Avelumab (Bavencio®)

Prior Authorization Drug Coverage Policy

Effective Date: 9/1/2020
Revision Date: n/a
Review Date: 9/17/2021
Lines of Business: Commercial
Policy type: Prior Authorization

This Drug Coverage Policy provides parameters for the coverage of avelumab (Bavencio®). Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine.

Drug Description[1-2]

Avelumab is a fully human IgG1 monoclonal antibody that specifically binds to PD-L1. This binding blocks the interaction between PD-L1 and its receptors, PD-1 and B7.1. Blocking PD-1 and B7.1 interaction restores anti-tumor T-cell function.

FDA Indications[1]

Avelumab is FDA indicated for the following:

- Treatment of metastatic Merkel Cell carcinoma (MCC) in adults and children ≥ 12 years of age.
- Maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma that has not progressed with first-line platinum-containing chemotherapy.
- Treatment of locally advanced or metastatic urothelial carcinoma in patients who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
- First-line treatment of advanced renal cell carcinoma (RCC) in combination with axitinib

NCCN Compendium Supported Indications[3]

- Gestational Trophoblastic Neoplasia
- Uterine Neoplasms

Coverage Determinations[1,3]

Avelumab will require prior authorization. This agent is considered medically necessary for the following oncology indications if all criteria below are met:

Merkel Cell Carcinoma

- The member has a diagnosis of metastatic MCC **AND**
- The member is 12 years of age or older **AND**
- The member will be using avelumab (Bavencio®) as monotherapy

Recommended dosage: 800 mg as an intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity.

Urothelial Carcinoma

- The member has a diagnosis of locally advanced or metastatic urothelial carcinoma **AND**
- The member will be using avelumab (Bavencio®) as monotherapy **AND**
- One of the following apply:
    - The member will be using avelumab (Bavencio®) as single-agent maintenance therapy if there is no progression on first-line platinum-containing chemotherapy **OR**
    - The member will be using avelumab (Bavencio®) as second or subsequent line systemic therapy, after disease progression on or after platinum-containing chemotherapy **OR**
    - The member has had disease progression within 12 months of neoadjuvant or adjuvant platinum-based chemotherapy

Recommended dosage: 800 mg as an intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity.

Renal Cell Carcinoma

- The member has a diagnosis of advanced RCC **AND**
- The member has not received prior systemic therapy directed at advanced or metastatic RCC **AND**
- The member will be using avelumab (Bavencio®) in combination with axitinib

Recommended dosage: 800 mg as an intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity, in combination with axitinib.

Gestational Trophoblastic Neoplasia

- Useful in certain circumstances as single-agent therapy for:
  - multiagent chemotherapy-resistant high-risk disease **OR**
  - recurrent or progressive intermediate trophoblastic tumor (placental site trophoblastic tumor or epithelioid trophoblastic tumor) following treatment with a platinum/etoposide-containing regimen

Uterine Neoplasms - Endometrial Carcinoma

- Used as a single agent second-line treatment for recurrent, metastatic, or high-risk microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors

Recommended dosage: 800 mg as an intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity.

All indications:

- Avelumab will be approved through clinical review for up to a 6-month duration

Coverage Limitations

Treatment with avelumab is not considered medically necessary for members with the following concomitant conditions:

- The member has experienced disease progression on avelumab.
- The member has received prior therapy with an anti-Programmed Cell Death Receptor 1 (PD-1), anti-Programmed Cell Death Receptor Ligand 1 (PD-L1) or anti-Programmed Cell Death Receptor Ligand 2 (PD-L2) agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (e.g., cytotoxic T-lymphocyte-associated protein 4 (CTLA-4), OX-40, CD137)
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary

Contraindications/Warnings/Precautions[1]

- There are no contraindications listed in the US manufacturer's labeling.
- Warnings/precautions:
  - Infusion-related reactions
  - Adrenal insufficiency
  - Diabetes mellitus, type 1
  - Immune-mediated colitis, hepatitis, nephritis, pneumonitis, hyperthyroidism/hypothyroidism/thyroiditis
  - Other immune-related toxicities – may affect any organ system
  - Embryo-fetal toxicity

For specific recommendations on contraindications, warnings and precautions, patient monitoring, and on dose adjustments and discontinuation, please refer to the current prescribing information.

Billing

Description: Injection, avelumab 10 mg
HCPCS: J9023

Disclaimer

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from Oncology Analytics, Inc.

References

1. Bavencio [package insert]. EMD Serono, Inc. Rockland, MA. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761049s000lbl.pdf
2. K Chin, VK Chand, DSA Nuyten. Avelumab: clinical trial innovation and collaboration to advance anti-PD-L1 immunotherapy. Ann Oncol 2017;28: 1658-66.
3. Avelumab. NCCN Drugs & Biologics Compendium. Available at http://www.nccn.org/professionals/drug_compendium/MatrixGenerator/Matrix.aspx?AID=412
4. Kaufman HL, Russell J, Hamid O, et al. Avelumab in patients with chemotherapy-refractory metastatic Merkel cell carcinoma: a multicenter, single-group, open-label, phase 2 trial. Lancet Oncol 2016;17: 1374-85.
5. Apolo AB, Infante JR, Balmanoukian A, et al. Avelumab, an Anti-Programmed Death-Ligand 1 Antibody, in Patients with Refractory Metastatic Urothelial Carcinoma: Results From a Multicenter, Phase 1b Study. J Clin Oncol 2017;35: 2117-42.
6. Motzer RJ, Penkov K, Haanen J, et al. Avelumab plus Axitinib versus Sunitinib for Advanced Renal Cell Carcinoma. NEJM 2019;380: 1103-15.