

## Bavencio<sup>®</sup> (avelumab) (Intravenous)

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### I. Length of Authorization

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

### II. Dosing Limits

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

- Bavencio 200 mg single-use vial: 4 vials per 14 days

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

- 80 billable units every 14 days (all indications)

### III. Initial Approval Criteria<sup>1</sup>

Coverage is provided in the following conditions:

#### Universal Criteria

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

#### Merkel Cell Carcinoma (MCC) † ⊕<sup>1,2,4,5</sup>

- Patient is at least 12 years of age; **AND**
- Used as a single agent; **AND**
- Patient has metastatic disease

#### Bladder Cancer/Urothelial Carcinoma †<sup>1,4,6,8</sup>

- Patient is at least 18 years of age; **AND**
- Used as a single agent; **AND**
- Used as subsequent therapy after previous platinum treatment\*; **AND**
  - Patient has a diagnosis of one of the following:
    - Locally advanced or metastatic urothelial carcinoma; **OR**

- Local bladder cancer recurrence or persistent disease in a preserved bladder; **OR**
- Local or metastatic bladder cancer recurrence post-cystectomy; **OR**
- Metastatic upper genitourinary (GU) tract tumors; **OR**
- Metastatic urothelial carcinoma of the prostate; **OR**
- Recurrent or metastatic primary carcinoma of the urethra; **AND**
  - Patient does not have recurrence of stage T3-4 disease or palpable inguinal lymph nodes; **OR**
- Used as first-line maintenance treatment; **AND**
  - Patient has locally advanced or metastatic urothelial carcinoma; **AND**
  - Patient has not progressed with first-line platinum-containing chemotherapy; **AND**
  - Treatment will be initiated within 4 – 10 weeks after the last dose of chemotherapy

**\* Note:**

- If platinum treatment occurred greater than 12 months ago, the patient should be re-treated with platinum-based therapy if the patient is still platinum eligible (see below for cisplatin- or carboplatin-ineligible comorbidities).
  - Cisplatin-ineligible comorbidities may include the following: GFR < 60 mL/min, PS ≥ 2, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, or grade ≥ 2 peripheral neuropathy, etc. Carboplatin may be substituted for cisplatin particularly in those patients with a GFR < 60 mL/min or a PS of 2.
  - Carboplatin-ineligible comorbidities may include the following: GFR < 30 mL/min, PS ≥ 3, grade ≥ 3 peripheral neuropathy, or NYHA class ≥ 3, etc.

### Renal Cell Carcinoma †<sup>1,4,9</sup>

- Patient is at least 18 years of age; **AND**
- Used in combination with axitinib; **AND**
- Used as first line therapy; **AND**
  - Used for the treatment of advanced disease; **OR**
  - Used for relapsed or metastatic disease with clear cell histology

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

## IV. Renewal Criteria<sup>1,2,8,9</sup>

Coverage can 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 infusion reactions, hepatotoxicity, immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction, myocarditis, pancreatitis, myositis, psoriasis, arthritis, exfoliative dermatitis, erythema

multiforme, pemphigoid, hypopituitarism, uveitis, Guillain-Barré syndrome, systemic inflammatory response, etc.), major adverse cardiovascular events (MACE) when used in combination with axitinib, etc.

## V. Dosage/Administration<sup>1,2,8,9</sup>

| Indication  | Dose  |
|---|---|
| All indications   | 800 mg via intravenous infusion over 60 minutes every 2 weeks 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><b>Weight &gt; 60 kg:</b></p> <ul style="list-style-type: none"> <li>Standard dose 800 mg IV every 2 weeks</li> </ul> <p><b>Weight is &lt; 60kg:</b></p> <ul style="list-style-type: none"> <li>Use 600 mg IV every 2 weeks</li> </ul> <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

- Bavencio [package insert]. New York, NY; EMD Serono, Inc; June 2020. Accessed July 2020.
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- 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.
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5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Merkel Cell Carcinoma. Version 1.2020. National Comprehensive Cancer Network, 2019. 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 2020.
6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 5.2020. National Comprehensive Cancer Network, 2020. 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 2020.
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11. Hematology/Oncology Pharmacy Association (2019). Intravenous Cancer Drug Waste Issue Brief. Retrieved from [http://www.hoparx.org/images/hopa/advocacy/Issue-Briefs/Drug\\_Waste\\_2019.pdf](http://www.hoparx.org/images/hopa/advocacy/Issue-Briefs/Drug_Waste_2019.pdf)
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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 |

| ICD-10  | ICD-10 Description  |
|---------|---|
| 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                                    |
| 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                                |

**BAVENCIO® (avelumab) Prior Auth Criteria**

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| ICD-10  | ICD-10 Description  |
|---------|---|
| 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  |
| Z85.51  | Personal history of malignant neoplasm of bladder                   |
| Z85.528 | Personal history of other malignant neoplasm of kidney              |
| 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: <http://www.cms.gov/medicare-coverage-database/search/advanced-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):

|   |   |
|---|---|
| <b>Jurisdiction(s):</b> J&M   | <b>NCD/LCD/Article Document (s):</b> A56141 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56141&amp;bc=gAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56141&amp;bc=gAAAAAAAAAAAA</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.                           |

**Medicare Part B Administrative Contractor (MAC) Jurisdictions**

| <b>Jurisdiction</b> | <b>Applicable State/US Territory</b> | <b>Contractor</b>                        |
|---------------------|--------------------------------------|--|
| K (13 & 14)         | NY, CT, MA, RI, VT, ME, NH           | National Government Services, Inc. (NGS) |
| 15                  | KY, OH                               | CGS Administrators, LLC                  |