BAVENCIO®
avelumab Injection 20 mg/mL

Coverage, Coding, and Payment Guide

J9023 - Injection, avelumab, 10 mg

Please see Important Safety Information on pages 13-15.
Click for full Prescribing Information and Medication Guide, or visit BAVENCIO.com.

CoverOne®

CoverOne® provides patient access and reimbursement support services to help eligible patients gain appropriate access to BAVENCIO® (avelumab) Injection 20 mg/mL in the United States.

We recognize that each patient's situation is different, and are dedicated to helping eligible patients one at a time.

844-8COVER1
(844-826-8371)
Monday–Friday
8:00 AM–8:00 PM ET

855-737-7671
(FOR BAVENCIO AND AXITINIB COMBINATION)
800-214-7295
(FOR BAVENCIO SINGLE-AGENT USE)

CoverOne.com

INDICATIONS

BAVENCIO® (avelumab) 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).

SELECTED SAFETY INFORMATION

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.

Please see Important Safety Information on pages 13-15.
Click for full Prescribing Information and Medication Guide, or visit BAVENCIO.com.

Table of Contents

BAVENCIO® avelumab Injection 20 mg/mL

Coverage, coding, and payment for BAVENCIO® (avelumab) Injection 20 mg/mL will vary by payer, plan, setting of care, and patient. The information in this guide provides a general coverage, coding, and payment framework for BAVENCIO across major payer segments. Healthcare professionals should always verify coverage, coding, and payment guidelines on a patient-specific basis.

The CoverOne® program provides patient access and reimbursement support services, and may be reached by calling **1-844-8COVER1 (844-826-8371)**.

Commonly Used Billing Codes for BAVENCIO

The codes discussed below may be appropriate when billing for BAVENCIO and its administration for the treatment of its FDA-approved indications.

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.

National Drug Codes (NDCs)

BAVENCIO NDC (11-digit)	Packaging
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)	**Packaging**
00069-0145-01	1 mg tablets in bottles of 180
00069-0151-11	5 mg tablets in bottles of 60

When used in combination with axitinib for first-line advanced RCC, review the full Prescribing Information for axitinib prior to initiation.

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**.

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	Description	Payer and Setting of Care
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[1]
- 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® (avelumab) Injection 20 mg/mL, 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. Other payers may have similar requirements[2]

The recommended dosage 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 a 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, review the full Prescribing Information for axitinib prior to initiation.

Current Procedural Terminology (CPT®)* Code for Drug Administration Service

CPT®	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)

The appropriate CPT® code for the administration of BAVENCIO will depend on the actual service performed. Providers should consult a current CPT® manual and always select the code that accurately describes the administration service based on the specific patient encounter.

Revenue Codes—For Use in the Hospital Setting 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.

Code	Code Description
0636	Pharmacy—Drugs Requiring Detailed Coding
025X	Pharmacy

Revenue code 0636 is required on Medicare hospital outpatient claims. 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.

Each CPT® code must be reported with a revenue code, which may vary depending on the type of procedure and the cost center in which the procedure is performed.

Revenue codes are not used in the physician office setting.

BAVENCIO® avelumab Injection 20 mg/mL

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes

All hospital and physician office claims must include at least one ICD-10-CM diagnosis code to describe the patient's condition.

Advanced Renal Cell Carcinoma

ICD-10-CM	Description
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

Metastatic Merkel Cell Carcinoma

ICD-10-CM	Description
C4A.0	Merkel cell carcinoma of lip
C4A.10	Merkel cell carcinoma of unspecified eyelid, including canthus
C4A.111	Merkel cell carcinoma of right upper eyelid, including canthus
C4A.112	Merkel cell carcinoma of right lower eyelid, including canthus
C4A.121	Merkel cell carcinoma of left upper eyelid, including canthus
C4A.122	Merkel cell carcinoma of left lower 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.4	Merkel cell carcinoma of scalp and neck
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

The ICD-10-CM diagnosis codes listed above are provided only as examples of potentially relevant codes. Providers should consult a current ICD-10-CM manual and always select the most appropriate diagnosis code(s) with the highest level of specificity to describe a patient's actual condition. All diagnosis codes should be supported with adequate documentation in the patient's medical record.

