Bavencio (avelumab)
PAM – 026

Iowa Medicaid Program	Prior Authorization	**Effective Date**	10/20/2017
Revision Number	8	**Last Reviewed**	10/16/2026
Reviewed By	Medicaid Medical Director	**Next Review**	10/15/2027
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 2026, the United States is expected to see 84,530 new cases of bladder cancer with an estimated 17,870 deaths. 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.[4]

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 80,500 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.[5]

Guidelines

The National Comprehensive Cancer Network (NCCN)
Clinical Practice Guidelines in Oncology document evidence-based, consensus-driven management to ensure that all patients receive preventive, diagnostic, treatment, and supportive services that are most likely to lead to optimal outcomes. The guidelines are developed and updated by 63 individual panels, comprising over 1,900 clinicians and oncology researchers from the 33 NCCN Member Institutions. The categories for recommendations are based on both the level of clinical evidence available and the degree of consensus within the NCCN Guidelines Panel.

The library of NCCN Guidelines® currently apply to more than 97 percent of people living with cancer or anyone at risk for a diagnosis of cancer in the United States. The guidelines incorporate real-time updates in keeping with the rapid advancements in the field of cancer research and management and are intended to assist all individuals who impact decision-making in cancer care, including physicians, nurses, pharmacists, payers, patients and their families, and others.

The NCCN Guidelines® provide recommendations based on the best evidence available at the time they are derived. Because new data are published continuously, it is essential that the NCCN Guidelines also be continuously updated and revised* to reflect new data and clinical information that may add to or alter current clinical practice standards.[6,7]

The information referenced at the time of this policy writing/revision (note version number and effective date) is from the NCCN Guidelines® for:[8]

- Merkel Cell Carcinoma (v.2.2026 – October 24, 2025)
- Bladder Cancer (v.3.2026 – August 6, 2026)
- Kidney Cancer (v.1.2027 – July 1, 2026)

Eastern Cooperative Oncology Group (ECOG) Performance Status Scale [9]

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.

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.

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. Bavencio® is used 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 July 28, 2026.

[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 July 28, 2026.

[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 July 28, 2026.

[4] SEER Cancer Stat Facts: Bladder Cancer. National Cancer Institute. Bethesda, MD. Available online at seer.cancer.gov/statfacts/html/urinb.html. Accessed July 28, 2026.

[5] Atkins MB, Bakouny ZE, Choueiri TK. Epidemiology, pathology, and pathogenesis of renal cell carcinoma. Shah SM, ed. UptoDate. Walthman, MA: UptoDate Inc. www.uptodate.com. Accessed July 28, 2026.

[6] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

[7] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

[8] NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are continuously updated and revised to reflect new data and clinical information that may add to or alter current clinical practice standards. To view the most recent and complete version, go online to NCCN.org. NCCN Guidelines® referenced at time of this revision (note version number and effective date):

- Merkel Cell Carcinoma (v.2.2026 – October 24, 2025)
- Bladder Cancer (v.3.2026 – August 6, 2026)
- Kidney Cancer (v.1.2027 – July 1, 2026)

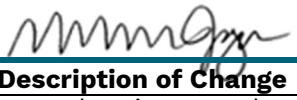
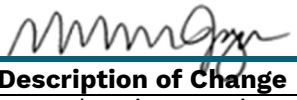
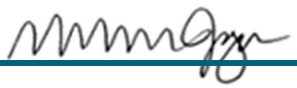
[9] Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655. PMID 7165009.

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.

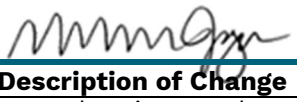
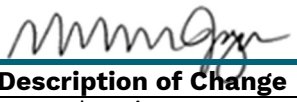
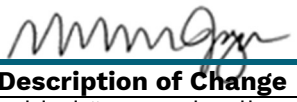
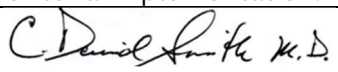
Criteria Change History

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
10/16/2026	CAC	Annual review. Updated SEER statistics data for bladder cancer and renal cell cancer. Updated references. Policy format update: Removed current NCCN Guidelines recommendations, as guidelines may change more frequently than the review cadence of this document. Will continue to reference NCCN when writing criteria, and include the specific version referenced at the time of the policy writing/revision.	8
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
10/17/2025	CAC	Annual review. No changes to dosing or administration.	7
Signature William (Bill) Jagiello, DO			
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			

Criteria Change History *(continued)*

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			
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