Bavencio (avelumab)
PAM – 026

Iowa Medicaid Program	Prior Authorization	**Effective Date**	10/20/2017
Revision Number	7	**Last Reviewed**	10/17/2025
Reviewed By	Medicaid Medical Director	**Next Review**	10/16/2026
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	11/27/2017

Overview

Medication: [1]	avelumab
Brand Name:	Bavencio®
Pharmacologic Category:	Antineoplastic; Immune Checkpoint Inhibitor; Programmed death ligand-1 (PD-L1) blocking antibody
FDA-Approved Indication(s): **1. Metastatic Merkel Cell Carcinoma (MCC)** a) Adults and pediatric patients 12 years and older with metastatic MCC **2. Locally Advanced or Metastatic Urothelial Carcinoma (UC)** a) First-line maintenance treatment of UC i. Maintenance treatment of patients with locally advanced or metastatic UC that has not progressed with first-line platinum-containing chemotherapy b) Previously-treated UC i. Patients with locally advanced or metastatic UC who: 1. Have disease progression during or following platinum-containing chemotherapy 2. Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy **3. Advanced Renal cell carcinoma (RCC)** a) First-line treatment, in combination with axitinib, of patients with advanced RCC	
How Supplied:	Single-dose vial, 200 mg/10 mL (20 mg/mL)
Dosage and Administration:	Administer via intravenous (IV) infusion: 1. MCC: 800 mg every 2 weeks until disease progression or unacceptable toxicity 2. UC: 800 mg every 2 weeks until disease progression or unacceptable toxicity 3. RCC: 800 mg every 2 weeks (in combination with axitinib) until disease progression or unacceptable toxicity
Benefit Category:	Medical

Descriptive Narrative

Merkel cell carcinoma (MCC) is a rare, aggressive, cutaneous malignancy which has a high propensity for recurrence and metastases. Patients typically present with a rapidly growing, painless, firm, nontender, shiny, flesh-colored or bluish-red, intracutaneous nodule commonly located in the head and neck region. MCC is often clinically misdiagnosed as a benign lesion (e.g., cyst, lipoma, pyogenic granuloma). Recognized risk factors for MCC include light skin color, increasing age, male sex, immunosuppression, and other malignancies.

Data from the Surveillance, Epidemiology, and End Results (SEER) Program database indicate that in the United States, the estimated annual incidence rate rose from 0.5 cases per 100,000 persons in 2000 to 0.7 cases per 100,000 persons in 2013. MCC incidence increases exponentially with advancing age, from 0.1 to 1 to 9.8 (per 100,000 person-years) among age groups 40 to 44, 60 to 64, and > 85 years, respectively. Due to aging of the population, the United States' MCC incidence is predicted to climb to more than 3,200 cases in 2025.[2]

Bladder cancer is the most common malignancy involving the urinary system. Urothelial (transitional cell) carcinoma is the predominant histologic type in the United States.[3] In 2024, the United States is expected to see 83,190 new cases of bladder cancer with an estimated 16,840 deaths.[4] About 90 percent of patients with bladder cancer are over the age of 55 years, with an average age of 73 years at the time of diagnosis. Overall, the chance that men will develop this cancer in their lifetime is about 1 in 28 men. For women, the chance is about 1 in 89. Urothelial cancer is strongly associated with smoking and increased dietary fat. Because these are also factors that predispose to other medical conditions, including cardiovascular, cerebrovascular, and pulmonary disease, patients with urothelial cancer often have significant comorbidities.[5]

Renal cell carcinomas (RCCs), which originate within the renal cortex, are responsible for 80 to 85 percent of all primary renal neoplasms. In the United States, there are approximately 82,000 new cases and almost 15,000 deaths from RCC each year. RCC occurs predominantly in the sixth to eighth decade of life, with median age at diagnosis of 64 years. RCC is approximately twofold more common in males compared with females.

Established risk factors for development of renal cell carcinoma include cigarette smoking, hypertension, obesity, acquired cystic disease of the kidney and chronic kidney disease, genetic factors, chronic hepatitis C infection, sickle cell disease, and kidney stones. Occupational exposure (i.e., exposure to toxic compounds), prolonged, heavy ingestion of analgesics, and the use of cytotoxic chemotherapy are also considered established risk factors.[6]

Guidelines

The National Comprehensive Cancer Network (NCCN) publishes guidelines for the prevention, diagnosis, and management of malignancies across the continuum of care. The NCCN Guidelines® are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to 97 percent of cancers affecting patients in the United States. The guidelines are developed and updated by 61 individual panels, comprising over 1,700 clinicians and oncology researchers from the 33 NCCN Member Institutions.

