

Bavencio[®] (avelumab) (Intravenous)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 80 billable units (800 mg) every 14 days (all indications)

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age, unless otherwise indicated; **AND**

Universal Criteria

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, dostarlimab, atezolizumab, durvalumab, cemiplimab, nivolumab/relatlimab, retifanlimab, tislelizumab, toripalimab, etc.), unless otherwise specified ^A; **AND**

Merkel Cell Carcinoma (MCC) † ‡ Φ ^{1,2,4,5,1e,2e}

- Patient is at least 12 years of age; **AND**
- Used as single-agent therapy; **AND**
 - Patient has primary locally advanced disease † Ω; **AND**
 - Both curative surgery and curative radiation therapy are not feasible; **OR**
 - Patient has had disease progression on neoadjuvant nivolumab therapy; **OR**
 - Patient has distant metastatic disease

Urothelial Carcinoma (Bladder Cancer) † ‡ ^{1,4,6,8,16}

- Used as single-agent therapy; **AND**

- Patient has one of the following diagnoses:
 - Locally advanced or metastatic urothelial carcinoma †
 - Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder treated with curative intent ‡
 - Metastatic or local bladder cancer recurrence post cystectomy treated with curative intent ‡
 - Metastatic upper genitourinary (GU) tract tumors ‡
 - Metastatic urothelial carcinoma of the prostate ‡
 - Recurrent or metastatic primary carcinoma of the urethra (*excluding recurrence of clinical stage T3-4 disease or palpable inguinal lymph nodes*) ‡;

AND

 - Used for disease that progressed during or following platinum-containing chemotherapy*; **OR**
 - Used as second-line treatment after chemotherapy other than a platinum **Ω**; **OR**
- Used as first-line maintenance treatment †; **AND**
 - Patient has locally advanced or metastatic urothelial carcinoma (inclusive of bladder, upper GU tract, urethra, and/or prostate cancer); **AND**
 - Patient has not progressed with first-line platinum-containing chemotherapy

* **Note:** 6,17,20

- *If patient was progression-free for > 12 months after platinum therapy, consider re-treatment with platinum-based therapy if the patient is still platinum eligible (see below for cisplatin- or platinum-ineligible comorbidities).*
 - *Cisplatin-ineligible comorbidities may include the following: CrCl < 60 mL/min, ECOG PS ≥ 2 or KPS < 70%, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, or grade ≥ 2 peripheral neuropathy, or NYHA Heart Failure class ≥ 3. Carboplatin may be substituted for cisplatin particularly in those patients with a CrCl < 60 mL/min or an ECOG PS of 2.*
 - *Platinum-ineligible comorbidities may include the following: CrCl < 30 mL/min, ECOG PS ≥ 3, grade ≥ 2 peripheral neuropathy, or NYHA Heart Failure class > 3, etc.*

Renal Cell Carcinoma (RCC) † ‡ ^{1,4,9,14}

- Used in combination with axitinib; **AND**
- Used as first-line therapy; **AND**
- Used for the treatment of advanced, relapsed, or stage IV* disease and clear cell histology

*When used as first line therapy for stage IV disease, disease must be M1 or unresectable T4, M0.

Gestational Trophoblastic Neoplasia ‡ Ω ^{4,13,15}

- Used as single-agent therapy for multiagent chemotherapy-resistant disease; **AND**
 - Patient has intermediate placental site trophoblastic tumor (PSTT) or epithelioid trophoblastic tumor (ETT); **AND**

- Patient has recurrent or progressive disease; **OR**
- Patient has high-risk disease (i.e., prognostic score ≥ 7 or FIGO stage IV disease)

Extranodal NK/T-Cell Lymphomas ‡^{4,22}

- Used as a single agent; **AND**
- Used for relapsed or refractory disease following additional therapy with an alternate asparaginase-based combination chemotherapy regimen not previously used; **AND**
- Participation in a clinical trial is unavailable

Thymic Carcinomas ‡^{4,24}

- Used in combination with axitinib; **AND**
 - Patient is unable to tolerate first-line combination regimens **Ω**; **AND**
 - Used as preoperative systemic therapy for surgically resectable disease if R0 resection is considered uncertain; **OR**
 - Used as postoperative systemic therapy after R1 (microscopic residual tumor) or R2 (macroscopic residual tumor) resection; **OR**
 - Used as first-line therapy for recurrent, advanced, or metastatic disease; **OR**
 - Used as second-line therapy; **AND**
 - Patient has unresectable or metastatic disease; **AND**
 - Used for disease that progressed after platinum-based chemotherapy, unless contraindicated

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

Ω Please note that the supporting data for this indication has been assessed and deemed to be of insufficient quality based on the review conducted for the Enhanced Oncology Value (EOV) program. However, due to the absence of viable alternative treatment options, this indication will be retained in our policy and evaluated on a case-by-case basis.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); ◊ Orphan Drug

IV. Renewal Criteria ^{Δ 1}

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe or life-threatening infusion-related reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, hepatotoxicity/hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatitis/dermatologic adverse reactions, etc.), major adverse cardiovascular events (MACE), complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.

^Δ Notes:

- Patients whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate PD-directed therapy and will be evaluated on a case-by-case basis.

