IMFINZI™
durvalumab
Injection for Intravenous Use 50 mg/mL

Coding Resource

1-844-ASK-A360
(1-844-275-2360)

1-844-FAX-A360
(1-844-329-2360)

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For more information, call AstraZeneca Access 360™ at **1-844-ASK-A360**, Monday through Friday, 8 AM to 8 PM ET.

IMFINZI is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

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.

It is important to note that the codes identified below are examples only. Each provider is responsible for ensuring all coding is accurate and documented in the medical record based on the condition of the patient. The use of the following codes does not guarantee reimbursement.

National Drug Code (NDC)

The National Drug Code (NDC) is a universal, unique, 3-segment number identifying drugs by manufacturer, dosage, and package size. Payers may require the submission of the 11-digit NDC on health care claim forms, and electronic claims may be denied for drugs billed without a valid 11-digit NDC. Contact your patient's health plan to determine claim submission requirements and to determine accurate reporting of NDC codes.

10-digit NDC

Dosage	Code
500 mg/10 mL single-dose vial	0310-4611-50
120 mg/2.4 mL single-dose vial	0310-4500-12

11-digit NDC

Dosage	Code
500 mg/10 mL single-dose vial	00310-4611-50
120 mg/2.4 mL single-dose vial	00310-4500-12

Select Safety Information

There are no contraindications for IMFINZI® (durvalumab).

Monitor patients for clinical signs and symptoms of immune-mediated pneumonitis, hepatitis, colitis or diarrhea, endocrinopathies, nephritis, rash or dermatitis, other immune-mediated adverse reactions, and infection. Please refer to the full Prescribing Information for important dose management information specific to adverse reactions.

Please see Important Safety Information throughout this brochure.

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Current Procedural Terminology (CPT)[1]

Submitting accurate codes and claims is important to ensure proper reimbursement of services. The chart below lists the potential Current Procedural Terminology (CPT) code for your reference when submitting claims for your IMFINZI patients.

Code	Description
INFUSION ADMINISTRATION	
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). [*Please note: report 96415 for infusion intervals of greater than 30 minutes beyond 1-hour increments]*
HOME INFUSION	
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)
99602	Each additional hour (List separately in addition to code for primary procedure) [Use 99602 in conjunction with 99601]

Healthcare Common Procedure Coding System (HCPCS)[2]

Submitting accurate codes and claims is important to ensure proper reimbursement of services.
The chart below lists potential code(s) for your reference when submitting claims for your IMFINZI patients. Any drug discarded should be billed on a separate line with the JW modifier. The unit field should reflect the amount of drug discarded. When submitting a claim using an HCPCS miscellaneous code include specific information:

- Medicine name (both brand and generic)
- Total dosage and strength
- Method of administration
- 11-digit National Drug Code (NDC)
- Basis of measurement (1 unit)
- Payer requirements for coding of newly approved medicines may vary.

Please contact the payer or Access 360 at **1-844-275-2360** for additional coding information.

Select Safety Information

Immune-Mediated Pneumonitis

In the combined safety database (n=1414), immune-mediated pneumonitis occurred in 32 patients (2.3%), including 1 fatal case (0.1%) and 6 Grade 3–4 cases (0.4%). In Study 1 (n=182), 1 patient (0.5%) died from immune-mediated pneumonitis. Monitor patients for signs and symptoms of pneumonitis and evaluate with radiographic imaging when suspected. Administer corticosteroids for ≥Grade 2 pneumonitis. Withhold IMFINZI for Grade 2 pneumonitis; permanently discontinue for Grade 3–4 pneumonitis.

Please see Important Safety Information on pages 6-8.