Guidelines are reviewed and updated on a continual basis to ensure that the recommendations take into account the most current evidence. To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.[7,8]

The information referenced at the time of this policy writing/revision is from the NCCN Guidelines® for (note version number and effective date):[9]

- Merkel Cell Carcinoma (v.1.2024 – November 22, 2023)
- Bladder Cancer (v.4.2024 – May 9, 2024)
- Kidney Cancer (v.2.2025 – September 6, 2024)

NCCN Guidelines® Recommendation(s) – Merkel Cell Carcinoma (MCC)

Principles of Systemic Therapy [a, b]
(1) Local Disease N0
  a. For primary disease, adjuvant systemic therapy is not recommended outside of a clinical trial.
  b. Primary locally advanced (if curative surgery and curative RT not feasible)
    i. Avelumab: Category 2A, Preferred Regimen
  c. Recurrent locally advanced (if curative surgery and curative RT not feasible)
    i. Avelumab: Category 2A, Other Recommended Regimen
(2) Regional Disease N+ [c]
  a. Recurrent regional disease (if curative surgery and curative RT not feasible)
    i. Avelumab: Category 2A, Other Recommended Regimen
(3) Disseminated Disease M1
  a. Avelumab: Category 2A, Other Recommended Regimen

[a] When available and clinically appropriate, enrollment in a clinical trial is recommended.
[b] Data from non-randomized trials in patients with MCC demonstrate that rates of durable response are improved with PD-1/PD-L1 blockade compared with cytotoxic therapy. The safety profiles for checkpoint immunotherapies are significantly different from cytotoxic therapies. Consult prescribing information for recommendations on detection and management of immune-related adverse events associated with checkpoint immunotherapies. Clinician and patient education is critical for safe administration of checkpoint immunotherapies.
[c] For regional disease, adjuvant chemotherapy is not routinely recommended as survival benefit has not been demonstrated in available retrospective studies but could be used on a case-by-case basis if clinical judgement dictates. No data are available to support the adjuvant use of immunotherapy outside of a clinical trial.

NCCN Guidelines® Recommendation(s) – Bladder Cancer

Principles of Systemic Therapy

- The presence of both non-nodal metastases and ECOG performance score ≥2 strongly predict poor outcome with chemotherapy. Patients without these adverse prognostic factors have the greatest benefit from chemotherapy. The impact of these factors in relation to immune checkpoint inhibition is not fully defined, but they remain poor prognostic indicators in general.
- For most patients, the risks of adding paclitaxel to gemcitabine and cisplatin outweigh the limited benefit seen in the randomized trial.
- A substantial proportion of patients cannot receive cisplatin-based chemotherapy due to renal impairment or other comorbidities (participation in clinical trials of new or more tolerable therapy is recommended).

(1) First-line systemic therapy for locally advanced or metastatic disease (Stage IV)
  a. Cisplatin eligible
    i. Gemcitabine and cisplatin (Category 1) followed by avelumab maintenance therapy (Category 1) [a] – Other Recommended Regimen
    ii. ddMVAC with growth factor support (Category 1) followed by avelumab maintenance therapy (Category 1) [a] – Useful in Certain Circumstances
  b. Cisplatin ineligible
    i. Gemcitabine and cisplatin (Category 1) followed by avelumab maintenance therapy (Category 1) [a] – Other Recommended Regimen

(2) Second-line systemic therapy for locally advanced or metastatic disease (Stage IV) (post-platinum or other chemotherapy) [b]
  a. Participation in clinical trials is recommended.
  b. Avelumab: Category 2A, Alternative Preferred Regimen

ddMVAC = dose-dense methotrexate, vinblastine, doxorubicin, and cisplatin

[a] Maintenance therapy with avelumab only if there is no progression on first-line platinum-containing chemotherapy.

[b] If progression-free survival >12 months after platinum (e.g., cisplatin or carboplatin), consider re-treatment with platinum if the patient is still platinum eligible.

