Clinical Policy: Avelumab (Bavencio)

Reference Number: PA.CP. PHAR.333
Effective Date: 01/18
Last Review Date: 07/18
Line of Business: Medicaid

Revision Log

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 Pennsylvania Health and Wellness® 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 10mg/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
Approval duration: 6 months

C. Other diagnoses/indications:

1. Refer to PA.CP.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to CP.PMN.53

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 – PA.CP.PMN.53 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.; 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	Approval Date
Specialist added to MCC and UC. Age added to MCC. Dose added to UC; "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.	02/18.09	