Please see Important Safety Information on pages 13-15.
Click for full Prescribing Information and Medication Guide, or visit BAVENCIO.com.

ICD-10-CM Diagnosis Codes (continued)

Metastatic Merkel Cell Carcinoma (continued)

ICD-10-CM	Description
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.71	Merkel cell carcinoma of right 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

Locally Advanced or Metastatic Urothelial Carcinoma

Code	Code Description
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
C67.9	Malignant neoplasm of bladder, unspecified
C65.1	Malignant neoplasm of the right renal pelvis
C65.2	Malignant neoplasm of the left renal pelvis
C65.9	Malignant neoplasm of the unspecified renal pelvis
C66.1	Malignant neoplasm of the right ureter
C66.2	Malignant neoplasm of the left ureter
C66.9	Malignant neoplasm of the unspecified ureter
C68.0	Malignant neoplasm of urethra
C61	Malignant neoplasm of prostate (reporting "urothelial carcinoma of the prostate")
Z85.51	Personal history of malignant neoplasm of bladder
D09.0	Carcinoma in situ of bladder

The ICD-10-CM diagnosis codes listed above are provided only as examples of potentially relevant codes. Providers should consult a current ICD-10-CM manual and always select the most appropriate diagnosis code(s) with the highest level of specificity to describe a patient's actual condition. All diagnosis codes should be supported with adequate documentation in the patient's medical record.

BAVENCIO® avelumab Injection 20 mg/mL

Medicare Fee-For-Service

BAVENCIO® (avelumab) Injection 20 mg/mL is eligible for Medicare Part B fee-for-service coverage when used for its FDA-approved indication and administered "incident to" a physician's service, and when reasonable and necessary for an individual patient.[3]

Medicare Administrative Contractors (MACs) have the discretion to issue Local Coverage Determinations (LCDs) or other written coverage and coding guidance for BAVENCIO. Medicare Part B claims for BAVENCIO in the physician office and hospital outpatient settings should be billed with HCPCS code J9023 (Injection, avelumab, 10 mg) for dates of service on or after January 1, 2018.

Beginning January 1, 2017, Medicare claims require the use of the JW modifier (drug amount discarded/not administered to any patient) when applicable.[2]

Medicare Part B payment for BAVENCIO in the physician office setting and Medicare Outpatient Prospective Payment System (OPPS) hospital outpatient setting is currently based on Average Sales Price + 6% except for applicable OPPS transactions when the drug is acquired through the 340B program as described below.[4,5]

Medicare payments are subject to 2% sequestration reductions as required under the Budget Control Act of 2011 (P.L. 112-25). CMS updates Part B drug payment rates on a quarterly basis.[6] The CARES Act temporarily suspended sequestration between May 1 and December 30, 2020. Additionally, *The Consolidated Appropriations Act, 2021* (Public Law 116-260) extended the sequestration suspension through March 2021, and *An Act to Prevent Across the Board Direct Spending Cuts, and for Other Purposes* (Public Law 117-7), extends the sequestration suspension through December 31, 2021. Please refer to your regional MAC for current guidance related to sequestration.[7]

Medicare OPPS Payment Policy for Certain Drugs Acquired Through the 340B Program by Certain 340B Covered Entities

According to CMS policy, "Beginning January 1, 2018, Medicare will pay an adjusted amount of the average sales price (ASP) minus 22.5 percent for certain separately payable drugs or biologicals (hereafter referred to as drug or drugs) that are acquired through the 340B Program and furnished to a Medicare beneficiary by a hospital paid under the OPPS that is not excepted from the payment adjustment policy."

