Medical Policy:

Bavencio® (avelumab) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.39	April 2, 2024	

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Barhemsys (amisulpride) is a selective dopamine-2 (D 2) and dopamine-3 (D 3) receptor antagonist. D 2 receptors are located in the chemoreceptor trigger zone (CTZ) and respond to the dopamine released from the nerve endings. Activation of CTZ relays stimuli to the vomiting center which is involved in emesis. Studies in multiple species indicate that D 3 receptors in the area postrema also play a role in emesis.

Amisulpride has no appreciable affinity for any other receptor types apart from low affinities for 5-HT 2B and 5-HT 7 receptors.

Length of Authorization

Coverage will be provided for 6 months and may be renewed

Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

• 80 billable units (800 mg) every 14 days (all indications)

Guideline

I. INITIAL CRITERIA

Bavencio is considered medically necessary for the following indications when prescribed by an oncologist:

1. **Merkel Cell Carcinoma (MCC); both**:*
    A. ≥ 12 years of age**; AND**
    B. Presence of metastatic disease
2. **Urothelial Carcinoma; both**: *
    A. ≥ 18 years of age**; AND**
    B. Locally advanced or metastatic disease; **AND**
    C. Patient has tried platinum-containing chemotherapy (cisplatin or carboplatin)
3. **Advanced Renal Cell Carcinoma**
    A. ≥ 18 years of age; **AND**
    B. Diagnosis of advanced renal cell carcinoma; **AND**
    C. Being used as first-line treatment with axitinib in untreated patients

*= FDA-approved indication

++ = Compendia-recommended indication

Authorization

1. Initial authorization period of 6 months
2. Annual approval unless unacceptable toxicity occurs (i.e., ileus, transaminitis, elevated creatinine kinase, pericardial effusion, tubulointerstitial nephritis, etc.)

Limitations/Exclusions

Bavencio is considered investigational when used for any indication not listed above; including but not limited to:

1. Adrenocortical cancer
2. Breast cancer
3. Chordoma
4. Gastro-intestinal cancers (e.g., colorectal, esophageal, and gastric cancers)
5. Mesothelioma
6. Neuroendocrine cancer
7. Non-small cell lung cancer
8. Ovarian cancer
9. Pancreatic cancer
10. Prostate cancer
11. Spindle cell cancer

Dosing and Administration

Indication	Dose
All Indications	Administer 800 mg intravenously every 14 days, until disease progression or unacceptable toxicity
Dosing should be calculated using actual body weight and not flat dosing (as applicable) based on the following: Weight > 60 kg: Standard dose 800 mg IV every 2 weeks Weight is ≤ 60kg: Use 600 mg IV every 2 weeks *Note: This information is not meant to replace clinical decision making when initiating or modifying medication*	

therapy and should only be used as a guide. Patient-specific variables should be taken into account.

Applicable Procedure Codes

Code	Description
J9023	Injection, avelumab, 10 mg
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)
96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump
96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (List separately in addition to code for primary procedure)

Applicable NDCs

Code	Description
44087-3535-01	Bavencio 200mg/10mL Solution J9023 Injection, avelumab, 10 mg

ICD-10 Diagnoses

Code	Description
C4A.0	Merkel cell carcinoma of lip
C4A.4	Merkel cell carcinoma of scalp and neck
C4A.10	Merkel cell carcinoma of unspecified eyelid, including canthus
C4A.11	Merkel cell carcinoma of right eyelid, including canthus
C4A.12	Merkel cell carcinoma of left eyelid, including canthus
C4A.20	Merkel cell carcinoma of unspecified ear and external auricular canal
C4A.21	Merkel cell carcinoma of right ear and external auricular canal
C4A.22	Merkel cell carcinoma of left ear and external auricular canal
C4A.30	Merkel cell carcinoma of unspecified part of face
C4A.31	Merkel cell carcinoma of nose
C4A.39	Merkel cell carcinoma of other parts of face
C4A.51	Merkel cell carcinoma of anal skin
C4A.52	Merkel cell carcinoma of skin of breast
C4A.59	Merkel cell carcinoma of other part of trunk
C4A.60	Merkel cell carcinoma of unspecified upper limb, including shoulder
C4A.61	Merkel cell carcinoma of right upper limb, including shoulder
C4A.62	Merkel cell carcinoma of left upper limb, including shoulder
C4A.70	Merkel cell carcinoma of unspecified lower limb, including hip
C4A.72	Merkel cell carcinoma of left lower limb, including hip
C4A.8	Merkel cell carcinoma of overlapping sites
C4A.9	Merkel cell carcinoma, unspecified
C61	Malignant neoplasm of prostate
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis

C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C66.1	Malignant neoplasm of right ureter
C66.2	Malignant neoplasm of left ureter
C66.9	Malignant neoplasm of unspecified ureter
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C68.0	Malignant neoplasm of urethra
D09.0	Carcinoma in situ of bladder
Z85.51	Personal history of malignant neoplasm of bladder

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	4/2/2024	Annual Review: Added headers for length of authorization and dosing limits. Removed PI link, added dosing chart. Initial Criteria: Urothelial Carcinoma; Removed the following to reword: "Disease must have progressed during or following platinum-containing chemotherapy; OR Disease must have progressed within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; OR Maintenance treatment of patients with locally advanced or metastatic Urothelial Carcinoma that has not progressed with first-line platinum-containing chemotherapy." Added: "Patient has tried platinum-containing chemotherapy (cisplatin or carboplatin)"
EmblemHealth & ConnectiCare	7/27/2023	Annual Review: Advanced Renal Cell Carcinoma Initial Criteria: Removed "Patient does NOT have any autoimmune diseases or conditions requiring systemic immunosuppression; and Documentation that ALT or AST ≤ 5 times ULN; OR < 3 times ULN with concurrent total bilirubin ≤ 2 times ULN" Removed redundant Bladder Cancer/Urothelial Carcinoma; Initial Criteria^{++} a. Must be used as subsequent therapy b. Member is diagnosed with one: i. Disease recurrence post-cystectomy ii. Recurrent or metastatic Primary Carcinoma of the Urethra iii. Metastatic Urothelial Carcinoma of the Prostate iv. Metastatic Upper GU Tract Tumors v. Locally advanced or metastatic Urothelial Carcinoma"

EmblemHealth & ConnectiCare	3/30/2022	Transferred policy to new template – removed in-applicable procedure codes.
EmblemHealth & ConnectiCare	7/15/2020	Added new FDA approved indication for Urothelial carcinoma as maintenance therapy for advanced or metastatic disease that has not progressed during first line platinum-containing chemotherapy.
EmblemHealth & ConnectiCare	09/30/2019	Added the new indication and guidelines for Advanced Renal Cell Carcinoma. Removed Renal Cell Cancer from the Limitations/Exclusions

References

1. Bavencio [package insert]. New York, NY; EMD Serono, Inc; May 2017. Accessed September 30, 2019.
2. Kaufman HL, Russell J, Hamid O, et al. Avelumab in patients with chemotherapy refractory metastatic Merkel cell carcinoma: a multicenter, single-group, open-label, phase 2 trial. Lancet Oncol. 2016 Oct;17(10):1374-1385.
3. NCCN Clinical Practice Guidelines in Oncology®. © 2017 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on May 25, 2017.
    a. Bladder Cancer (V.5.2017). Revised May 25, 2017.
    b. Merkel Cell Carcinoma (V.1.2018). Revised September 18, 2017.
4. Specialty-matched clinical peer review.