

Clinical Policy: Avelumab (Bavencio)

Reference Number: LA.PHAR.333

Effective Date: 11.04.23

Last Review Date: ~~03.05.2505.01.24~~

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 \geq 12 years;
4. Request meets one of the following (a or b):*
 - a. Dose does not exceed 800 mg (4 vials) every two weeks;

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- 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 \geq 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 \geq 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, b, or e-e~~):
 - a. Gestational trophoblastic neoplasia;
 - b. Endometrial carcinoma;
 - c. Salivary gland tumors;
 - d. Thymic carcinoma;
 - e. Extranodal NK/T-cell lymphomas;
2. Prescribed or in consultation with an oncologist;
3. Age \geq 18 years;
4. For gestational trophoblastic neoplasia: Prescribed as a single agent following failure of \geq 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;

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5. For endometrial carcinoma, both of the following (a and b):
 - a. Prescribed as a single agent second-line or subsequent treatment (see *Appendix B*);
 - b. Disease is recurrent or metastatic for microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors;
 6. For salivary gland tumors, ~~used in combination with Inlyta*~~ for recurrent adenoid cystic carcinoma with either of the following (a or b):
 - a. Distant metastases in patients with a performance status of 0-3;
 - b. Unresectable locoregional recurrence or second primary with prior radiation therapy;
 7. For thymic carcinoma, use in combination with Inlyta* for locally advanced or metastatic disease following treatment or intolerability to a first-line combination therapy regimen (see Appendix B);
**Prior authorization may be required for Inlyta.*
 8. For extranodal NK-T-cell lymphomas, prescribed for relapsed/refractory disease following additional therapy with an alternative combination chemotherapy regimen (see Appendix B) not previously used, if a clinical trial is unavailable;
- 7-9. 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):

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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 NCCN: National Comprehensive Cancer Network
 FDA: Food and Drug Administration
 MCC: Merkel cell carcinoma RCC: renal cell carcinoma
 MSI-H: microsatellite instability-high 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
Thymic carcinoma		
Examples of systemic chemotherapeutic agents: <u>carboplatin/paclitaxel, carboplatin/paclitaxel/ramucirumab, cyclophosphamide/doxorubicin/cisplatin/ prednisone, doxorubicin/cisplatin/</u>	<u>Varies</u>	<u>Varies</u>

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
vincristine/cyclophosphamide, cisplatin/etoposide, etoposide/ifosfamide/cisplatin		
Extranodal NK/T-cell lymphomas		
Examples of systemic chemotherapeutic agents: pegaspargase/dexamethasone/methotrexate/ifosfamide/etoposide, pegaspargase/gemcitabine/oxaliplatin, pegaspargase/dexamethasone/cisplatin/gemcitabine, pegaspargase/methotrexate/dexamethasone	Varies	Varies

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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 5 mg PO BID	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.; ~~September 2023~~[October 2024](#). Available at: <https://www.bavencio.com/>. Accessed ~~October 12, 2023~~[December 2, 2024](#).
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed ~~November 28, 2023~~[December 2, 2024](#).
3. National Comprehensive Cancer Network. Merkel Cell Carcinoma Version 1.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/mcc.pdf. Accessed ~~November 28, 2023~~[December 2, 2024](#).
4. National Comprehensive Cancer Network. Bladder Cancer Version ~~3.2023~~[5.2024](#). Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed ~~November 28, 2023~~[December 2, 2024](#).
5. National Comprehensive Cancer Network. Kidney Cancer Version ~~1.2024~~[2.2025](#). Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed ~~November 28, 2023~~[December 2, 2024](#).

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6. National Comprehensive Cancer Network. Gestational Trophoblastic Neoplasia Version ~~42~~.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/gtn.pdf. Accessed ~~November 28, 2023~~December 2, 2024.
7. National Comprehensive Cancer Network. Uterine Neoplasms Version ~~43~~.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed ~~November 28, 2023~~December 2, 2024.
8. National Comprehensive Cancer Network. Head and Neck Cancers Version 1.~~2024~~2025. Available at https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed ~~November 28, 2023~~December 2, 2024.
9. National Comprehensive Cancer Network. T-Cell Lymphomas Version 1.2025. Available at https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed ~~December 2, 2024~~.
- ~~8~~10. National Comprehensive Cancer Network. Thymomas and Thymic Carcinomas Version 1.2025. Available at https://www.nccn.org/professionals/physician_gls/pdf/thymic.pdf. Accessed ~~December 2, 2024~~.

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	10.05.23
Annual review: no significant changes; per NCCN guidelines added coverage criteria for salivary gland tumors (category 2B recommendation); references reviewed and updated.	05.01.24	<u>08.20.24</u>
<u>Annual review: per NCCN guidelines added criteria for off-label use for thymic carcinoma and extranodal NK/T-cell lymphomas; for off-label use for salivary gland tumors, removed the requirement for combination use with Inlyta since Bavencio also has a 2A rec for use without Inlyta; references reviewed and updated.</u>	<u>03.05.25</u>	

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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

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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.

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