Clinical Policy: Avelumab (Bavencio)

Reference Number: CP. PHAR.333
Effective Date: 05.01.17
Last Review Date: 02.18 Revision Log
Line of Business: Medicaid

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

Description

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

FDA Approved Indication(s)

Bavencio is indicated:

- For the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC).
  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.
- For the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) who:
  - have disease progression during or following platinum-containing chemotherapy; or
  - have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

  This indication is approved under accelerated approval based on tumor response rate 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 (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® 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 MCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 12 years;
4. Dose does not exceed 10 mg/kg every two weeks.

Approval duration: 6 months

B. Bladder Cancer Including Urothelial Carcinoma (must meet all)**:**

1. Prescribed by or in consultation with an oncologist;
2. Meets a or b:

a. FDA approved use:
   i. Diagnosis of UC;
   ii. Disease progression during or following platinum-containing chemotherapy;
b. Off-label NCCN recommended use:
   i. Diagnosis of bladder cancer
   ii. Disease recurrence post cystectomy;

3. Request meets one of the following (a or b):
   a. Dose does not exceed 10 mg/kg every two weeks;
   b. Dose is supported by practice guidelines or peer-reviewed practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Bavencio for MCC or bladder cancer/UC and has received this medication for at least 30 days;
2. Member is responding positively to therapy (e.g., no disease progression or unacceptable toxicity);
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 10 mg/kg 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).*

Approval duration: 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
MCC: Merkel 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
Cisplatin-, oxaliplatin- (Eloxatin®), or carboplatin-based combination chemotherapy.	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.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MCC	10 mg/kg administered as an IV infusion every 2 weeks until disease progression or unacceptable toxicity.	10 mg/kg every 2 weeks
UC		

VI. Product Availability

Injection: 200 mg/10 mL (20 mg/mL) solution in single-dose vial

VII. References

1. Bavencio Prescribing Information. Rockland, MA: EMD Serono, Inc.; June 2017. Available at: https://www.bavencio.com/. Accessed November 2017.
2. Avelumab. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed November 2017.
3. Merkel cell carcinoma (Version 1.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed November 2017.
4. Bladder cancer (Version 5.2017) In: National Comprehensive Cancer Network. Available at: www.nccn.org. Accessed November 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.01.17	04.17
Converted to new template. Urothelial carcinoma added as labeled indication. Re-auth: removed max dose requirement and modified approval duration from 6 to 12 months.	06.01.17	07.17
1Q18 annual review: - Specialist added to MCC and UC. - Age added to MCC. - Dose added to UC;	11.20.17	02.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
-"Locally advanced or metastatic" removed given inclusion of criteria requiring progression following platinum-based chemotherapy - NCCN bladder cancer use delineating "as a single agent" removed. - References reviewed and updated.		

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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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 the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.