Evolent Clinical Guideline 3087 for Bavencio™ (avelumab)

Guideline Number:	Applicable Codes	
Evolent_CG_3087		
"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc. *© 2017 - 2025 Evolent. All rights Reserved.*		
Original Date:	**Last Revised Date:**	**Implementation Date:**
April 2017	May 2025	May 2025

TABLE OF CONTENTS

STATEMENT **2**
PURPOSE 2
INDICATIONS **2**
MERKEL CELL CARCINOMA (MCC) 2
RENAL CELL CARCINOMA (RCC) 2
UROTHELIAL CARCINOMA INCLUDING CARCINOMAS OF THE UPPER GENITO-URINARY TRACT & URETHRA 2
CONTRAINDICATIONS/WARNINGS **3**
EXCLUSION CRITERIA **3**
CODING AND STANDARDS **3**
CODES 4
APPLICABLE LINES OF BUSINESS 4
POLICY HISTORY **4**
LEGAL AND COMPLIANCE **4**
GUIDELINE APPROVAL 4
Committee *4*
DISCLAIMER 4
REFERENCES **6**

STATEMENT

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.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent 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.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Merkel Cell Carcinoma (MCC)

- The member is an adult or pediatric member 12 years and older with metastatic/recurrent/inoperable MCC, and Bavencio (avelumab) will be used as a single agent, with or without surgery and/or radiation therapy.

Renal Cell Carcinoma (RCC)

- NOTE: Bavencio (avelumab) + Inlyta (axitinib) is not supported by Evolent Policy for subsequent treatment of advanced or metastatic renal cell carcinoma. This policy position 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 Evolent recommended alternatives agents/regimens, including but not limited to regimens at **Evolent Pathways**.

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

- 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
- 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.

CONTRAINDICATIONS/WARNINGS

- None

EXCLUSION CRITERIA

- Bavencio (avelumab) is used 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)].
- Dosing exceeds single dose limit of Bavencio (avelumab) 800 mg.
- 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:
    - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
    - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
    - 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.
    - 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).
    - 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.
    - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
    - 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.

CODING AND STANDARDS

Codes

- J9023 - Injection, avelumab, 10 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
May 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1306 Bavencio (avelumab) • Updated indication section • Updated references
May 2024	• Updated NCH verbiage to Evolent

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update

this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Kaufman HL, et al. Updated efficacy of avelumab in patients with previously treated metastatic Merkel cell carcinoma after ≥1 year of follow-up: JAVELIN Merkel 200, a phase 2 clinical trial. *J Immunother Cancer*. 2018 Jan 19;6(1):7. doi: 10.1186/s40425-017-0310-x.
2. Powles T, et al. Avelumab Maintenance Therapy for Advanced or Metastatic Urothelial Carcinoma. *N Engl J Med*. 2020 Sep 24;383(13):1218-1230. doi: 10.1056/NEJMoa2002788.
3. Bavencio prescribing information. EMD Serono, Inc. Boston, MA 2024.
4. Clinical Pharmacology Elsevier Gold Standard 2025.
5. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2025.
6. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2025.
7. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2025.
8. 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.
9. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf**.
10. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: **http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm**.