Bavencio® (avelumab)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter.

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]

Prior authorization validity is provided in the following conditions:

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

Universal Criteria

- Member has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy unless otherwise specified [Δ]; **AND**

Merkel Cell Carcinoma (MCC) † ‡ Φ [1,2,4,5]

- Member is at least 12 years of age; **AND**
- Used as single-agent therapy; **AND**
  - Member has primary locally advanced disease ‡; **AND**
    - Both curative surgery and curative radiation therapy are not feasible; **OR**
  - Member has recurrent locally advanced disease ‡; **AND**
    - Both curative surgery and curative radiation therapy are not feasible; **OR**
    - Member has had disease progression on neoadjuvant nivolumab therapy; **OR**
  - Member has in-transit N+ regional disease; **OR**
  - Member has metastatic disease; **OR**
  - Member has primary or recurrent regional disease ‡; **AND**
    - Both curative surgery and curative radiation therapy are not feasible

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

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

***Note:** [6,17,20]

– *If member was progression free for > 12 months after platinum therapy, consider re-treatment with platinum-based therapy if the member 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, grade ≥ 2 peripheral neuropathy, or NYHA Heart Failure class ≥ 3. Carboplatin may be substituted for cisplatin in the metastatic setting for cisplatin-ineligible members such as those with a GFR less than 60 mL/min.*
- *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 ‡ [4,13,15]

- Used as single-agent therapy for multiagent chemotherapy-resistant disease; **AND**
  - Member has intermediate placental site trophoblastic tumor (PSTT) or epithelioid trophoblastic tumor (ETT); **AND**
    - Member has recurrent or progressive disease; **OR**
  - Member has high-risk disease (i.e., prognostic score ≥ 7 or FIGO stage IV disease)

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

- Used as subsequent therapy for recurrent disease; **AND**
- Will not be used for either of the following:
  - Therapy for locoregional recurrence in members with no prior radiation therapy to site of recurrence, or previous vaginal brachytherapy only; **OR**

- Therapy after surgical exploration for locoregional recurrence in members with disease confined to the vagina or paravaginal soft tissue; **AND**

- Used as one of the following:
  - Single agent therapy for microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors; **OR**
  - Therapy in combination with axitinib for mismatch repair proficient (pMMR) tumors

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**
  - Member is unable to tolerate first-line combination regimens; **AND**
    - 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 subsequent therapy; **AND**
    - Member has unresectable or metastatic disease

Colon Cancer ‡ [4,28]

- Member has MSI-H/dMMR disease OR polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) > 50 mut/Mb] as determined by an FDA-approved or Clinical Laboratory Improvement Amendments (CLIA)-compliant test❖; **AND**
- Used as a single agent for locally unresectable, medically inoperable, advanced or metastatic disease

Rectal Cancer ‡ [4,29]

- Member has MSI-H/dMMR disease OR POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB > 50 mut/Mb) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used as a single agent for locally unresectable, medically inoperable, advanced or metastatic disease

Small Bowel Adenocarcinoma ‡ [4,27]

- Member has MSI-H/dMMR disease OR POLE/POLD1 mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) > 50 mut/Mb] as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used as single agent treatment; **AND**
  - Member has advanced or metastatic disease; **OR**
  - Member has locally unresectable or medically inoperable disease; **AND**
    - Used as primary treatment

❖ *If confirmed using an immunotherapy assay- http://www.fda.gov/CompanionDiagnostics*

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

IV. Renewal Criteria Δ 1

Prior authorization validity may be renewed based upon the following criteria:

- Member 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:**

- Members 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 1,13,18,26-29

Indication	Dose
All Indications	Administer 800 mg intravenously every 14 days, 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 is ≤ 66 kg**: • Use 600 mg (10mg/kg) 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. Member-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

VII. References

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C18.0	Malignant neoplasm of cecum
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction

ICD-10	ICD-10 Description
C20	Malignant neoplasm of rectum
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
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
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
C64.1	Malignant neoplasm of right kidney, except renal pelvis

ICD-10	ICD-10 Description
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
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
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

ICD-10	ICD-10 Description
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
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.238	Personal history of other malignant neoplasm of thymus
Z85.42	Personal history of malignant neoplasm of other parts of uterus
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		
Jurisdictio	**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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
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