Clinical Policy: Avelumab (Bavencio)

Reference Number: CP.PHAR.333
Effective Date: 05.01.17
Last Review Date: 02.19
Line of Business: Medicaid, HIM-Medical Benefit

Coding Implications
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(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.
- For use in combination with axitinib for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

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 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. 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 UC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease progression during or following 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;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed 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. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid and HIM-Medical Benefit.

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 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 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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid and HIM-Medical Benefit.

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 policies – CP.PMN.53 for Medicaid and HIM-Medical Benefit or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
MCC: Merkel cell carcinoma
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
Cisplatin-, oxaliplatin- (Eloxatin®) or carboplatin-containing 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.

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.; May 2019. Available at: https://www.bavencio.com/. Accessed May 29, 2019.
2. Avelumab. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 29, 2019.

3. Merkel cell carcinoma (Version 1.2019). National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed September 27, 2018.
4. Bladder cancer (Version 5.2018) National Comprehensive Cancer Network. Available at: www.nccn.org. Accessed September 2018.
5. Kidney Cancer (Version 4.2019) National Comprehensive Cancer Network. Available at www.nccn.org. Accessed May 29, 2019.

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	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; -"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.	11.20.17	02.18
1Q 2019 annual review; HIM Medical-Benefit line of business added; no significant changes from previously approved corporate policy; 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.	11.13.18	02.19
RT4: criteria added for new FDA-approved indication for RCC; references reviewed and updated.	05.29.19	

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.

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.