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Coding Resource

Healthcare Common Procedure Coding System (HCPCS)[2] (Continued)

Code	Description	Vial Size	Billing Units	NDC
PHYSICIAN OFFICE				
J9999	Not otherwise classified, antineoplastic drugs			
J3490	Unclassified drugs			
J3590	Unclassified biologic			
HOSPITAL OUTPATIENT[3]				
C9492	**INJECTION, DURVALUMAB, 10 MG[3] (effective for DOS on/after 10/1/17)**	500 mg/10 mL	50 units	0310-4611-50
		120 mg/2.4 mL	12 units	0310-4500-12

Place of Service Codes[4]

The Place of Service (POS) code set provides setting information necessary to appropriately pay professional service claims. The place of service is the location of the provider's face-to-face encounter with the beneficiary. The physician practice setting is indicated with POS code 11. In order to differentiate between on-campus and off-campus (located farther than 250 yards from a hospital's main campus) provider-based departments CMS created a POS code (POS 19) and revised the POS code description for outpatient hospital (POS 22). Professional services delivered in outpatient hospital settings must now specifically include the off-campus or on-campus POS on the claim form. In addition, for off-campus items and services furnished, a PO modifier must be added to each of these codes on the claim form. Please contact the payer or Access 360 at **1-844-275-2360** for additional coding information.

Code	Location	Description
11	Office	Location, other than a hospital, skilled nursing facility, military treatment facility, community health center, state or local public health clinic, or intermediate care facility, where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
19	Off Campus: Outpatient Hospital	A portion of an off-campus hospital provider based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Effective January 1, 2016)
22	On Campus: Outpatient Hospital	A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Effective January 1, 2016)

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Revenue Codes[5]*

Code	Description
0258	IV solutions (Pharmacy series 025X)
0263	Drug/supply delivery (IV Therapy series 026X)
0636	Drugs requiring detailed coding (Pharmacy extension series 063X)

**Certain classes of drugs that require detailed coding including chemotherapy drugs, oral anti-emetic drugs, immunosuppressive drugs, and others must be billed with revenue codes 0634, 0635 or 0636 and detailed CPT or HCPCS coding according to UB04 editor guidelines. Revenue code 0250—pharmacy is not appropriate for billing these categories of drugs.*

Diagnosis Codes[6]

When filing claims, providers often indicate a diagnosis code reflecting the patient's condition. Based on the indications for IMFINZI, examples of diagnosis codes that may be appropriate are listed below.

It is important to note that the codes identified below are examples only. Each provider is responsible for ensuring all coding is accurate and documented in the medical record based on the condition of the patient.

The use of the following codes does not guarantee reimbursement.

International Classification of Diseases, Tenth Revision, Clinical Modification = ICD-10-CM

ICD-1Ø-CM	Description
C61	Malignant neoplasm of the prostate
C65.1	Malignant neoplasm of the right renal pelvis
C65.2	Malignant neoplasm of the left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C66.1	Malignant neoplasm of the right ureter
C66.2	Malignant neoplasm of the left ureter
C66.9	Malignant neoplasm of unspecified ureter
C67.Ø	Malignant neoplasm of trigone of bladder

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Diagnosis Codes[6] (Continued)

ICD-10-CM	Description
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 lesion of bladder
C67.9	Malignant neoplasm of bladder, unspecified
C68.0	Malignant neoplasm of urethra
D09.0	Carcinoma in situ of the bladder
Z85.51	Personal history of malignant neoplasm of bladder
Z85.59	Personal history of malignant neoplasm of other urinary tract organ
Z92.21	Personal history of antineoplastic chemotherapy
Z92.3	Personal history of irradiation

Select Safety Information

Immune-Mediated Hepatitis

In the combined safety database (n=1414), immune-mediated hepatitis occurred in 16 patients (1.1%), including 1 fatal case (<0.1%) and 9 Grade 3 cases (0.6%). Grade 3–4 elevations in ALT occurred in 40/1342 patients (3.0%), AST in 58/1336 patients (4.3%), and total bilirubin in 37/1341 patients (2.8%). In Study 1 (n=182), 1 patient (0.5%) died from immune-mediated hepatitis, and 2 patients (1.1%) experienced immune-mediated hepatitis, including 1 Grade 3 case (0.5%). Monitor patients for abnormal liver tests in each cycle during treatment with IMFINZI. Administer corticosteroids and withhold IMFINZI for Grade 2–3 ALT or AST >3–5X ULN or ≤8X ULN or total bilirubin >1.5–3X ULN or ≤5X ULN. Permanently discontinue IMFINZI in patients with Grade 3 ALT or AST >8X ULN or total bilirubin >5X ULN, or in patients with concurrent ALT or AST >3X ULN and total bilirubin >2X ULN with no other cause.

