

## Coding for BAVENCIO® (avelumab) Injection 20 mg/mL

BAVENCIO is indicated for:

- The treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC). This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials
- The maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy
- The treatment of patients with locally advanced or metastatic UC who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

BAVENCIO in combination with axitinib is indicated for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

Please refer to the tables below for examples of codes that may be appropriate for BAVENCIO for the treatment of its FDA-approved indications.

### Healthcare Common Procedure Coding System (HCPCS)

HCPCS coding requirements will vary by payer, setting of care, and date of service. Please verify patient-specific insurance benefits to confirm specific coding and billing guidelines for BAVENCIO.

HCPCS Code	HCPCS Description	Note
J9023	Injection, avelumab, 10 mg	For all payers and settings of care for which HCPCS codes are reported

- J9023 is effective for claims with dates of service on or after January 1, 2018<sup>1</sup>
- 1 unit of J9023 equals 10 mg of avelumab. As a result, 20 units of J9023 equals one 200 mg single-use vial of BAVENCIO, and 80 units equals 800 mg, the recommended dosage for BAVENCIO. Actual units reported will vary by dosage required for each individual patient, and any specific billing instructions required by the local payer
- Beginning January 1, 2017, Medicare claims require the use of the JW modifier (drug amount discarded/not administered to any patient) when applicable.<sup>2</sup> Other payers may have similar requirements
- If applicable for Medicare OPPS, the TB modifier (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes) should be reported by 340B providers between January 1, 2018 and September 30, 2020 since BAVENCIO was a transitional pass-through drug during that time. Effective October 1, 2020, the JG modifier (Drug or biological acquired with 340B drug pricing program discount) should be reported for applicable 340B providers submitting claims under the Medicare OPPS. 340B drug modifiers are subject to change in the future by CMS.

### National Drug Codes (NDCs)

BAVENCIO NDC (11-digit)	Description
44087-3535-01	BAVENCIO is supplied in a single-dose vial of 200 mg/10 mL (20 mg/mL) individually packed
AXITINIB NDCs (11-digit)	Description
00069-0145-01	1 mg tablets in bottles of 180
00069-0151-11	5 mg tablets in bottles of 60

### Current Procedural Terminology (CPT®) Codes for Drug Administration Service

The recommended dose of BAVENCIO is 800 mg administered as an intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity. In the event of grade 1 or 2 infusion-related reaction, the Dosage Modification section of the Prescribing Information directs providers to interrupt or slow the infusion rate. Please refer to the full BAVENCIO Prescribing Information for complete Dosage and Administration guidelines. When used in combination with axitinib for advanced RCC, also review the full Prescribing Information for axitinib prior to initiation.

CPT Code	CPT Code Description
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)

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## Revenue Codes (for Hospital Claims Only)

All hospital claim forms must include a revenue code for each charge line item. The following revenue codes are most relevant for physician-administered drugs.

Revenue Code <sup>3</sup>	Revenue Code Description
0636	Pharmacy – drugs requiring detailed coding
025X	Pharmacy

## Examples of ICD-10-CM<sup>4</sup> Diagnosis Codes for Metastatic Merkel Cell Carcinoma

Code	Code Description	Code	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.51	Merkel cell carcinoma of anal skin
C4A.111	Merkel cell carcinoma of right upper eyelid, including canthus	C4A.52	Merkel cell carcinoma of skin of breast
C4A.112	Merkel cell carcinoma of right lower eyelid, including canthus	C4A.59	Merkel cell carcinoma of other part of trunk
C4A.121	Merkel cell carcinoma of left upper eyelid, including canthus	C4A.60	Merkel cell carcinoma of unspecified upper limb, including shoulder
C4A.122	Merkel cell carcinoma of left lower eyelid, including canthus	C4A.61	Merkel cell carcinoma of right upper limb, including shoulder
C4A.20	Merkel cell carcinoma of unspecified ear and external auricular canal	C4A.62	Merkel cell carcinoma of left upper limb, including shoulder
C4A.21	Merkel cell carcinoma of right ear and external auricular canal	C4A.70	Merkel cell carcinoma of unspecified lower limb, including hip
C4A.22	Merkel cell carcinoma of left ear and external auricular canal	C4A.71	Merkel cell carcinoma of right lower limb, including hip
C4A.30	Merkel cell carcinoma of unspecified part of face	C4A.72	Merkel cell carcinoma of left lower limb, including hip
C4A.31	Merkel cell carcinoma of nose	C4A.8	Merkel cell carcinoma of overlapping sites
C4A.39	Merkel cell carcinoma of other parts of face	C4A.9	Merkel cell carcinoma, unspecified

