Reference number(s)
2130-A

STANDARD MEDICARE PART B MANAGEMENT

BAVENCIO (avelumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Metastatic Merkel Cell Carcinoma (MCC)
   Treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma
2. Locally Advanced or Metastatic Urothelial Carcinoma (UC)
   i. Maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy
   ii. 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
3. Advanced Renal Cell Carcinoma (RCC)
   First-line treatment of patients with advanced renal cell carcinoma in combination with axitinib

B. Compendial Uses
1. Urothelial carcinoma
   i. Bladder cancer
   ii. Primary carcinoma of the urethra
   iii. Upper genitourinary (GU) tract tumor
   iv. Urothelial carcinoma of the prostate
2. Merkel cell carcinoma
3. Renal cell carcinoma
4. Gestational trophoblastic neoplasia
5. Endometrial carcinoma

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. Merkel Cell Carcinoma
Authorization of 12 months may be granted for the treatment of Merkel cell carcinoma in members with metastatic disease.

B. Urothelial Carcinoma – Bladder Cancer
Authorization of 12 months may be granted for the treatment of bladder cancer as a single agent when either of the following criteria is met:

1. The requested drug will be used as maintenance therapy if there is no progression on first-line platinum-containing chemotherapy.
2. The requested drug will be used as subsequent therapy in any of the following settings:
   i. Disease is locally advanced or metastatic
   ii. Member has muscle invasive local recurrence or persistent disease in a preserved bladder
   iii. Member has metastatic or local recurrence post-cystectomy
   iv. Member has Stage II or IIIA disease and tumor is present following primary treatment

C. Urothelial Carcinoma – Primary Carcinoma of the Urethra

Authorization of 12 months may be granted for the treatment of primary carcinoma of the urethra as a single agent when either of the following criteria is met:

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

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

Authorization of 12 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. The requested drug will be used as maintenance therapy if there is no progression on first-line platinum-containing chemotherapy.
2. The requested drug will be used as subsequent therapy for locally advanced or metastatic disease

E. Renal cell carcinoma

Authorization of 12 months may be granted for the treatment of advanced, relapsed, or stage IV renal cell carcinoma when Bavencio is given in combination with axitinib as first-line treatment for the disease.

F. Gestational trophoblastic Neoplasia

Authorization of 12 months may be granted for the treatment of gestational trophoblastic neoplasia as a single agent 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 12 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.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

A. The member is currently receiving therapy with Bavencio.
B. Bavencio is being used to treat an indication enumerated in Section II.
C. The member is receiving benefit from therapy. Benefit is defined as:
   i. No evidence of unacceptable toxicity while on the current regimen and
   ii. No evidence of disease progression while on the current regimen

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Bavencio.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. NCCN Guideline: Gestational trophoblastic neoplasia
4. NCCN Guideline: Merkel cell carcinoma
5. NCCN Guideline: Kidney cancer
6. NCCN Guideline: Bladder cancer
7. NCCN Guideline: Uterine neoplasms

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Bavencio are covered in addition to the following:

1. Urothelial carcinoma
    i. Bladder cancer
    ii. Primary carcinoma of the urethra
    iii. Upper genitourinary (GU) tract tumor
    iv. Urothelial carcinoma of the prostate
2. Merkel cell carcinoma
3. Renal cell carcinoma
4. Gestational trophoblastic neoplasia
5. Endometrial carcinoma

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for urothelial carcinoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for Merkel cell carcinoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for renal cell carcinoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for gestational trophoblastic neoplasia can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in

an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for endometrial carcinoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

VI. REFERENCES

1. Bavencio [package insert]. Rockland, MA: EMD Serono, Inc.; November 2020.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 5, 2022.