

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

A. Quantity Limit (max daily dose) [NDC Unit]:

- Bavencio 200 mg/10 mL single-dose vial: 4 vials per 14 days

B. 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, etc.), unless otherwise specified; **AND**

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

- Patient is at least 12 years of age; **AND**
- Used as single-agent therapy; **AND**
- Patient has metastatic or recurrent disseminated 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
 - Metastatic or local bladder cancer recurrence post-cystectomy
 - Metastatic upper genitourinary (GU) tract tumors
 - Metastatic urothelial carcinoma of the prostate
 - Recurrent or metastatic primary carcinoma of the urethra (*excluding recurrence of 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; **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:* 6,7,17,20

- *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, PS ≥ 2, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, grade ≥ 2 peripheral neuropathy, or NYHA class ≥ 3. Carboplatin may be substituted for cisplatin particularly in those patients with a CrCl < 60 mL/min or a PS of 2.*
 - *Platinum-ineligible comorbidities may include the following: CrCl < 30 mL/min, PS ≥ 3, grade ≥ 2 peripheral neuropathy, or NYHA 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

Gestational Trophoblastic Neoplasia ‡ 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; **AND**
 - Patient was previously treated with a platinum-based regimen; **OR**
 - Patient has high-risk disease (i.e., prognostic score ≥ 7 or FIGO stage IV disease)

Endometrial Carcinoma (Uterine Neoplasms) ‡ 4,18

- Used as single-agent therapy; **AND**
- Patient has recurrent or metastatic disease; **AND**
- Used as second-line treatment for microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors

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

IV. Renewal Criteria ^{1,2}

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, hepatotoxicity, severe and fatal immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatitis/dermatologic adverse reactions, etc.), major adverse cardiovascular events (MACE) when used in combination with axitinib, complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.

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><u>Weight > 60 kg:</u></p> <ul style="list-style-type: none"> • Standard dose 800 mg IV every 2 weeks <p><u>Weight is ≤ 60kg:</u></p> <ul style="list-style-type: none"> • Use 600 mg 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

1. Bavencio [package insert]. Rockland, MA; EMD Serono, Inc; July 2022. Accessed July 2022.
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3. Novakovic AM, Wilkins JJ, Dai H, et al. Changing body weight-based dosing to a flat dose for avelumab in metastatic Merkel cell and advanced urothelial carcinoma. *Clin Pharmacol Ther.* 2019 Sep 25.
4. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) avelumab. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed July 2022.
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Merkel Cell Carcinoma. Version 2.2022. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed July 2022.
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Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|---------|---|
| 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 |
| 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 |
| C54.0 | Malignant neoplasm of isthmus uteri |
| C54.1 | Malignant neoplasm of endometrium |
| C54.2 | Malignant neoplasm of myometrium |
| C54.3 | Malignant neoplasm of fundus uteri |
| C54.8 | Malignant neoplasm of overlapping sites of corpus uteri |

| ICD-10 | ICD-10 Description |
|---------|---|
| C54.9 | Malignant neoplasm of corpus uteri, unspecified |
| C55 | Malignant neoplasm of uterus, part 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 |
| C68.0 | Malignant neoplasm of urethra |
| C7B.1 | Secondary Merkel cell carcinoma |
| D09.0 | Carcinoma in situ of bladder |
| D39.2 | Neoplasm of uncertain behavior of placenta |
| O01.9 | Hydatidiform mole, unspecified |
| 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)

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at:

<https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered 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, LLC |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA, LLC |
| 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 |