycin, etoposide, gemcitabine, ifosfamide, mesna, methotrexate, paclitaxel, vincristine. | Varies | Varies |
| **Endometrial carcinoma** | | |
| **Examples of systemic chemotherapeutic agents:** carboplatin/paclitaxel, cisplatin/doxorubicin, carboplatin/paclitaxel/bevacizumab, doxorubicin, topotecan, temsirolimus, ifosfamide | Varies | Varies |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*
None reported

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| MCC, UC | 800 mg IV infusion every 2 weeks until disease progression or unacceptable toxicity | 800 mg every 2 weeks |
| RCC | 800 mg IV infusion every 2 weeks in combination with axitinib | 800 mg every 2 weeks |

## VI. Product Availability

Single-dose vials: 200 mg/10 mL (20 mg/mL)

## VII. References

1. Bavencio Prescribing Information. Rockland, MA: EMD Serono, Inc.; July 2022. Available at: https://www.bavencio.com/. Accessed November 22, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed November 22, 2022.
3. National Comprehensive Cancer Network. Merkel Cell Carcinoma Version 2.2022. Available at www.nccn.org. Accessed November 22, 2022.
4. National Comprehensive Cancer Network. Bladder Cancer Version 2.2022. Available at: www.nccn.org. Accessed November 22, 2022.

5. National Comprehensive Cancer Network. Kidney Cancer Version 3.202. Available at: www.nccn.org. Accessed November 22, 2022.
6. National Comprehensive Cancer Network. Gestational Trophoblastic Neoplasia Version 1.2022. Available at www.nccn.org. Accessed November 22, 2022.
7. National Comprehensive Cancer Network. Uterine Neoplasms Version 1.2022. Available at www.nccn.org. Accessed November 22, 2022.

**Coding Implications**
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|---|---|
| J9023 | Injection, avelumab, 10 mg |

| Reviews, Revisions, and Approvals | Date | LDH Approval Date |
|---|---|---|
| Converted corporate to local policy. | 06.19.23 | |

**Important Reminder**
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or

withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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