Additionally, "For CY 2018, CMS designated rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals are excepted from the 340B payment adjustment." CMS has also stated that this new policy does not apply to Critical Access Hospitals or Maryland Waiver hospitals, neither of which are paid under the Medicare OPPS.[8]

Effective October 1, 2020, BAVENCIO was re-designated a non pass-through separately reimbursed drug under OPPS with Status Indicator "K". As a result, OPPS payment for BAVENCIO when acquired under the 340B program is made at the single rate of ASP – 22.5% as of October 1, 2020.

340B providers should report applicable BAVENCIO claims to Medicare OPPS using the JG modifier (drug or biological acquired with 340B drug pricing program discount).

Modifier "JG" - Drug or biological acquired with 340B drug pricing program discount.

It is also important to note that Medicare will continue to pay for separately payable drugs **that were not acquired through the 340B Program** and furnished by a hospital paid under the OPPS at ASP + 6%.

NOTE: This CMS Medicare reimbursement policy for certain 340B covered entities is subject to change in the future.

Please contact your local MAC or the CoverOne® program to verify specific BAVENCIO coverage, coding, and payment details for your geographic area and clinical care setting. The CoverOne program is available to assist patients and providers and may be reached by calling 1-844-8COVER1 (844-826-8371).

Medicare Advantage

Medicare Advantage plans must provide access to all Part A and Part B benefits that would be available in Original Medicare Fee-for-Service.[9] However, Medicare Advantage plans may require prior authorization for BAVENCIO. Additionally, starting in 2019, Medicare Advantage plans have the discretion to use step therapy limits for Part B drugs under certain circumstances. This CMS guidance recognizes that MA plans may apply step therapy for Part B drugs as long as it does not create an undue access barrier for beneficiaries.[a] Contact CoverOne or the Medicare Advantage plan directly to confirm plan-specific coverage requirements.

[a]CMS Memo to MA Plans, Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage, August 7, 2018.

IMPORTANT NOTE:

Many Medicare enrollees receive coverage through a Medicare Advantage plan. Reimbursement policies under these plans may differ from those of traditional Medicare and may vary from plan to plan.

Medicaid

Medicaid coverage, coding, and payment policies will vary by state Medicaid program and should be verified for each particular state. In addition, some Medicaid plans may require prior authorization for BAVENCIO® (avelumab) Injection 20 mg/mL.

HCPCS code J9023 (Injection, avelumab, 10 mg) should be used to bill for BAVENCIO in the physician office and hospital outpatient settings, unless otherwise directed by the state Medicaid program. Providers are also required to report the 11-digit NDC on Medicaid claims for all provider-administered drugs.

Medicaid programs use a variety of payment methodologies for drugs and biologicals in the physician office setting, including Average Wholesale Price (AWP),[b] ASP, state-specific fee schedules, or percentage of charges.

Medicaid programs use a variety of payment methodologies for drugs and biologicals in the hospital outpatient setting, including AWP, ASP, ambulatory payment groups, state-specific fee schedules, preset per-diem/per-visit rates, or percentage of charges.

There is significant variation in Medicaid payment amounts among states. Providers should verify payment rates for their state Medicaid program.

The CoverOne® program is available to assist patients and providers in verifying state Medicaid policies for BAVENCIO and may be reached by calling **1-844-8COVER1 (844-826-8371)**.

IMPORTANT NOTE:

Many Medicaid enrollees receive coverage through Medicaid managed care plans. Coverage and payment policies under these plans may differ from those of traditional Medicaid and may vary from plan to plan.

[b]AWP is set by certain third-party pricing services. EMD Serono, Inc. and Pfizer Inc do not set AWP.

Commercial Payers

Coverage, coding, and payment guidelines vary significantly by private/commercial payer, plan, setting of care, and patient. Additionally, benefits may also depend on the specific contract terms that a provider negotiates with a given plan. Patients and providers should verify patient-specific benefits to determine if BAVENCIO is covered under each specific plan and if prior authorization is required.