Please see Important Safety Information on pages 6-8.

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Important Safety Information (Continued)

Immune-Mediated Colitis

In the combined safety database (n=1414), immune-mediated colitis or diarrhea occurred in 18 patients (1.3%), including 1 Grade 4 case (<0.1%) and 4 Grade 3 cases (0.3%). In Study 1 (n=182), 23 patients (12.6%) experienced colitis or diarrhea, including 2 Grade 3–4 cases (1.1%). Monitor patients for signs and symptoms of colitis or diarrhea. Administer corticosteroids for ≥Grade 2 colitis or diarrhea. Withhold IMFINZI for Grade 2 colitis or diarrhea; permanently discontinue for Grade 3–4 colitis or diarrhea.

Immune-Mediated Endocrinopathies

- Immune-mediated thyroid disorders, adrenal insufficiency, type 1 diabetes mellitus and hypophysitis/hypopituitarism have occurred with IMFINZI. Monitor patients for clinical signs and symptoms of endocrinopathies. For Grade 2–4 endocrinopathies (except hypothyroidism) withhold dose until clinically stable and offer symptomatic management for hyperthyroidism. For Grade 2–4 hypothyroidism, initiate thyroid hormone replacement as needed
- Thyroid disorders—In the combined safety database (n=1414), immune-mediated hypothyroidism and hyperthyroidism occurred in 136 patients (9.6%) and 81 patients (5.7%), respectively. Thyroiditis occurred in 10 patients (0.7%), including 1 Grade 3 case (<0.1%) in a patient who had a myocardial infarction. In 9 patients with thyroiditis, transient hyperthyroidism preceded hypothyroidism. Treatment with a beta-blocker and/or thioamide was administered for hyperthyroidism in five of these patients. In Study 1 (n=182), Grade 1–2 hypothyroidism or thyroiditis occurred in 10 patients (5.5%). Grade 1–2 hyperthyroidism or thyroiditis leading to hyperthyroidism occurred in 9 patients (4.9%). Monitor patients for abnormal thyroid function tests prior to and periodically during treatment
- Immune-mediated adrenal insufficiency—In the combined safety database (n=1414), immune-mediated adrenal insufficiency occurred in 13 patients (0.9%), including 2 Grade 3 cases (0.1%). In Study 1 (n=182), Grade 1 adrenal insufficiency occurred in 1 patient (0.5%). Administer corticosteroids and hormone replacement as clinically indicated
- Type 1 diabetes mellitus—In the combined safety database (n=1414), new onset type 1 diabetes mellitus without an alternative etiology occurred in 1 patient (<0.1%). For type 1 diabetes mellitus, initiate insulin as indicated and withhold IMFINZI until clinically stable
- Hypophysitis—In the combined safety database (n=1414), hypopituitarism leading to adrenal insufficiency and diabetes insipidus occurred in 1 patient (<0.1%). Administer corticosteroids and hormone replacement as clinically indicated

Please see Important Safety Information continued on next page.

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Important Safety Information (Continued)

Other Immune-Mediated Adverse Reactions

- IMFINZI has caused immune-mediated rash. Other immune-related adverse reactions, including aseptic meningitis, hemolytic anemia, immune thrombocytopenic purpura, myocarditis, myositis, nephritis, and ocular inflammatory toxicity including uveitis and keratitis, have occurred in ≤1.0% of patients treated with IMFINZI
- Immune-mediated rash or dermatitis—In the combined safety database (n=1414), immune-mediated rash or dermatitis occurred in 220 patients (15.6%) and 4 patients (0.3%) developed vitiligo. In Study 1 (n=182), 20 patients (11.0%) developed rash, including 1 Grade 3 case (0.5%). Patients should be monitored for signs and symptoms of rash or dermatitis. Administer corticosteroids if indicated. Withhold IMFINZI for Grade 3 rash or dermatitis or Grade 2 rash or dermatitis lasting >1 week. Permanently discontinue IMFINZI in patients with Grade 4 rash or dermatitis
- Immune thrombocytopenic purpura—In the combined safety database (n=1414), 1 fatal case (<0.1%) of immune thrombocytopenic purpura occurred. Monitor patients for signs and symptoms of immune thrombocytopenic purpura
- Nephritis—In the combined safety database (n=1414), immune-mediated nephritis occurred in 3 patients (0.2%), including 2 Grade 3 cases (0.1%). Monitor patients for abnormal renal function tests prior to and during each cycle of IMFINZI. Administer corticosteroids for ≥Grade 2 nephritis (creatinine >1.5X ULN). Withhold IMFINZI for Grade 2 nephritis; permanently discontinue for ≥Grade 3 nephritis (creatinine >3X ULN)