## Examples of ICD-10-CM<sup>4</sup> Diagnosis Codes for Locally Advanced or Metastatic Urothelial Carcinoma

Code	Code Description	Code	Code Description
C67.0	Malignant neoplasm of trigone of bladder	C65.1	Malignant neoplasm of the right renal pelvis
C67.1	Malignant neoplasm of dome of bladder	C65.2	Malignant neoplasm of the left renal pelvis
C67.2	Malignant neoplasm of lateral wall of bladder	C65.9	Malignant neoplasm of the unspecified renal pelvis
C67.3	Malignant neoplasm of anterior wall of bladder	C66.1	Malignant neoplasm of the right ureter
C67.4	Malignant neoplasm of posterior wall of bladder	C66.2	Malignant neoplasm of the left ureter
C67.5	Malignant neoplasm of bladder neck	C66.9	Malignant neoplasm of the unspecified ureter
C67.6	Malignant neoplasm of ureteric orifice	C68.0	Malignant neoplasm of urethra
C67.7	Malignant neoplasm of urachus	C61	Malignant neoplasm of prostate (reporting "urothelial carcinoma of the prostate")
C67.8	Malignant neoplasm of overlapping sites of bladder	Z85.51	Personal history of malignant neoplasm of bladder
C67.9	Malignant neoplasm of bladder, unspecified	D09.0	Carcinoma in situ of bladder

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Examples of ICD-10-CM<sup>4</sup> Diagnosis Codes for Advanced Renal Cell Carcinoma

Code	Code Description	Code	Code Description
C64.1	Malignant neoplasm of right kidney, except renal pelvis	C65.1	Malignant neoplasm of the right renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis	C65.2	Malignant neoplasm of the left renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis	C65.9	Malignant neoplasm of the unspecified renal pelvis

Please contact **CoverOne® at 1-844-8COVER1 (844-826-8371)** for support with payer-specific BAVENCIO® (avelumab) questions or assistance verifying insurance benefits for a specific patient.

Pfizer Oncology Together™ provides personalized support and financial assistance resources to help patients access their prescribed axitinib. To learn more, call **1-877-744-5675** (Monday–Friday 8 AM–8 PM ET) or visit

[PfizerOncologyTogether.com](https://www.pfizeroncologytogether.com).

**This document is for informational purposes only. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for products and services rendered. EMD Serono, Inc. and Pfizer Inc do not guarantee coverage and/or reimbursement for BAVENCIO. Coverage, coding, and reimbursement policies vary significantly by payer, patient, and setting of care. Actual coverage and reimbursement decisions are made by individual payers following the receipt of claims. Patients and healthcare professionals should always verify coverage, coding, and reimbursement guidelines on a payer- and patient-specific basis.**

<sup>1</sup>Centers for Medicare and Medicaid Services (CMS), October 2020 Alpha-Numeric HCPCS File, November 2020. <sup>2</sup>Source: Centers for Medicare and Medicaid Services. Transmittal R3538CP: JW Modifier: Drug amount discarded/not administered to any patient. <sup>3</sup>Revenue code 0636 is required by Medicare. For payers other than Medicare, the revenue code may vary; although some private payers and Medicaid plans accept revenue code 0636, others may require a different revenue code, such as 0250. <sup>4</sup>International Classification of Diseases, 10th Revision, Clinical Modification.

## IMPORTANT SAFETY INFORMATION FOR BAVENCIO® (avelumab) Injection 20 mg/mL

BAVENCIO can cause **severe and fatal immune-mediated adverse reactions** in any organ system or tissue and at any time after starting treatment with a PD-1/PD-L1 blocking antibody, including after discontinuation of treatment.

**Early identification and management of immune-mediated adverse reactions are essential** to ensure safe use of PD-1/PD-L1 blocking antibodies. Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

**No dose reduction for BAVENCIO is recommended. For immune-mediated adverse reactions, withhold or permanently discontinue BAVENCIO depending on severity.** In general, withhold BAVENCIO for severe (Grade 3) immune-mediated adverse reactions. Permanently discontinue BAVENCIO for life-threatening (Grade 4) immune-mediated adverse reactions, recurrent severe (Grade 3) immune-mediated reactions that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks of initiating corticosteroids. In general, if BAVENCIO requires interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroid therapy. Toxicity management guidelines for adverse reactions that do not necessarily require systemic corticosteroids (eg, endocrinopathies and dermatologic reactions) are discussed in subsequent sections.