HCPCS code J9023 (Injection, avelumab, 10 mg) should be used to bill for BAVENCIO in the physician and hospital outpatient settings, unless otherwise directed by the private/commercial payer. Many private payers also require the reporting of 11-digit NDC codes in addition to HCPCS codes.

Private insurers use a variety of payment methodologies for drugs and biologicals administered in the physician office and hospital outpatient settings, including AWP, ASP, invoice, or percentage of charges.

The exact payment mechanism used by a specific payer usually depends on the provider's contractual agreement with that payer.

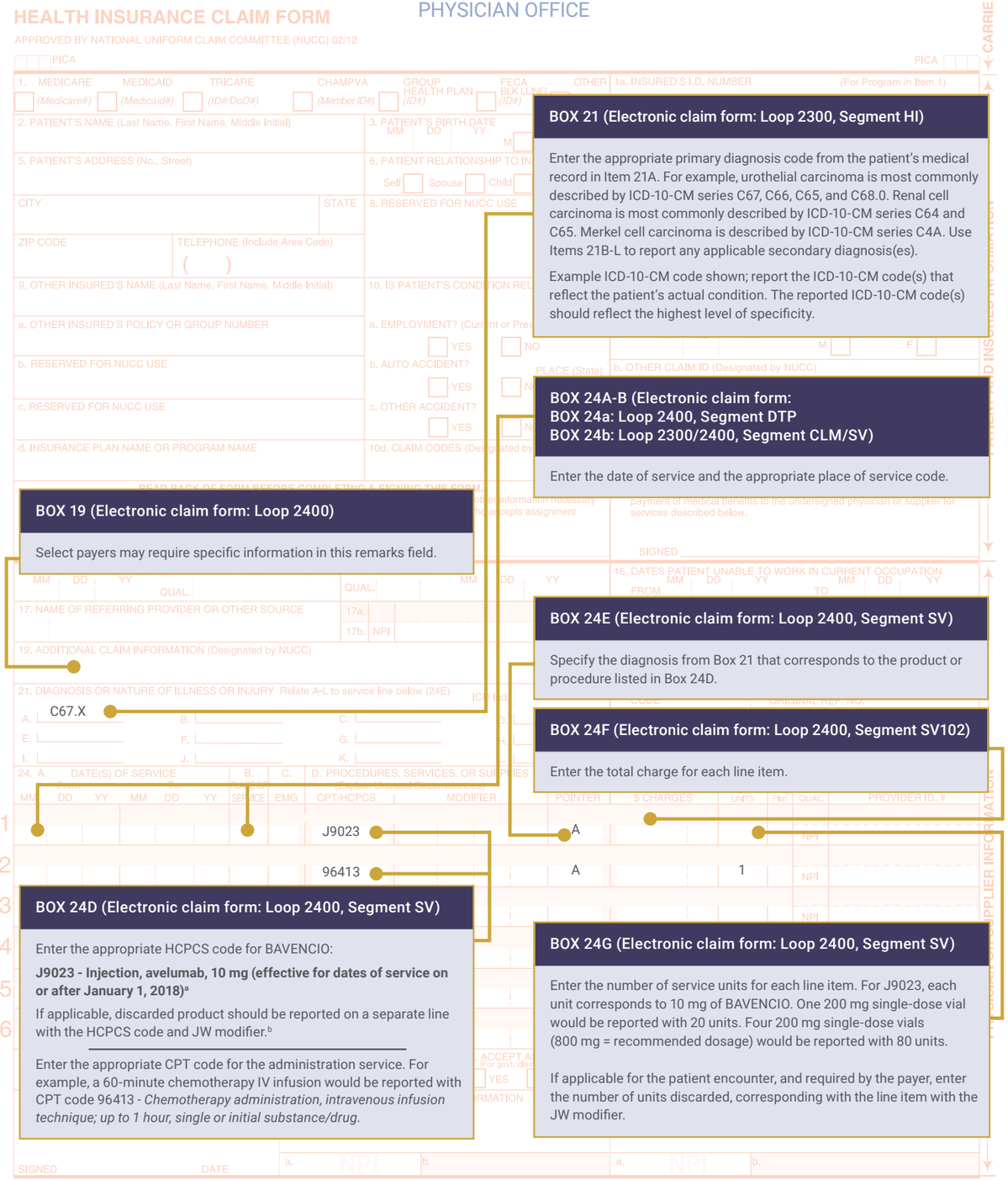
The CoverOne program is available to assist patients and providers in verifying private insurance benefits and may be reached by calling **1-844-8COVER1 (844-826-8371)**.