NCCN Guidelines® Recommendation(s) – Kidney Cancer

Principles of Systemic Therapy in Kidney Cancer
– Stage IV (M1 or Unresectable T4, M0) or Relapsed Disease

(1) First-line therapy for clear cell histology [a]
  a. Favorable risk – axitinib + avelumab: Category 2A, Other Recommended Regimen
  b. Poor/intermediate risk – axitinib + avelumab: Category 2A, Other Recommended Regimen

(2) Subsequent therapy for clear cell histology [b]
  a. IO Therapy naïve – axitinib + avelumab: Category 3, Useful in Certain Circumstances [c]
  b. Prior IO therapy – axitinib + avelumab: Category 3, Useful in Certain Circumstances [c]

[a] Divided according to risk, from *Risk Models to Direct Treatment* [Memorial Sloan Kettering Cancer Center (MSKCC) Prognostic Model]

[b] Divided according to Immuno-oncology (IO) Therapy History Status

[c] **NOTE:** Category 3 indicates that based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate. Therapy listed here for informational purposes only.

NCCN Categories of Evidence and Consensus (all recommendations are category 2A unless otherwise indicated)	
Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

NCCN Categories of Preference (all recommendations are considered appropriate)	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for select patient populations (defined with recommendation).

Eastern Cooperative Oncology Group (ECOG) Performance Status Scale [10]

Developed by the Eastern Cooperative Oncology Group (ECOG), now part of the ECOG-ACRIN Cancer Research Group, and published in 1982, the ECOG Performance Status Scale describes a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). It is used by doctors and researchers to assess how a patient's disease is progressing, how the disease affects the daily living abilities of the patient, and to determine appropriate treatment and prognosis.

Grade	**ECOG Performance Status** **[Synonyms: WHO/Zubrod score]**
0	Fully active, able to carry on all pre-disease performance without restriction.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.
2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours.
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours.
4	Completely disabled; cannot carry on any self-care; totally confined to bed or chair.
5	Dead.

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Criteria

Prior authorization is required.

Merkel Cell Carcinoma (MCC) – Initial Approval Criteria

Bavencio® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of metastatic Merkel cell carcinoma (MCC); **AND**
2. Member is 12 years of age or older; **AND**
3. Member does not have an active or history of an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant; **AND**
4. Member has not had a prior organ or allogeneic stem cell transplant; **AND**
5. Member does not have significant acute or chronic infection; **AND**
6. Member does not have active or history of central nervous system (CNS) metastases; **AND**
7. Member has not been previously treated with anti-PD-1 (programmed death receptor-1), anti-PD-L1 (programmed death ligand-1), or anti-CTLA-4 (cytotoxic T-lymphocyte antigen 4) antibodies; **AND**
8. Member has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; **AND**
9. Prescribed by, or in consultation with, a hematologist or oncologist; **AND**
10. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 800 mg every 2 weeks; or,
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

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Urothelial Carcinoma (UC) – Initial Approval Criteria

Bavencio® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of recurrent, advanced, or metastatic urothelial carcinoma; **AND**
2. Member has received prior treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin) and meets **ONE** of the following (a, b, or c):
    a. Is using Bavencio® as subsequent therapy after disease progression during or following the platinum-containing regimen; or
    b. Is using Bavencio® as maintenance therapy following completion of the platinum-containing regimen with no evidence or disease progression; or
    c. Has confirmed disease progression within 12 months of receiving neoadjuvant or adjuvant treatment with platinum-containing regimen; **AND**
3. Member is 18 years of age or older; **AND**
4. Member does not have an active or history of an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant; **AND**
5. Member has not had a prior organ or allogeneic stem cell transplant; **AND**
6. Member does not have significant acute or chronic infection; **AND**
7. Member does not have active or history of central nervous system (CNS) metastases; **AND**
8. Member has not been previously treated with anti-PD-1 (programmed death receptor-1), anti-PD-L1 (programmed death ligand-1), or anti-CTLA-4 (cytotoxic T-lymphocyte antigen 4) antibodies; **AND**
9. Member has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; **AND**
10. Prescribed by, or in consultation with, a hematologist or oncologist; **AND**
11. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 800 mg every 2 weeks; or,
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Renal Cell Carcinoma (RCC) – Initial Approval Criteria

Bavencio® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of advanced renal cell carcinoma (RCC) (histological confirmation with clear cell component; **AND**
2. Member is using as first-line therapy in combination with axitinib; **AND**
3. Member is 18 years of age or older; **AND**
4. Member does not have an active or history of an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant; **AND**
5. Member does not have newly diagnosed or active brain metastases; **AND**
6. Member has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; **AND**
7. Prescribed by, or in consultation with, a hematologist or oncologist; **AND**
8. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 800 mg every 2 weeks; or,
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Continuation Criteria (all above indications)