BAVENCIO can cause **immune-mediated pneumonitis**. Withhold BAVENCIO for Grade 2, and permanently discontinue for Grade 3 or Grade 4 pneumonitis. Immune-mediated pneumonitis occurred in 1.2% (21/1738) of patients, including fatal (0.1%), Grade 4 (0.1%), Grade 3 (0.3%), and Grade 2 (0.6%) adverse reactions. Systemic corticosteroids were required in all (21/21) patients with pneumonitis.

BAVENCIO can cause **immune-mediated colitis**. The primary component of immune-mediated colitis consisted of diarrhea. Cytomegalovirus infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies. Withhold BAVENCIO for Grade 2 or Grade 3, and permanently discontinue for Grade 4 colitis. Immune-mediated colitis occurred in 1.5% (26/1738) of patients, including Grade 3 (0.4%) and Grade 2 (0.7%) adverse reactions. Systemic corticosteroids were required in all (26/26) patients with colitis.

BAVENCIO can cause **hepatotoxicity and immune-mediated hepatitis**. Withhold or permanently discontinue BAVENCIO based on tumor involvement of the liver and severity of aspartate aminotransferase (AST), alanine aminotransferase (ALT), or total bilirubin elevation. Immune-mediated hepatitis occurred with BAVENCIO as a single agent in 0.9% (16/1738) of patients, including fatal (0.1%), Grade 3 (0.6%), and Grade 2 (0.1%) adverse reactions. Systemic corticosteroids were required in all (16/16) patients with hepatitis.

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**IMPORTANT SAFETY INFORMATION FOR BAVENCIO® (avelumab) Injection 20 mg/mL (cont'd)**

BAVENCIO **in combination with axitinib** can cause **hepatotoxicity** with higher than expected frequencies of Grade 3 and 4 ALT and AST elevation compared to BAVENCIO alone. Consider more frequent monitoring of liver enzymes as compared to when the drugs are used as monotherapy. Withhold or permanently discontinue both BAVENCIO and axitinib based on severity of AST, ALT, or total bilirubin elevation, and consider administering corticosteroids as needed. Consider rechallenge with BAVENCIO or axitinib, or sequential rechallenge with both BAVENCIO and axitinib, after recovery. In patients treated with BAVENCIO in combination with axitinib in the advanced RCC trials, increased ALT and increased AST were reported in 9% (Grade 3) and 7% (Grade 4) of patients. Immune-mediated hepatitis was reported in 7% of patients including 4.9% with Grade 3 or 4 immune-mediated hepatitis. Thirty-four patients were treated with corticosteroids and one patient was treated with a non-steroidal immunosuppressant.

BAVENCIO can cause primary or secondary **immune-mediated adrenal insufficiency**. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement, as clinically indicated. Withhold BAVENCIO for Grade 3 or Grade 4 endocrinopathies until clinically stable or permanently discontinue depending on severity. Immune-mediated adrenal insufficiency occurred in 0.5% (8/1738) of patients, including Grade 3 (0.1%) and Grade 2 (0.3%) adverse reactions. Systemic corticosteroids were required in all (8/8) patients with adrenal insufficiency.

BAVENCIO can cause **immune-mediated hypophysitis**. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement, as clinically indicated. Withhold BAVENCIO for Grade 3 or Grade 4 endocrinopathies until clinically stable or permanently discontinue depending on severity. Immune-mediated pituitary disorders occurred in 0.1% (1/1738) of patients, which was a Grade 2 (0.1%) adverse reaction.

BAVENCIO can cause **immune-mediated thyroid disorders**. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or institute medical management of hyperthyroidism, as clinically indicated. Withhold BAVENCIO for Grade 3 or Grade 4 endocrinopathies until clinically stable or permanently discontinue depending on severity. Thyroiditis occurred in 0.2% (4/1738) of patients, including Grade 2 (0.1%) adverse reactions. Hyperthyroidism occurred in 0.4% (7/1738) of patients, including Grade 2 (0.3%) adverse reactions. Systemic corticosteroids were required in 29% (2/7) of patients with hyperthyroidism. Hypothyroidism occurred in 5% (90/1738) of patients, including Grade 3 (0.2%) and Grade 2 (3.7%) adverse reactions. Systemic corticosteroids were required in 7% (6/90) of patients with hypothyroidism.