BAVENCIO® avelumab Injection 20 mg/mL

SAMPLE CMS-1500 Claim Form for BAVENCIO® (avelumab) Injection 20 mg/mL

CoverOne®

PHYSICIAN OFFICE



BOX 21 (Electronic claim form: Loop 2300, Segment HI)

Enter the appropriate primary diagnosis code from the patient's medical record in Item 21A. For example, urothelial carcinoma is most commonly described by ICD-10-CM series C67, C66, C65, and C68.0. Renal cell carcinoma is most commonly described by ICD-10-CM series C64 and C65. Merkel cell carcinoma is described by ICD-10-CM series C4A. Use Items 21B-L to report any applicable secondary diagnosis(es).

Example ICD-10-CM code shown; report the ICD-10-CM code(s) that reflect the patient's actual condition. The reported ICD-10-CM code(s) should reflect the highest level of specificity.

BOX 24A-B (Electronic claim form: BOX 24a: Loop 2400, Segment DTP BOX 24b: Loop 2300/2400, Segment CLM/SV)

Enter the date of service and the appropriate place of service code.

BOX 19 (Electronic claim form: Loop 2400)

Select payers may require specific information in this remarks field.

BOX 24E (Electronic claim form: Loop 2400, Segment SV)

Specify the diagnosis from Box 21 that corresponds to the product or procedure listed in Box 24D.

BOX 24F (Electronic claim form: Loop 2400, Segment SV102)

Enter the total charge for each line item.

BOX 24D (Electronic claim form: Loop 2400, Segment SV)

Enter the appropriate HCPCS code for BAVENCIO:

J9023 - Injection, avelumab, 10 mg (effective for dates of service on or after January 1, 2018)[a]

If applicable, discarded product should be reported on a separate line with the HCPCS code and JW modifier.[b]

Enter the appropriate CPT code for the administration service. For example, a 60-minute chemotherapy IV infusion would be reported with CPT code 96413 - *Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.*

BOX 24G (Electronic claim form: Loop 2400, Segment SV)

Enter the number of service units for each line item. For J9023, each unit corresponds to 10 mg of BAVENCIO. One 200 mg single-dose vial would be reported with 20 units. Four 200 mg single-dose vials (800 mg = recommended dosage) would be reported with 80 units.

If applicable for the patient encounter, and required by the payer, enter the number of units discarded, corresponding with the line item with the JW modifier.

[a]Source: Centers for Medicare and Medicaid Services, 2021 Alpha-Numeric Healthcare Common Procedure Coding System File, October 2021.

[b]Beginning January 1, 2017, Medicare claims require the use of the JW modifier (drug amount discarded/not administered to any patient) when applicable. (Source: Centers for Medicare and Medicaid Services. Transmittal R3538CP: JW Modifier—Drug amount discarded/not administered to any patient.) Other payers may have similar requirements.

