

Policy Title:	Bavencio (avelumab) Intravenous		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	10/02/2019, 12/11/2019		
Revision Date:	10/02/2019, 12/11/2019		

Purpose: To support safe, effective and appropriate use of Bavencio (avelumab).

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement: Bavencio (avelumab) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure: Coverage of Bavencio (avelumab) will be reviewed prospectively via the prior authorization process based on criteria below:

Initial Criteria:

- Used as a single agent; AND
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, atezolizumab, durvalumab, etc.) unless otherwise specified; AND

Merkel Cell Carcinoma (MCC)

- Patient must be at least 12 years old; AND
- Patient has metastatic disease

Bladder Cancer/Urothelial Carcinoma

- Patient must be at least 18 years old; AND
- Must be used as subsequent therapy after previous platinum treatment; AND
- Patient has a diagnosis of one of the following:
 - Locally advanced or metastatic Urothelial Carcinoma; OR
 - Disease recurrence post-cystectomy; OR
 - Metastatic Upper Genitourinary Tract Tumors; OR
 - Metastatic Urothelial Carcinoma of the Prostate; OR
 - Recurrent or metastatic Primary Carcinoma of the Urethra; AND
- Patient does not have recurrent stage T3-4 disease or palpable inguinal lymph nodes.

Renal Cell Carcinoma

- Patient must be at least 18 years old; AND

- Used in combination with axitinib; AND
- Used as first line therapy; AND
 - Used for the treatment of advanced disease; OR
 - Used for the relapsed or metastatic disease with clear cell histology

Continuation of Therapy criteria :

- Patient continues to meet initial criteria; AND
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; AND
- Patient is tolerating treatment and is not experiencing any unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe infusion reactions, immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction, skin, etc.).

Coverage durations:

- Initial & Renewal coverage = 6 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

Dosage/Administration:

Indication	Dose (1 billable unit = 10mg)
All indications	800mg every 2 weeks

Dosing Limits:

Maximum Units (per dose and over time):

- 80 billable units every 14 days (all indications)

Investigational Use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug Information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes: Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT code is:

HCPCS/CPT Code	Description
J9023	Injection, avelumab, 10 mg

References:

1. Bavencio [package insert]. New York, NY; EMD Serono, Inc; October 2018.
2. Kaufman HL, Russell J, Hamid O, et al. Avelumab in patients with chemotherapyrefractory metastatic Merkel cell carcinoma: a multicentre, single-group, open-label, phase 2 trial. *Lancet Oncol.* 2016 Oct;17(10):1374-1385.
3. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) avelumab. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2019.