MEDICA®

Bavencio® (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 [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) † Φ [1,2,4,5]

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

Urothelial Carcinoma (Bladder Cancer) † [1,4,6,8,16]

- Used as a single agent; **AND**
  - Patient has one of the following diagnoses:
    - Locally advanced or metastatic urothelial carcinoma; **OR**

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- Local muscle invasive 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 *(disease progression and second-line treatment only)*; **AND**

- Used for disease that progressed during or following platinum-containing chemotherapy*; **OR**
- Used as second-line treatment after therapy other than a platinum or an immune checkpoint inhibitor; **OR**

- Used as first-line maintenance treatment; **AND**
  - Patient has locally advanced or metastatic urothelial carcinoma (inclusive of the bladder, upper GU tract, urethra, and/or prostate); **AND**
  - Patient has not progressed with first-line platinum-containing chemotherapy

**** Note:*** [6,7,17]

- *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 carboplatin-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.*
  - *Carboplatin-ineligible comorbidities may include the following: CrCl < 30 mL/min, PS > 3, grade > 3 peripheral neuropathy, or NYHA class > 3, etc.*

Renal Cell Carcinoma † [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 with 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/etoposide-containing regimen; **OR**
  - Patient has high-risk disease (i.e., prognostic score ≥ 7 or FIGO stage IV disease)

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Endometrial Carcinoma (Uterine Cancer) ‡ [4,18]

- Used as a single agent; **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); Φ 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 infusion reactions, hepatotoxicity, immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatitis/skin adverse reactions, etc.), major adverse cardiovascular events (MACE) when used in combination with axitinib, etc.

V. Dosage/Administration [1,13,18]

Indication	Dose
All indications	800 mg via intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity.
Dosing should be calculated using actual body weight and not flat dosing (as applicable) based on the following: **Weight > 60 kg**: • Standard dose 800 mg IV every 2 weeks **Weight is ≤ 60kg**: • Use 600 mg IV every 2 weeks *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.*	

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

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VII. References

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Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2021.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C21.0	Malignant neoplasm of anus, unspecified
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
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

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ICD-10	ICD-10 Description
C63.2	Malignant neoplasm of scrotum
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

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/new-search/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

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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

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