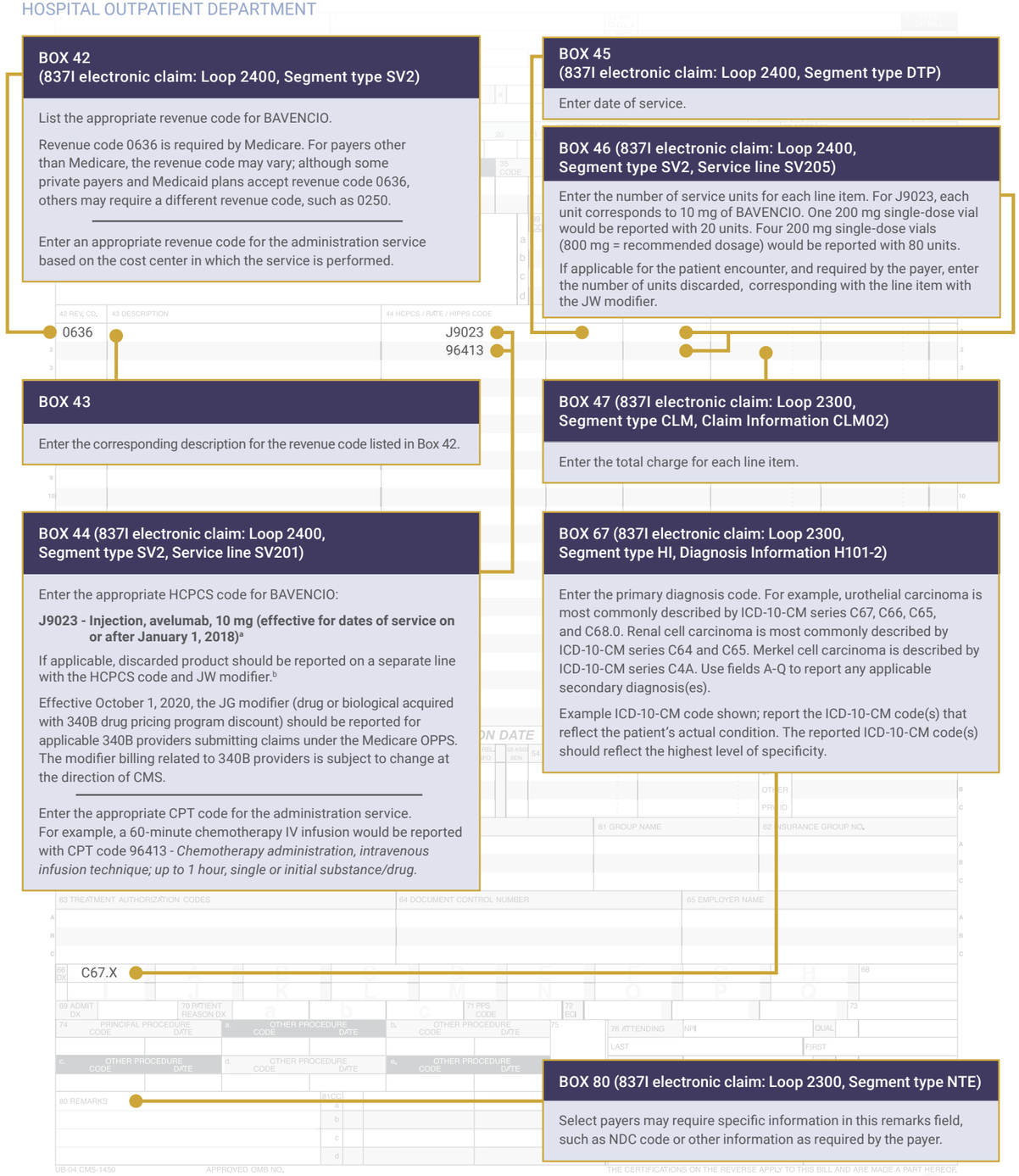
It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for products and services rendered. EMD Serono, Inc. and Pfizer Inc do not guarantee coverage and/or reimbursement for BAVENCIO. Coverage, coding, and reimbursement policies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

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

SAMPLE UB-04/CMS-1450 Claim Form for BAVENCIO® (avelumab) Injection 20 mg/mL

CoverOne®

HOSPITAL OUTPATIENT DEPARTMENT



BOX 42 (837I electronic claim: Loop 2400, Segment type SV2)

List the appropriate revenue code for BAVENCIO.

