Clinical Policy: Avelumab (Bavencio)

Reference Number: CP. PHAR.333
Effective Date: 05/17
Last Review Date: 07/17
Line of Business: Medicaid

Revision Log

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

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. Dose does not exceed 10mg/kg every two weeks.

Approval duration: 6 months

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

1. Diagnosis of UC;
2. Meets a or b:
   a. FDA approved use: disease is locally advanced or metastatic and (a or b):
      i. has progressed during or following platinum-containing chemotherapy;

ii. has progressed within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy;

b. Off-label NCCN recommended: prescribed as a single agent for disease recurrence post cystectomy.

Approval duration: 6 months

C. Other diagnoses/indications:

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy (e.g., no disease progression and no unacceptable toxicity).

Approval duration: 12 months

B. Other diagnoses/indications (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.PHAR.57 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.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
IV: intravenous
MCC: Merkel cell carcinoma
UC: urothelial carcinoma

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MCC	10 mg/kg administered as an intravenous (IV) infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity	10 mg/kg IV 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.; May 2017. Available at: https://www.bavencio.com/. Accessed May 26, 2017.
2. Kaufman HL, Russell J, Hamid O, et al. Avelumab in patients with chemotherapy-refractory metastatic Merkel cell carcinoma: a multicentre, single-group, open-label, phase 2 trial. Lancet Oncol 2016; 17:1374.
3. Tothill R, Estall V, Rischin D. Merkel cell carcinoma: emerging biology, current approaches, and future directions. Am Soc Clin Oncol Educ Book 2015; e519.
4. Merkel cell carcinoma (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed April 5, 2017.
5. National Comprehensive Cancer Network. Bladder Cancer Version 5.2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed May 26, 2017.
6. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 26, 2017.

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created	04/17	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.	06/17	07/17

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.