Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2021**
Policy Number: PA.CP.PHAR.333	**Effective Date: 01/01/2018** **Revision Date: 01/2021**
Policy Name: Avelumab (Bavencio)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

1Q 2021 annual review: for UC, recurrent disease added per NCCN, and platinum-based chemotherapy history added per label and NCCN; gestational trophoblastic neoplasia off-label use added per NCCN; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Avelumab (Bavencio)

Reference Number: PA.CP. PHAR.333
Effective Date: 01/2018
Last Review Date: 01/2021 Revision Log

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

FDA approved indication
Bavencio is indicated for:

- 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.
- 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).

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. Request meets one of the following (a or b):
   a. Dose does not exceed 800 mg 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).*

Approval duration: 6 months

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

1. Diagnosis of recurrent, advanced or metastatic UC;
2. Prescribed by or in consultation with an oncologist;

3. Age ≥ 18 years;
4. Indicated for one of the following (a, b, or c):
   a. Maintenance treatment where disease has not progressed with first-line platinum-containing chemotherapy;
   b. Treatment where disease has progressed during or following platinum-containing chemotherapy;
   c. Treatment where disease has progressed within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 800 mg 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).*

Approval duration: 6 months

C. Renal Cell Carcinoma (must meet all)**:**
1. Diagnosis of advanced RCC (e.g., relapse or stage IV disease);
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 is required for Inlyta*
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg 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).*

Approval duration: 6 months

D. Gestational Trophoblastic Neoplasia (off-label) (must meet all)**:**
1. Diagnosis of gestational trophoblastic neoplasia;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 12 years;
4. Prescribed as a single agent following failure of ≥ 2 systemic chemotherapeutic agents (*Appendix B*);
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg 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:
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. 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 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 (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 PA.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
MCC: Merkel cell carcinoma
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
Examples of systemic chemotherapeutic agents: bleomycin, carboplatin, cyclophosphamide, dactinomycin, etoposide, gemcitabine, ifosfamide, mesna, methotrexate, placlitaxel, vincristine.	**Gestational Trophoblastic Neoplasia** 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.; June 2020. Available at: https://www.bavencio.com/. Accessed November 6, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed November 6, 2020.
3. National Comprehensive Cancer Network. Merkel Cell Carcinoma Version 1.2020. Available at www.nccn.org. Accessed November 6, 2020.
4. National Comprehensive Cancer Network. Bladder Cancer Version 6.2020. Available at: www.nccn.org. Accessed November 6, 2020.
5. National Comprehensive Cancer Network. Kidney Cancer Version 2.2020. Available at www.nccn.org. Accessed November 6, 2020.
6. National Comprehensive Cancer Network. Gestational Trophoblastic Neoplasia Version 3.2020 Available at www.nccn.org. Accessed November 6, 2020.

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	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	
1Q 2019 annual review: age added to UC; reference to bladder cancer as off-label use is removed from the UC criteria set as it and other cancers are included under UC histology; references reviewed and updated.	01/19	

Reviews, Revisions, and Approvals	Date	Approval Date
1Q 2020 annual review: age added to UC; criteria added for new FDA-approved indication for RCC; max dose clarified to 800 mg every 2 weeks; references reviewed and updated.	01/2020	
1Q 2021 annual review: for UC, recurrent disease added per NCCN, and platinum-based chemotherapy history added per label and NCCN; gestational trophoblastic neoplasia off-label use added per NCCN; references reviewed and updated.	01/2021	