

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

## 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; **AND**
  - A. Individual is 12 years of age or older ; **AND**
  - B. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2; **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**

- II. Individual has a diagnosis of locally advanced or metastatic Urothelial Carcinoma; **AND**
  - A. Individual is using 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 on or after disease progression with platinum regimen, **or** as maintenance therapy following completion of platinum regimen with no evidence of disease progression); **OR**
    2. Has demonstrated 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**

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New Program Date 06/19/2017

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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- III. Individual has a diagnosis of advanced Renal Cell Carcinoma (RCC); **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.

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

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 9, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 9, 2020.
  - a. Bladder Cancer. V5.2020. Revised May 12, 2020.
  - b. Kidney Cancer. V2.2020. Revised August 5, 2019.
  - c. Merkel Cell Carcinoma: Version 1.2020. Revised October 2, 2019.

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

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