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.

Enter an appropriate revenue code for the administration service based on the cost center in which the service is performed.

BOX 45 (837I electronic claim: Loop 2400, Segment type DTP)

Enter date of service.

BOX 46 (837I electronic claim: Loop 2400, Segment type SV2, Service line SV205)

Enter the number of service units for each line item. For J9023, each unit corresponds to 10 mg of BAVENCIO. One 200 mg single-dose vial would be reported with 20 units. Four 200 mg single-dose vials (800 mg = recommended dosage) would be reported with 80 units.

If applicable for the patient encounter, and required by the payer, enter the number of units discarded, corresponding with the line item with the JW modifier.

BOX 43

Enter the corresponding description for the revenue code listed in Box 42.

BOX 47 (837I electronic claim: Loop 2300, Segment type CLM, Claim Information CLM02)

Enter the total charge for each line item.

BOX 44 (837I electronic claim: Loop 2400, Segment type SV2, Service line SV201)

Enter the appropriate HCPCS code for BAVENCIO:

J9023 - Injection, avelumab, 10 mg (effective for dates of service on or after January 1, 2018)[a]

If applicable, discarded product should be reported on a separate line with the HCPCS code and JW modifier.[b]

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. The modifier billing related to 340B providers is subject to change at the direction of CMS.

Enter the appropriate CPT code for the administration service. For example, a 60-minute chemotherapy IV infusion would be reported with CPT code 96413 - *Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.*

BOX 67 (837I electronic claim: Loop 2300, Segment type HI, Diagnosis Information H101-2)

Enter the primary diagnosis code. For example, urothelial carcinoma is most commonly described by ICD-10-CM series C67, C66, C65, and C68.0. Renal cell carcinoma is most commonly described by ICD-10-CM series C64 and C65. Merkel cell carcinoma is described by ICD-10-CM series C4A. Use fields A-Q to report any applicable secondary diagnosis(es).

Example ICD-10-CM code shown; report the ICD-10-CM code(s) that reflect the patient's actual condition. The reported ICD-10-CM code(s) should reflect the highest level of specificity.

BOX 80 (837I electronic claim: Loop 2300, Segment type NTE)

Select payers may require specific information in this remarks field, such as NDC code or other information as required by the payer.

[a]Centers for Medicare and Medicaid Services (CMS), 2021 Alpha-Numeric Healthcare Common Procedure Coding System File, October 2021.

[b]Beginning January 1, 2017, Medicare claims require the use of the JW modifier (drug amount discarded/not administered to any patient) when applicable. (Source: Centers for Medicare and Medicaid Services. Transmittal R3538CP: JW Modifier—Drug amount discarded/not administered to any patient.) Other payers may have similar requirements.

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 receipt of claims. Patients and healthcare professionals should always verify coverage, coding, and reimbursement guidelines on a payer- and patient-specific basis.

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

BAVENCIO® avelumab Injection 20 mg/mL

CoverOne®

CoverOne® is a patient access and reimbursement support program available to help eligible patients gain appropriate access to BAVENCIO® (avelumab) Injection 20 mg/mL in the United States. CoverOne offers the following:

Reimbursement Support

- Insurance Benefit Verification
- Prior Authorization Assistance
- Information on Relevant Billing Codes for BAVENCIO
  - HCPCS, CPT®, ICD-10-CM, NDC
- Denied/Underpaid Claims Assistance
- Payer Research (non–patient specific)–Medicare, Private Payers, State Medicaid

Patient Assistance Program

CoverOne includes a patient assistance program that provides BAVENCIO at no charge for eligible patients who meet certain income, insurance (i.e., uninsured), and residency eligibility criteria.

- To determine patient eligibility, providers should complete and fax a CoverOne Enrollment Form **prior to treatment**, or submit an online enrollment form at **CoverOne.com**
- Patient assistance is not applied retroactively

Co-pay Assistance Program

CoverOne provides co-pay assistance for privately insured BAVENCIO patients with co-pay/co-insurance responsibilities who meet the program eligibility criteria.