V. Dosage/Administration ^{1,13,18}

Indication	Dose
All indications	Administer 800 mg intravenously every 14 days, until disease progression or unacceptable toxicity
<p><u>Dosing should be calculated using actual body weight and not flat dosing (as applicable) based on the following:</u></p> <p>Weight is ≤ 66 kg:</p> <ul style="list-style-type: none"> • Use 600 mg (10mg/kg) IV every 2 weeks <p><i>Note: This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide. Patient-specific variables should be taken into account.</i></p>	

VI. Billing Code/Availability Information

HCPCS Code:

- J9023 – Injection, avelumab, 10 mg; 1 billable unit = 10 mg

NDC:

- Bavencio 200 mg/10 mL single-dose vial: 44087-3535-xx

VII. References (STANDARD)

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C37	Malignant neoplasm of thymus
C4A.0	Merkel cell carcinoma of lip
C4A.10	Merkel cell carcinoma of eyelid, including canthus
C4A.111	Merkel cell carcinoma of right upper eyelid, including canthus
C4A.112	Merkel cell carcinoma of right lower eyelid, including canthus
C4A.121	Merkel cell carcinoma of left upper eyelid, including canthus
C4A.122	Merkel cell carcinoma of left lower eyelid, including canthus
C4A.20	Merkel cell carcinoma of unspecified ear and external auricular canal
C4A.21	Merkel cell carcinoma of right ear and external auricular canal

ICD-10	ICD-10 Description
C4A.22	Merkel cell carcinoma of left ear and external auricular canal
C4A.30	Merkel cell carcinoma of unspecified part of face
C4A.31	Merkel cell carcinoma of nose
C4A.39	Merkel cell carcinoma of other parts of face
C4A.4	Merkel cell carcinoma of scalp and neck
C4A.51	Merkel cell carcinoma of anal skin
C4A.52	Merkel cell carcinoma of skin of breast
C4A.59	Merkel cell carcinoma of other part of trunk
C4A.60	Merkel cell carcinoma of unspecified upper limb, including shoulder
C4A.61	Merkel cell carcinoma of right upper limb, including shoulder
C4A.62	Merkel cell carcinoma of left upper limb, including shoulder
C4A.70	Merkel cell carcinoma of unspecified lower limb, including hip
C4A.71	Merkel cell carcinoma of right lower limb, including hip
C4A.72	Merkel cell carcinoma of left lower limb, including hip
C4A.8	Merkel cell carcinoma of overlapping sites
C4A.9	Merkel cell carcinoma, unspecified
C58	Malignant neoplasm of placenta
C61	Malignant neoplasm of prostate
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C66.1	Malignant neoplasm of right ureter
C66.2	Malignant neoplasm of left ureter
C66.9	Malignant neoplasm of unspecified ureter
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified

ICD-10	ICD-10 Description
C68.0	Malignant neoplasm of urethra
C7B.1	Secondary Merkel cell carcinoma
C84.90	Mature T/NK-cell lymphomas, unspecified, unspecified site
C84.91	Mature T/NK-cell lymphomas, unspecified, lymph nodes of head, face, and neck
C84.92	Mature T/NK-cell lymphomas, unspecified, intrathoracic lymph nodes
C84.93	Mature T/NK-cell lymphomas, unspecified, intra-abdominal lymph nodes
C84.94	Mature T/NK-cell lymphomas, unspecified, lymph nodes of axilla and upper limb
C84.95	Mature T/NK-cell lymphomas, unspecified, lymph nodes of inguinal region and lower limb
C84.96	Mature T/NK-cell lymphomas, unspecified, intrapelvic lymph nodes
C84.97	Mature T/NK-cell lymphomas, unspecified, spleen
C84.98	Mature T/NK-cell lymphomas, unspecified, lymph nodes of multiple sites
C84.99	Mature T/NK-cell lymphomas, unspecified, extranodal and solid organ sites
C84.Z0	Other mature T/NK-cell lymphomas, unspecified site
C84.Z1	Other mature T/NK-cell lymphomas, lymph nodes of head, face, and neck
C84.Z2	Other mature T/NK-cell lymphomas, intrathoracic lymph nodes
C84.Z3	Other mature T/NK-cell lymphomas, intra-abdominal lymph nodes
C84.Z4	Other mature T/NK-cell lymphomas, lymph nodes of axilla and upper limb
C84.Z5	Other mature T/NK-cell lymphomas, lymph nodes of inguinal region and lower limb
C84.Z6	Other mature T/NK-cell lymphomas, intrapelvic lymph nodes
C84.Z7	Other mature T/NK-cell lymphomas, spleen
C84.Z8	Other mature T/NK-cell lymphomas, lymph nodes of multiple sites
C84.Z9	Other mature T/NK-cell lymphomas, extranodal and solid organ sites
C86.00	Extranodal NK/T-cell lymphoma, nasal type not having achieved remission
D09.0	Carcinoma in situ of bladder
D15.0	Benign neoplasm of thymus
D38.4	Neoplasm of uncertain behavior of thymus
D39.2	Neoplasm of uncertain behavior of placenta
O01.9	Hydatidiform mole, unspecified
Z85.238	Personal history of other malignant neoplasm of thymus
Z85.51	Personal history of malignant neoplasm of bladder
Z85.59	Personal history of malignant neoplasm of other urinary tract organ
Z85.821	Personal history of Merkel cell carcinoma

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local

Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC