<u>Place of Service</u> Office Administration Infusion Center Administration Outpatient Facility Administration Home Infusion

HCPCS: J9023 per 10 mg

Condition listed in policy (see criteria for details)

- Endometrial carcinoma
- <u>Gestational trophoblastic neoplasia</u>
- Merkel cell carcinoma
- Renal cell carcinoma
- Urothelial carcinoma

AHFS therapeutic class: Antineoplastic agent

Mechanism of action: Programmed death ligand-1 (PD-L1) blocking antibody

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s) All requests for Bavencio[®] (avelumab) must be <u>sent for clinical review</u> and receive authorization <u>prior to drug administration or claim payment</u>.

Endometrial carcinoma

- 1. Being used for recurrent or metastatic disease, AND
- 2. Being used as a single agent, AND
- 3. Patient has received prior chemotherapy, AND
- 4. Provider attestation of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors

Covered Dose

Up to 800 mg IV every 2 weeks, OR up to 10 mg/kg IV every 2 weeks

Coverage Period Indefinitely

ICD-10: C61, C65.1, C65.2, C65.9, C66.1, C66.2, C66.9, C67.0-C67.9, C68.0, D09.0, Z85.51, Z85.59

Gestational trophoblastic neoplasia

- 1. Being used as a single agent, AND
- 2. Disease has progressed on a multiagent chemotherapy regimen

PHP Medi-Cal

avelumab (Bavencio®)

Covered Dose

Up to 800 mg IV every 2 weeks, OR up to 10 mg/kg IV every 2 weeks

Coverage Period Indefinitely

ICD-10: D39.2, C58, O01.9

Merkel cell carcinoma

- 1. Disseminated, metastatic or relapsed disease, AND
- 2. Being used as a single agent

Covered Dose

Up to 800 mg IV every 2 weeks, OR up to 10 mg/kg IV every 2 weeks

Coverage Period

Indefinitely

ICD-10:

C4A.0, C4A.10-C4A.12, C4A.20-C4A.22, C4A.30, C4A.31, C4A.39, C4A.4, C4A.51, C4A.52, C4A.59-C4A.62, C4A.70-C4A.72, C4A.8, C4A.9, C7B.1, Z85.821

Renal cell carcinoma

- 1. Advanced or metastatic disease, AND
- 2. First line treatment, AND
- 3. Being used in combination with Inlyta (axitinib)

Covered Dose

Up to 800 mg IV every 2 weeks in combination with axitinib 5 mg orally twice daily

Coverage Period

Indefinitely

ICD-10:

C64.1, C64.2, C64.9, C65.1, C65.2, C65.9, Z85.528

<u>Urothelial carcinoma</u>

- 1. Locally advanced, recurrent, or metastatic disease, AND
- 2. Being used as a single agent, AND
- 3. Patient has received prior treatment with a platinum-containing chemotherapy

Covered Dose

Up to 800 mg IV every 2 weeks OR up to 10 mg/kg IV every 2 weeks

Coverage Period

PHP Medi-Cal

avelumab (Bavencio®)

ICD-10:

C61, C65.1, C65.2, C65.9, C66.1, C66.2, C66.9, C67.0-C67.9, C68.0, D09.0, Z85.51, Z85.59

(3) The following condition(s) <u>DO NOT</u> require Prior Authorization/Preservice All requests for Bavencio[®] (avelumab) must be <u>sent for clinical review</u> and receive authorization <u>prior to drug administration or claim payment</u>.

(4) This Medication is NOT medically necessary for the following condition(s)

<u>Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety</u> <u>Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed</u> <u>indication.</u>

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How Supplied:

• 200 mg (single-use vial)

(6) References

- AHFS[®]. Available by subscription at <u>http://www.lexi.com</u>
- Bavencio® (avelumab) [Prescribing information]. Rockland, MA: EMD Serono, Inc.; 7/2022.
- DrugDex[®]. Available by subscription at <u>http://www.micromedexsolutions.com/home/dispatch</u>
- National Comprehensive Cancer Network. Bladder cancer (Version 3.2023). Available at http://www.nccn.org
- National Comprehensive Cancer Network. Gestational trophoblastic neoplasia (Version 1.2023). Available at <u>http://www.nccn.org</u>.
- National Comprehensive Cancer Network. Kidney cancer (Version 1.2024). Available at http://www.nccn.org
- National Comprehensive Cancer Network. Merkel cell carcinoma (Version 1.2023). Available at http://www.nccn.org
- National Comprehensive Cancer Network. Uterine neoplasms. (Version 2.2023). Available at http://www.nccn.org.
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(7) Policy Update

Date of last review: 3Q2023

Date of next review: 3Q2024

Changes from previous policy version:

No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity Reviewed by P&T Committee