- Privately insured patients may apply for assistance through the CoverOne Co-pay Program by faxing a completed CoverOne Enrollment Form, or by submitting an online enrollment form at **CoverOne.com**
  - Government-insured patients, including beneficiaries of Medicare and Medicaid or other federal or state healthcare programs, are not eligible for the CoverOne Co-pay Assistance Program
- Limits, terms, and conditions apply. Full terms and conditions for co-pay assistance can be found at **CoverOne.com**
- CoverOne will notify you of the eligibility determination as soon as possible
- Enrolled patients **may be eligible to pay as little as a $0 co-pay** for each treatment for BAVENCIO, up to a maximum co-pay assistance amount of $30,000 per year
  - Once the annual co-pay assistance limit is reached, enrolled patients are responsible for paying all co-pays and any balance not covered by CoverOne
- For enrolled patients, disbursement of co-pay assistance funds occurs after the patient has received treatment in an outpatient setting, and an Explanation of Benefits (EOB) showing a separately payable BAVENCIO claim eligible for co-pay assistance is sent to CoverOne
- EMD Serono and Pfizer Inc reserve the right to rescind, revoke, or amend the program without notice at any time

CoverOne
PO Box 29293
Phoenix, AZ 85038-9293

PHONE: **844-8COVER1** (844-826-8371) | FAX: **855-737-7671** (FOR BAVENCIO AND AXITINIB COMBINATION)
800-214-7295 (FOR BAVENCIO SINGLE-AGENT USE)

CoverOne.com | Monday–Friday, 8:00 AM–8:00 PM ET

When BAVENCIO is used in combination with axitinib for first-line advanced RCC, review the full Prescribing Information for axitinib prior to initiation.

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 8:00 AM–8:00 PM ET) or visit **PfizerOncologyTogether.com.**

INDICATIONS and IMPORTANT SAFETY INFORMATION for BAVENCIO® (avelumab)

INDICATIONS

BAVENCIO® (avelumab) 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).

IMPORTANT SAFETY INFORMATION

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.

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.

Click for full Prescribing Information and Medication Guide, or visit BAVENCIO.com.

BAVENCIO® avelumab Injection 20 mg/mL

IMPORTANT SAFETY INFORMATION for BAVENCIO® (avelumab) (cont'd)

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%).

IMPORTANT SAFETY INFORMATION for BAVENCIO® (avelumab) (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%).

Click for full Prescribing Information and Medication Guide, or visit BAVENCIO.com.

BAVENCIO® avelumab Injection 20 mg/mL

BAVENCIO®
avelumab Injection 20 mg/mL

Please see Important Safety Information on pages 13-15.
Click for full Prescribing Information and Medication Guide, or visit BAVENCIO.com.

References: 1. Centers for Medicare and Medicaid Services CMS, Alpha-Numeric HCPCS File, October 2021. **2.** CMS, JW Modifier: Drug amount discarded/not administered to any patient; Transmittal R3538. **3.** Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual, Chapter 15. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf. Accessed November 4, 2021. **4.** Social Security Act, Section 1847A. https://www.ssa.gov/OP_Home/ssact/title18/1847A.htm. Accessed November 4, 2021. **5.** CMS, CY2022 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1753-F), November 2021. **6.** CMS, Medicare Part B ASP Files. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html. Accessed November 4, 2021. **7.** CARES Act, Public Law 116-136, Section 3709, March 27, 2020. **8.** CMS, Medicare-FFS Program. Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS). Frequently asked questions. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Billing-340B-Modifiers-under-Hospital-OPPS.pdf. Accessed November 4, 2021. **9.** Centers for Medicare and Medicaid Services. Medicare Managed Care Model Chapter 4. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf. Accessed November 4, 2021.

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.

EMD Serono Pfizer

January 2022 US-AVE-00901