Bavencio (avelumab)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Bavencio (avelumab)

APPROVAL CRITERIA

Requests for Bavencio (avelumab) may be approved if the following criteria are met:

I. Individual has a diagnosis of metastatic Merkel cell carcinoma (Label, NCCN 2A); **AND**
   A. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2; **AND**
   B. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   C. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

II. Individual has a diagnosis of locally advanced or metastatic Urothelial Carcinoma (Label, NCCN 1, 2A); **AND**
   A. Individual is using agent as monotherapy: **AND**
   B. Individual has a current ECOG performance status of 0-2; **AND**
   C. Individual meets **one** of the following criteria:
      1. Individual is using after platinum-containing chemotherapy (either as subsequent therapy after disease progression during or following platinum regimen, ***or*** as maintenance therapy following completion of platinum regimen with no evidence of disease progression); **OR**
      2. Has confirmed disease progression within 12 months of receiving neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; **AND**
   D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

III. Individual has a diagnosis of multi-agent chemotherapy-resistant gestational trophoblastic neoplasia (NCCN 2A); **AND**
   A. Individual has intermediate OR high-risk disease; **AND**
   B. Individual is using as single-agent therapy; **AND**
   C. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**

D. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

IV. Individual has a diagnosis of endometrial carcinoma (NCCN 2A); **AND**
- A. Individual is using for recurrent or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors; **AND**
- B. Individual is using as monotherapy; **AND**
- C. Individual is using as second-line treatment or subsequent therapy; **AND**
- D. Individual has a current ECOG performance status of 0-2; **AND**
- E. Individual has not received treatment with another anti-PD1 or anti-PD-L1 agent; **AND**
- F. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

V. Individual has a diagnosis of advanced Renal Cell Carcinoma (RCC) (Label, NCCN 2A); **AND**
- A. Individual is using as first-line therapy; **AND**
- B. Individual is using in combination with axitinib (Inlyta); **AND**
- C. Individual has histological confirmation of RCC with clear cell component; **AND**
- D. Individual has an ECOG performance status of 0-2; **AND**
- E. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
- F. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

VI. Individual has a diagnosis of Extranodal NK/T-Cell Lymphomas (NCCN 2A); **AND**
- A. Individual is using for relapsed/refractory disease; **AND**
- B. Individual is using as a single agent; **AND**
- C. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
- D. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

VII. Individual has a diagnosis of Thymoma or Thymic cancer (NCCN 2A); **AND**
- A. Individual is using in combination with axitinib (Inlyta); **AND**
- B. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
- C. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

Requests for Bavencio (avelumab) may not be approved when the above criteria are not met and for all other indications.

Key References:

1. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 15, 2025.
    a. Bladder cancer. V5.2024. Revised October 28, 2024.
    b. Gestational Trophoblastic Neoplastic. V1.2025. Revised December 17, 2024.
    c. Kidney Cancer. V3.2025. Revised January 9, 2025
    d. Merkel Cell Carcinoma. V1.2024. Revised November 22, 2023.
    e. Uterine neoplasms. V1.2025. Revised December 16, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.