Avelumab (Bavencio®)

NDC CODE(S) 44087-3535-XX BAVENCIO 200MG/10ML Solution (SERONO)

DESCRIPTION

Avelumab is a programmed death ligand-1 (PD-L1) blocking antibody. PD-L1 may be expressed on tumor cells and tumor-infiltrating immune cells and can contribute to the inhibition of the anti-tumor immune response in the tumor microenvironment. By binding to receptors found on T cells and antigen presenting cells, PD-L1 suppresses cytotoxic T-cell activity, T-cell proliferation and cytokine proliferation. Avelumab binds to PD-L1 and its receptors and blocks its inhibitory effects on the immune response, including those on the anti-tumor immune responses.

POLICY

- Avelumab is considered ***medically necessary*** for the treatment of the following if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
  - Bladder cancer with histology of urothelial carcinoma /Urothelial carcinoma
  - Gestational Trophoblastic Neoplasia
  - Merkel cell carcinoma (MCC)
  - Renal cell carcinoma (RCC)
- Avelumab for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

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)

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

Bladder Cancer/Urothelial Carcinoma

- Patient is at least 18 years of age; **AND**
- Used as a single agent; **AND**
- Used as subsequent therapy after previous platinum* or other treatment; **AND**
  - Patient has a diagnosis of one of the following:
    - Locally advanced or metastatic urothelial carcinoma; **OR**
    - 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; **OR**
- Used as first-line maintenance treatment; **AND**
  - Patient has locally advanced or metastatic urothelial carcinoma (inclusive of the bladder, upper GU, urethra, and/or prostate); **AND**
  - Patient has not progressed with first-line platinum-containing 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

- 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

Gestational Trophoblastic Neoplasia

- Patient is at least 18 years of age; **AND**
- 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 methotrexate-resistant high risk disease (i.e., Prognostic score ≥7 OR FIGO stage IV disease)

RENEWAL CRITERIA

- Patient continues to meet the universal and other indication-specific relevant criteria identified in Initial Approval Criteria; **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, complications of allogeneic HSCT, etc.

DOSAGE/ADMINISTRATION

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.

LENGTH OF AUTHORIZATION

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

DOSING LIMITS

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

80 billable units every 14 days (all indications)

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

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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, 2021. The NCCN Compendium® is 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 April 2021.
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EFFECTIVE DATE 9/30/2021

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