BAVENCIO can cause **immune-mediated type I diabetes mellitus**, which can present with diabetic ketoacidosis. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold BAVENCIO for Grade 3 or Grade 4 endocrinopathies until clinically stable or permanently discontinue depending on severity. Immune-mediated type I diabetes mellitus occurred in 0.1% (2/1738) of patients, including Grade 3 (0.1%) adverse reactions.

BAVENCIO can cause **immune-mediated nephritis with renal dysfunction**. Withhold BAVENCIO for Grade 2 or Grade 3, and permanently discontinue for Grade 4 increased blood creatinine. Immune-mediated nephritis with renal dysfunction occurred in 0.1% (1/1738) of patients, which was a Grade 2 (0.1%) adverse reaction. Systemic corticosteroids were required in this patient.

BAVENCIO can cause **immune-mediated dermatologic adverse reactions**, including rash or dermatitis. Exfoliative dermatitis including Stevens Johnson Syndrome (SJS), drug rash with eosinophilia and systemic symptoms (DRESS), and toxic epidermal necrolysis (TEN), has occurred with PD-1/PD-L1 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Withhold BAVENCIO for suspected and permanently discontinue for confirmed SJS, TEN, or DRESS. Immune-mediated dermatologic adverse reactions occurred in 5% (90/1738) of patients, including Grade 3 (0.1%) and Grade 2 (2.0%) adverse reactions. Systemic corticosteroids were required in 29% (26/90) of patients with dermatologic adverse reactions.

BAVENCIO can result in **other immune-mediated adverse reactions**. Other clinically significant immune-mediated adverse reactions occurred at an incidence of <1% in patients who received BAVENCIO or were reported with the use of other PD-1/PD-L1 blocking antibodies. For **myocarditis**, permanently discontinue BAVENCIO for Grade 2, Grade 3, or Grade 4. For **neurological toxicities**, withhold BAVENCIO for Grade 2 and permanently discontinue for Grade 3 or Grade 4.

BAVENCIO can cause severe or life-threatening **infusion-related reactions**. Premedicate patients with an antihistamine and acetaminophen prior to the first 4 infusions and for subsequent infusions based upon clinical judgment and presence/severity of prior infusion reactions. Monitor patients for signs and symptoms of infusion-related reactions, including pyrexia, chills, flushing, hypotension, dyspnea, wheezing, back pain, abdominal pain, and urticaria. Interrupt or slow the rate of infusion for Grade 1 or Grade 2 infusion-related reactions. Permanently discontinue BAVENCIO for Grade 3 or Grade 4 infusion-related reactions. Infusion-related reactions occurred in 25% of patients, including three (0.2%) Grade 4 and nine (0.5%) Grade 3 infusion-related reactions. Eleven (92%) of the 12 patients with Grade ≥3 reactions were treated with intravenous corticosteroids.

Fatal and other serious **complications of allogeneic hematopoietic stem cell transplantation (HSCT)** can occur in patients who receive HSCT before or after being treated with a PD-1/PD-L1 blocking antibody. Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1 blocking antibody prior to or after an allogeneic HSCT.

BAVENCIO **in combination with axitinib** can cause **major adverse cardiovascular events (MACE)** including severe and fatal events. Consider baseline and periodic evaluations of left ventricular ejection fraction. Monitor for signs and symptoms of cardiovascular events. Optimize management of cardiovascular risk factors, such as hypertension, diabetes, or dyslipidemia. Permanently discontinue BAVENCIO and axitinib for Grade 3-4 cardiovascular events. MACE occurred in 7% of patients with advanced RCC treated with BAVENCIO in combination with axitinib compared to 3.4% treated with sunitinib in a randomized trial. These events included death due to cardiac events (1.4%), Grade 3-4 myocardial infarction (2.8%), and Grade 3-4 congestive heart failure (1.8%).

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**IMPORTANT SAFETY INFORMATION FOR BAVENCIO® (avelumab) Injection 20 mg/mL (cont'd)**

BAVENCIO can cause **fetal harm** when administered to a pregnant woman. Advise patients of the potential risk to a fetus including the risk of fetal death. Advise females of childbearing potential to use effective contraception during treatment with BAVENCIO and for at least 1 month after the last dose of BAVENCIO. It is not known whether BAVENCIO is excreted in human milk. Advise a lactating woman **not to breastfeed** during treatment and for at least 1 month after the last dose of BAVENCIO due to the potential for serious adverse reactions in breastfed infants.

