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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 02/12/2026

Bavencio[®] (avelumab)

HCPCS: J9023

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. Treatment must follow the FDA approved indications or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1 or 2A recommendation
 - i. Must be used with concomitant treatment according to FDA indication or NCCN Category 1 or 2A recommendation
 - b. Prescribed by or in consultation with an oncologist or hematologist
 - c. No prior failure of a programmed death receptor-1 (PD-1) inhibitor
 - d. Patient is not receiving therapy for a chronic condition, such as an autoimmune disease, that requires treatment with a systemic immunosuppressant
 - e. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the BCBSM/BCN utilization management medical drug list
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing
 - b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
 - c. Renewal Criteria: Treatment may be continued until disease progression or until unacceptable toxicity occurs

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Bavencio is a programmed death ligand-1 (PD-L1) blocking antibody indicated for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC); for patients with locally advanced or metastatic urothelial carcinoma (UC) 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; as maintenance therapy in UC for those who have not progressed with first-line platinum-containing chemotherapy; and for first-line treatment, in combination with axitinib, for patients with advanced renal cell carcinoma (RCC).
- The National Comprehensive Cancer Network (NCCN) guidelines category 1 and 2A recommendations are based on uniform NCCN consensus that the recommendations are appropriate. Treatment regimens have been studied and shown to be efficacious when administered as listed in the guidelines. Category 2B and 3 recommendations do not have a high level of evidence to support use and also do not have a uniform consensus from the NCCN panel that the recommendations are appropriate.
- There are no studies to support use of Bavencio following failure. NCCN treatment guidelines also do not recommend use of Bavencio or other PD-L1 checkpoint inhibitors following a previous failure.
- Bavencio has not been studied in patients on chronic immunosuppressant therapy and therefore, should not be used in patients on chronic immunosuppressants

References:

1. Bavencio [prescribing information]. New York, NY: EMD Serono and Pfizer; June 2025.
2. 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;17:1374-1385.
3. National Comprehensive Cancer Network. Merkel cell carcinoma (Version 2.2026). 2025 Oct 24. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mcc.pdf. Accessed December 9, 2025.
4. National Comprehensive Cancer Network. Bladder cancer (Version 2.2025). 2025 Oct 10. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed December 9, 2025.
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 Ib study. *J Clin Oncol*. 2017 April 4.
6. UpToDate (database online). Staging and Treatment of Merkel Cell Carcinoma. Waltham, MA; Wolters Kluwer, Inc.; 2017. Available at: <http://www.uptodate.com>. Accessed July 28, 2017.
7. Cairns P. Renal cell carcinoma. *Cancer Biomark*. 2011; 9 (1-6): 461 – 473.
8. National Comprehensive Cancer Network. Kidney cancer (Version 1.2026). 2025 July 24. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed December 9, 2025.
9. Motzer RJ, Penkov K, Hannon J, et al. Avelumab plus axitinib versus sunitinib for advanced renal cell carcinoma. *NEJM*. 2019; 380: 1103 – 1115.

Policy History												
#	Date	Change Description										
2.1	Effective Date: 02/12/2026	Updated criteria to align with standard PD-L1 criteria										
2.0	Effective Date: 02/13/2025	Annual review – no changes to the policy were made at this time										
1.9	Effective Date: 02/08/2024	Annual review – no changes to the policy were made at this time										
1.8	Effective Date: 02/02/2023	Updated approval length to allow for FDA recommended dosing for at least 60 days										
1.7	Effective Date: 08/04/2022	Updated approval length to allow for FDA recommended dosing or up to 6 months at a time										
1.6	Effective Date: 08/12/2021	Annual review – no changes to the policy were made at this time										
1.5	Effective Date: 12/01/2021	UM medical management system update for BCBS <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
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BCBS	Yes											
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1.4	Effective Date: 08/13/2020	Added new indication of maintenance therapy for advanced or metastatic urothelial carcinoma										
1.3	Effective Date: 08/15/2019	Added new indication of renal cell carcinoma										
1.2	Effective Date: 02/01/2019	UM medical management system update for MAPPO and BCNA <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	Yes	MAPPO	Yes	BCNA	Yes
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BCBS	No											
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1.1	Effective Date: 11/01/2018	Updated criteria per oncology vendor										
1.0	Effective Date: 04/01/2017	New policy <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	Yes	MAPPO	No	BCNA	No
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://daily.med.nlm.nih.gov/dailymed/index.cfm>.*