Bavencio® is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy, as demonstrated by tumor response or lack of disease progression, and an acceptable toxicity profile; **AND**
3. Prescribed by, or in consultation with, a hematologist or oncologist; **AND**
4. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 800 mg every 2 weeks (until disease progression or unacceptable toxicity); or,
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	6 months	12 months
Quantity Limits	800 mg every 2 weeks	800 mg every 2 weeks until disease progression or unacceptable toxicity

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J9023	Injection, avelumab, 10 mg

ICD-10	Description
C4A.0 – C4A.9	Merkel cell carcinoma
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1, C65.2, C65.9	Malignant neoplasm of renal pelvis
C66.1, C66.2, C66.9	Malignant neoplasm of ureter
C67.0 – C67.9	Malignant neoplasm of bladder
C68.0	Malignant neoplasm of urethra

NDC (Strength)	Labeler	Dosage	Pkg Size	Pkg Qty	Units/ Pkg
44087-3535-01 (200 mg/10 mL)	EMD Serono, Inc. (44087)	10 mg	1	EA	20

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government

agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Bavencio® prescribing information (06/2025). EMD Serono, Inc.: Rockland, MA. Available online: www.bavencio.com/hcp. Accessed August 12, 2025.

[2] Tai P, Nghiem PT, Park SY. Pathogenesis, clinical features, and diagnosis of Merkel cell (neuroendocrine) carcinoma. Corona R, Yushak M, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed September 7, 2024.

[3] Bellmunt J, Valderrama BP. Treatment of metastatic urothelial cancer of the bladder and urinary tract. Shah SM, ed. UptoDate. Walthman, MA: UptoDate Inc. www.uptodate.com. Accessed September 7, 2024.

[4] SEER Cancer Stat Facts: Bladder Cancer. National Cancer Institute. Bethesda, MD. Available online at seer.cancer.gov. Accessed September 7, 2024.

[5] American Cancer Society. Key Statistics for Bladder Cancer. Available online at seer.cancer.gov/statfacts/html/urinb.html. Accessed September 7, 2024.

[6] Atkins MB, Bakouny Z, Choueiri TK. Epidemiology, pathology, and pathogenesis of renal cell carcinoma. Shah SM, ed. UptoDate. Walthman, MA: UptoDate Inc. www.uptodate.com. Accessed September 7, 2024.

[7] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[8] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[9] NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version, go online to NCCN.org. NCCN Guidelines® referenced (note version number and effective date):

- Merkel Cell Carcinoma (v.1.2024 – November 22, 2023)
- Bladder Cancer (v.4.2024 – May 9, 2024)
- Kidney Cancer (v.2.2025 – September 6, 2024)

[10] Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655. PMID 7165009.

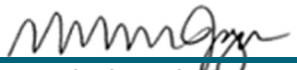
Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

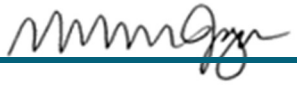
Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
10/17/2025	CAC	Annual review. No changes to dosing or administration.	7
Signature			

Change Date	Changed By	Description of Change	Version
10/18/2024	CAC	Annual review. Reviewed and updated NCCN Guidelines®. Updated references where applicable.	6
Signature William (Bill) Jagiello, DO			

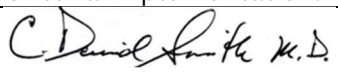
Change Date	Changed By	Description of Change	Version
10/20/2023	CAC	Annual review. Removed “Accelerated Approval” information from Overview table regarding MCC indication (full FDA approval received effective 9/6/2023). Updated statistics in Descriptive Overview. Updated NCCN Guidelines. Added dosing into the criteria.	5
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
10/21/2022	CAC	Annual review. Updated annual cancer statistics where applicable, as well as NCCN guideline references (no changes to actual guidelines noted).	4
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
10/15/2021	CAC	Annual review.	3
Signature William (Bill) Jagiello, DO			

Criteria Change History *(continued)*

Change Date	Changed By	Description of Change	Version
10/18/2019	CAC	Added “or renal cell carcinoma” to criteria 1.	2
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
10/19/2017	CAC	Criteria implementation.	1
Signature C. David Smith			

CAC = Medicaid Clinical Advisory Committee