Drug Policy:

Bavencio™ (avelumab)

POLICY NUMBER UM ONC_1306	SUBJECT Bavencio™ (avelumab)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 04/05/17, 04/11/18, 04/10/19, 12/11/19, 04/08/20, 08/12/20, 08/11/21	APPROVAL DATE August 11, 2021	EFFECTIVE DATE August 27, 2021	COMMITTEE APPROVAL DATES 04/05/17, 04/11/18, 04/10/19, 12/11/19, 04/08/20, 08/12/20, 08/11/21	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1	NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Bavencio (avelumab) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR

3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When applicable, generic alternatives are preferred over brand-name drugs.

B. Merkel Cell Carcinoma (MCC)

1. The member has metastatic Merkel Cell Carcinoma, and Avelumab is being used as a single agent, with or without surgery and/or radiation therapy.

C. Metastatic Urothelial Carcinoma including carcinomas of the upper Genito-Urinary Tract & Urethra

1. Maintenance Therapy after systemic chemotherapy: Member has metastatic urothelial carcinoma and has experienced CR/PR/SD with 4-6 cycles of first line cisplatin/carboplatin + gemcitabine chemotherapy, AND Bavencio (avelumab) is being used as a single agent.
2. For clinical setting other than maintenance therapy:

   NOTE: Keytruda (pembrolizumab) is the preferred agent per NCH Policy & NCH Pathway, over other Check-Point Inhibitors (PD-1 or PD-L1 inhibitors i.e., Opdivo, Tecentriq, Bavencio, Imfinzi), for second line therapy of metastatic urothelial carcinoma following platinum containing therapy, or for first line therapy if platinum-based therapy is contraindicated regardless of the PD-L1 status; the member should not have received prior therapy with a Check-Point Inhibitor. This recommendation is based on the fact that only Keytruda has Level 1 evidence in this setting showing a survival advantage.

D. Renal Cell Carcinoma (RCC)

1. NOTE: Avelumab + axitinib is a non-preferred regimen for metastatic renal cell carcinoma per NCH Policy & NCH Pathway. Opdivo (nivolumab)- given as a single agent or in combination with 4 cycles of Ipilimumab at 1mg/kg- is the preferred agent/regimen over other regimens containing PD-1 or PD-L1 inhibitors (e.g. [Avelumab + Axitinib] & [Pembrolizumab + Axitinib]) for metastatic renal cell carcinoma. This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) showing superior outcomes with [axitinib + pembrolizumab] compared to [ipilimumab + nivolumab].

III. EXCLUSION CRITERIA

A. Bavencio (avelumab) use after disease progression with the same regimen or disease progression on prior PD-1 or PD-L1 inhibitor therapy.

B. Dosing exceeds single dose limit of Bavencio (avelumab) 10mg/kg.

C. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Powles et al. JAVELIN Bladder 100 trial. N Engl J Med 2020;383:1218-1230. DOI: 10.1056/NEJMoa2002788

B. Bavencio prescribing information. EMD Serono, Inc. Rockland, MA 2020.

C. Clinical Pharmacology Elsevier Gold Standard 2021.

D. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.

E. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2021.

F. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2021.