Infection

Severe infections, including sepsis, necrotizing fasciitis, and osteomyelitis, occurred in patients receiving IMFINZI. In the combined safety database (n=1414), infections occurred in 531 patients (37.6%). In Study 1 (n=182), infections occurred in 54 patients (29.7%). 11 patients (6.0%) experienced Grade 3–4 infection and 5 patients (2.7%) were experiencing infection at the time of death. 8 patients (4.4%) experienced urinary tract infection, the most common ≥Grade 3 infection. Monitor patients for signs and symptoms of infection and treat with anti-infectives for suspected or confirmed infections. Withhold IMFINZI for ≥Grade 3 infection.

Infusion-Related Reactions

In the combined safety database (n=1414), severe infusion-related reactions occurred in 26 patients (1.8%). In Study 1 (n=182), infusion-related reactions occurred in 3 patients (1.6%). There were 5 Grade 3 (0.4%) and no Grade 4 or 5 reactions. Patients should be monitored for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion for Grade 1–2 infusion-related reactions and permanently discontinue for Grade 3–4 infusion-related reactions.

Please see Important Safety Information continued on next page.

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Important Safety Information (Continued)

Embryo-Fetal Toxicity

Based on its mechanism of action and data from animal studies, IMFINZI can cause fetal harm when administered to a pregnant woman. There are no data on the use of IMFINZI in pregnant women. Advise pregnant women of the potential risk to a fetus and advise women of reproductive potential to use effective contraception during treatment and for at least 3 months after the last dose of IMFINZI.

Nursing Mothers

There is no information regarding the presence of IMFINZI in human milk; however, because of the potential for adverse reactions in breastfed infants from IMFINZI, advise a lactating woman not to breastfeed during treatment and for at least 3 months after the last dose.

Most Common Adverse Reactions

- The most common adverse reactions (≥15%) were fatigue (39%), musculoskeletal pain (24%), constipation (21%), decreased appetite (19%), nausea (16%), peripheral edema (15%), and urinary tract infection (15%). The most common Grade 3 or 4 adverse reactions (≥3%) were fatigue, urinary tract infection, musculoskeletal pain, abdominal pain, dehydration, and general physical health deterioration
- Adverse reactions leading to discontinuation of IMFINZI occurred in 3.3% of patients. Serious adverse reactions occurred in 46% of patients. The most frequent serious adverse reactions (>2%) were acute kidney injury (4.9%), urinary tract infection (4.4%), musculoskeletal pain (4.4%), liver injury (3.3%), general physical health deterioration (3.3%), sepsis, abdominal pain, and pyrexia/tumor associated fever (2.7% each)

The safety and effectiveness of IMFINZI have not been established in pediatric patients.

Please see accompanying complete Prescribing Information including Patient Information (Medication Guide).

References:

1. **American Medical Association. CPT® 2017 *Professional Edition*. Chicago, IL: American Medical Association; 2017.**
2. **Centers for Medicare & Medicaid Services. HCPCS Release & Code Sets. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html. Accessed March 16, 2017.**
3. **Centers for Medicare & Medicaid Services. CMS Manual System: October 2017 update of the hospital Outpatient Prospective Payment System (OPPS), Change Request 10236. August 25, 2017.**
4. **Centers for Medicare & Medicaid Services. Place of Service Codes for Professional Claims Database (updated November 2016). https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Website-POS-database.pdf. Accessed March 16, 2017.**
5. **Noridian Healthcare Solutions. Revenue Codes. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes. Accessed March 27, 2017.**
6. **American Medical Association. *ICD-10-CM 2017: The Complete Official Codebook*. Chicago, IL: American Medical Association; 2017.**

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

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