Bavencio (avelumab)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Bavencio (avelumab) policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Metastatic Merkel Cell Carcinoma (MCC)
Treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma.

B. Locally Advanced or Metastatic Urothelial Carcinoma (UC): *First-line maintenance treatment of urothelial carcinoma*
Maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma that has not progressed with first-line platinum-containing chemotherapy.

C. Locally Advanced or Metastatic Urothelial Carcinoma (UC): *Previously-treated urothelial carcinoma*
Treatment of patients with locally advanced or metastatic urothelial carcinoma 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.

D. Advanced Renal Cell Carcinoma (RCC)
First-line treatment of patients with advanced renal cell carcinoma in combination with axitinib.

Compendial Indications

A. Urothelial carcinoma
   1. Bladder cancer
   2. Primary carcinoma of the urethra
   3. Upper genitourinary (GU) tract tumors
   4. Urothelial carcinoma of the prostate

B. Merkel cell carcinoma

C. Renal cell carcinoma

D. Gestational trophoblastic neoplasia

E. Endometrial carcinoma

Limitations of use:

Coverage will not be provided for members who have experienced disease progression while on PD-1 or PD-L1 inhibitor therapy.

POLICY

Criteria for Initial Approval

A. Merkel Cell Carcinoma

Authorization of 6 months may be granted for the treatment of Merkel cell carcinoma in members with metastatic disease.

B. Urothelial Carcinoma – Bladder Cancer

Authorization of 6 months may be granted for treatment of bladder cancer as a single agent when either of the following criteria is met:

1. Used as subsequent therapy in any of the following settings:
   a. Disease is locally advanced or metastatic.
   b. Member has metastatic or local recurrence post-cystectomy.
   c. Member has muscle invasive local recurrence or persistent disease in a preserved bladder.
   d. Member has stage II or IIIA disease and tumor is present following primary treatment.
2. Used as maintenance therapy if there is no progression on first-line platinum-containing chemotherapy.

C. Urothelial Carcinoma – Primary Carcinoma of the Urethra

Authorization of 6 months may be granted for treatment of primary carcinoma of the urethra as a single agent when either of the following criteria is met:

1. Used as subsequent systemic therapy for recurrent, locally advanced, or metastatic disease
2. Used as maintenance therapy if there is no progression on first-line platinum-containing chemotherapy.

D. Urothelial Carcinoma – Upper Genitourinary (GU) Tract Tumors or Urothelial Carcinoma of the Prostate

Authorization of 6 months may be granted for the treatment of upper genitourinary (GU) tract tumors or urothelial carcinoma of the prostate as a single agent when either of the following criteria is met:

1. Used as subsequent therapy for locally advanced or metastatic disease.
2. Used as maintenance therapy if there is no progression on first-line platinum-containing chemotherapy.

E. Renal Cell Carcinoma

Authorization of 6 months may be granted for treatment of advanced, relapsed, or stage IV renal cell carcinoma when given in combination with axitinib as first-line treatment for the disease.

F. Gestational Trophoblastic Neoplasia

Authorization of 6 months may be granted as a single agent for treatment of gestational trophoblastic neoplasia for multiagent chemotherapy-resistant disease when either of the following criteria is met:

1. Member has recurrent or progressive intermediate trophoblastic tumor (placental site trophoblastic tumor or epithelioid trophoblastic tumor) following treatment with a platinum-based regimen.
2. Member has high-risk disease.

G. Endometrial Carcinoma

Authorization of 6 months may be granted as a single agent for second-line treatment of recurrent or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors.

Continuation of Therapy

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Criteria for Initial Approval section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Bavencio is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

CLINICAL RATIONALE

Bavencio (avelumab) is a programmed death ligand-1 (PD-L1) blocking antibody indicated for the treatment of certain patients with Merkel cell carcinoma (MCC), renal cell carcinoma, or urothelial carcinoma. Bavencio is administered as an intravenous infusion of 800 MG every 2 weeks until disease progression or unacceptable toxicity. Approval for Merkel cell carcinoma was based on data from the open-label Phase 2 JAVELIN Merkel 200 study where the objective response rate (ORR) with Bavencio was 31.8 percent, which included a 9.1 percent complete response rate. After a median follow-up of 10.4 months, 82 percent of patients continued to respond to therapy.

Bavencio is approved for the first-line treatment of advanced renal cell carcinoma (RCC) in combination with Inlyta (axitinib). The approval of Bavencio with Inlyta was based on positive results from the Phase 3 JAVELIN Renal 101 study where combination treatment with both agents improved median progression-free survival (PFS) compared with Sutent (sunitinib) by 5.4 months in the intent-to-treat (ITT) patient population. The median PFS for Bavencio in combination with Inlyta was 13.8 months, compared with 8.4 months with Sutent. The JAVELIN study also showed that the combination significantly lowered the risk of disease progression or death by 31% compared with Sutent.

Additionally, Bavencio is approved for the treatment of advanced urothelial carcinoma that progressed during or after platinum-based chemotherapy, based on the results of two Phase 1 expansion cohorts. Bavencio is also indicated for use as maintenance treatment for patients with locally advanced or metastatic urothelial carcinoma that has not progressed with first-line platinum-based chemotherapy based on data from the Phase 3 JAVELIN Bladder 100 study which showed a significant improvement in median overall survival (OS) of 7.1 months with Bavencio as front-line maintenance treatment plus best supportive care (BSC) versus BSC alone.

Warnings and precautions for Bavencio include severe and fatal immune-mediated adverse reactions, infusion-related reactions, complications of allogeneic hematopoietic stem cell transplantation, major adverse cardiovascular events and embryo-fetal toxicity. Bavencio is an additional option for treatment of Merkel cell carcinoma (MCC), renal cell carcinoma, and urothelial carcinoma.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J9023 – Injection, avelumab, 10 mg

REFERENCES

- Bavencio [package insert]. Rockland, MA: EMD Serono, Inc.; July 2022.
- The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 24, 2023

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POLICY HISTORY

Policy #: 05.05.00
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