**The most common adverse reactions** (all grades, ≥20%) in patients with **metastatic Merkel cell carcinoma (MCC)** were fatigue (50%), musculoskeletal pain (32%), diarrhea (23%), nausea (22%), infusion-related reaction (22%), rash (22%), decreased appetite (20%), and peripheral edema (20%).

**Selected treatment-emergent laboratory abnormalities** (all grades, ≥20%) in patients with **metastatic MCC** were lymphopenia (49%), anemia (35%), increased aspartate aminotransferase (34%), thrombocytopenia (27%), and increased alanine aminotransferase (20%).

A **fatal adverse reaction** (sepsis) occurred in one (0.3%) patient with **locally advanced or metastatic urothelial carcinoma (UC)** receiving BAVENCIO + best supportive care (BSC) as first-line maintenance treatment. In patients with previously treated locally advanced or metastatic UC, fourteen patients (6%) who were treated with BAVENCIO experienced either pneumonitis, respiratory failure, sepsis/urosepsis, cerebrovascular accident, or gastrointestinal adverse events, which led to death.

**The most common adverse reactions** (all grades, ≥20%) in patients with **locally advanced or metastatic UC** receiving BAVENCIO + BSC (vs BSC alone) as first-line maintenance treatment were fatigue (35% vs 13%), musculoskeletal pain (24% vs 15%), urinary tract infection (20% vs 11%), and rash (20% vs 2.3%). In patients with previously treated locally advanced or metastatic UC receiving BAVENCIO, the most common adverse reactions (all grades, ≥20%) were fatigue, infusion-related reaction, musculoskeletal pain, nausea, decreased appetite, and urinary tract infection.

**Selected laboratory abnormalities** (all grades, ≥20%) in patients with **locally advanced or metastatic UC** receiving BAVENCIO + BSC (vs BSC alone) as first-line maintenance treatment were blood triglycerides increased (34% vs 28%), alkaline phosphatase increased (30% vs 20%), blood sodium decreased (28% vs 20%), lipase increased (25% vs 16%), aspartate aminotransferase (AST) increased (24% vs 12%), blood potassium increased (24% vs 16%), alanine aminotransferase (ALT) increased (24% vs 12%), blood cholesterol increased (22% vs 16%), serum amylase increased (21% vs 12%), hemoglobin decreased (28% vs 18%), and white blood cell decreased (20% vs 10%).

**Fatal adverse reactions** occurred in 1.8% of patients with **advanced renal cell carcinoma (RCC)** receiving BAVENCIO in combination with axitinib. These included sudden cardiac death (1.2%), stroke (0.2%), myocarditis (0.2%), and necrotizing pancreatitis (0.2%).

**The most common adverse reactions** (all grades, ≥20%) in patients with **advanced RCC** receiving BAVENCIO in combination with axitinib (vs sunitinib) were diarrhea (62% vs 48%), fatigue (53% vs 54%), hypertension (50% vs 36%), musculoskeletal pain (40% vs 33%), nausea (34% vs 39%), mucositis (34% vs 35%), palmar-plantar erythrodysesthesia (33% vs 34%), dysphonia (31% vs 3.2%), decreased appetite (26% vs 29%), hypothyroidism (25% vs 14%), rash (25% vs 16%), hepatotoxicity (24% vs 18%), cough (23% vs 19%), dyspnea (23% vs 16%), abdominal pain (22% vs 19%), and headache (21% vs 16%).

**Selected laboratory abnormalities** (all grades, ≥20%) worsening from baseline in patients with **advanced RCC** receiving BAVENCIO in combination with axitinib (vs sunitinib) were blood triglycerides increased (71% vs 48%), blood creatinine increased (62% vs 68%), blood cholesterol increased (57% vs 22%), alanine aminotransferase increased (ALT) (50% vs 46%), aspartate aminotransferase increased (AST) (47% vs 57%), blood sodium decreased (38% vs 37%), lipase increased (37% vs 25%), blood potassium increased (35% vs 28%), platelet count decreased (27% vs 80%), blood bilirubin increased (21% vs 23%), and hemoglobin decreased (21% vs 65%).

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