

# Drug Policy:

## Bavencio™ (avelumab)

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| <b>POLICY NUMBER</b><br>UM ONC_1306   | <b>SUBJECT</b><br>Bavencio™ (avelumab) | <b>DEPT/PROGRAM</b><br>UM Dept  | <b>PAGE 1 of 3</b>  |
| <b>DATES COMMITTEE REVIEWED</b><br>04/05/17, 04/11/18, 04/10/19, 12/11/19,<br>04/08/20, 08/12/20, 08/11/21, 11/15/21,<br>05/11/22, 07/13/22, 11/09/22, 03/08/23 | <b>APPROVAL DATE</b><br>March 8, 2023  | <b>EFFECTIVE DATE</b><br>March 31, 2023                               | <b>COMMITTEE APPROVAL DATES</b><br>04/05/17, 04/11/18, 04/10/19, 12/11/19,<br>04/08/20, 08/12/20, 08/11/21, 11/15/21,<br>05/11/22, 07/13/22, 11/09/22, 03/08/23 |
| <b>PRIMARY BUSINESS OWNER:</b> UM   |  | <b>COMMITTEE/BOARD APPROVAL</b><br>Utilization Management Committee   |   |
| <b>URAC STANDARDS</b><br>HUM v8: UM 1-2; UM 2-1   | <b>NCQA STANDARDS</b><br>UM 2          | <b>ADDITIONAL AREAS OF IMPACT</b>                                     |   |
| <b>CMS REQUIREMENTS</b>   | <b>STATE/FEDERAL REQUIREMENTS</b>      | <b>APPLICABLE LINES OF BUSINESS</b><br>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. Continuation requests for a not-approvable medication shall be exempt from this NCH policy provided:

1. The requested medication was used within the last year, **AND**
2. The member has not experienced disease progression and/or no intolerance to the requested medication, **AND**
3. Additional medication(s) are not being added to the continuation request.

#### B. Merkel Cell Carcinoma (MCC)

1. The member is an adult or pediatric member 12 years and older with metastatic/recurrent/inoperable Merkel Cell Carcinoma, and Avelumab will be used as a single agent, with or without surgery and/or radiation therapy.

#### **C. Renal Cell Carcinoma (RCC)**

1. Bavencio (avelumab) may be used in combination with Inlyta (axitinib) as first line therapy in members with advanced/metastatic RCC.
2. **NOTE:** Per NCH Policy, Bavencio (avelumab) + Inlyta (axitinib) is not approvable for subsequent treatment of advanced or metastatic renal cell carcinoma. This recommendation is based on the lack of Level 1 evidence (randomized trials and/or meta-analyses) to show superior outcomes with Bavencio (avelumab) + Inlyta (axitinib) in the subsequent line setting compared to NCH recommended alternatives agents/regimens, including but not limited to regimens at <http://pathways.newcenturyhealth.com>.

#### **D. Urothelial Carcinoma including carcinomas of the upper Genito-Urinary Tract & Urethra**

1. Bavencio (avelumab) may be used as a single agent, as second line/subsequent therapy following prior platinum-based chemotherapy, and in a member with locally advanced or metastatic urothelial carcinoma including the upper genito-urinary tract/urethra **OR**
2. Member has locally advanced or metastatic urothelial carcinoma, including carcinoma of the upper genitourinary tract/urethra, and has experienced a complete/partial response or stable disease after 4-6 cycles of first line platinum (cisplatin/carboplatin) containing chemotherapy **AND** Bavencio (avelumab) is being used as a single agent for maintenance therapy following the above first line platinum containing chemotherapy.

### **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 [e.g., Opdivo (nivolumab), Keytruda (pembrolizumab)].
- B. Dosing exceeds single dose limit of Bavencio (avelumab) 800 mg.
- C. Investigational use of Bavencio (avelumab) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
  1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  3. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
  4. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
  5. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
  6. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.

7. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
8. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

#### 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 Clinical Trial. Avelumab Maintenance Therapy for Advanced or Metastatic Urothelial Carcinoma. N Engl J Med 2020;383:1218-1230. DOI: 10.1056/NEJMoa2002788
- B. Bavencio prescribing information. EMD Serono, Inc. Rockland, MA 2022.
- C. Clinical Pharmacology Elsevier Gold Standard 2023.
- D. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2023.
- E. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.
- F. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2023.
- G. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.
- H. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.
- I. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.
- J. NCQA UM 2023 Standards and Elements.