IMFINZI™
durvalumab
Injection for Intravenous Use 50 mg/mL

Coding Resource

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

1-844-FAX-A360
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www.MyAccess360.com

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 unresectable Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

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).

IMFINZI can cause serious, potentially fatal adverse reactions including immune-mediated pneumonitis, hepatitis, colitis or diarrhea, endocrinopathies, nephritis, rash or dermatitis, other immune-mediated adverse reactions, infection, and infusion-related reactions. Please refer to the full Prescribing Information for important dosage modification and management information specific to adverse reactions.

Immune-Mediated Pneumonitis

IMFINZI can cause immune-mediated pneumonitis, defined as requiring use of corticosteroids. Fatal cases have been reported. Monitor patients for signs and symptoms of pneumonitis and evaluate with radiographic imaging when suspected. Administer corticosteroids for Grade 2 or greater pneumonitis. Withhold IMFINZI for Grade 2 pneumonitis; permanently discontinue for Grade 3 or 4 pneumonitis.

In clinical studies enrolling 1889 patients with various cancers who received IMFINZI, pneumonitis occurred in 5% of patients, including Grade 3 (0.8%), Grade 4 (<0.1%), and Grade 5 (0.3%) pneumonitis. Pneumonitis led to discontinuation of IMFINZI in 1.5% of the 1889 patients. In the PACIFIC study, the incidence of pneumonitis (including radiation pneumonitis) was 34%, including Grade 3 (3.4%) and Grade 5 (1.1%) pneumonitis in the IMFINZI arm. In the PACIFIC study, pneumonitis led to discontinuation of IMFINZI in 6% of patients.

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 (Continued)

Immune-Mediated Hepatitis

IMFINZI can cause immune-mediated hepatitis, defined as requiring use of corticosteroids. Fatal cases have been reported. Monitor patients for signs and symptoms of hepatitis during and after discontinuation of IMFINZI, including clinical chemistry monitoring. Administer corticosteroids for Grade 2 or higher elevations of ALT, AST, and/or total bilirubin. Withhold IMFINZI for ALT or AST greater than 3 but less than or equal to 8 times the ULN or total bilirubin greater than 1.5 but less than or equal to 5 times the ULN; permanently discontinue IMFINZI for ALT or AST greater than 8 times the ULN or total bilirubin greater than 5 times the ULN or concurrent ALT or AST greater than 3 times the ULN and total bilirubin greater than 2 times the ULN with no other cause.

In clinical studies enrolling 1889 patients with various cancers who received IMFINZI, hepatitis occurred in 12% of patients, including Grade 3 (4.4%), Grade 4 (0.4%), and Grade 5 (0.2%) hepatitis. Hepatitis led to discontinuation of IMFINZI in 0.7% of the 1889 patients.

Please see Important Safety Information continued on next page.

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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]**	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 POS 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)

Select Safety Information (Continued)

Immune-Mediated Colitis

IMFINZI can cause immune-mediated colitis, defined as requiring use of corticosteroids. Administer corticosteroids for Grade 2 or greater colitis or diarrhea. Withhold IMFINZI for Grade 2 colitis or diarrhea; permanently discontinue for Grade 3 or 4 colitis or diarrhea.

In clinical studies enrolling 1889 patients with various cancers who received IMFINZI, colitis or diarrhea occurred in 18% of patients, including Grade 3 (1.0%) and Grade 4 (0.1%) colitis. Diarrhea or colitis led to discontinuation of IMFINZI in 0.4% of the 1889 patients.

Please see Important Safety Information continued on next page.

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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-10-CM	Description
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung

Please see Important Safety Information continued on next page.

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Diagnosis Codes[6] (Continued)

ICD-10-CM	Description
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
Z85.118	Personal history of malignant neoplasm of bronchus and lung (Conditions classifiable to C34)
Z92.21	Personal history of antineoplastic chemotherapy
Z92.3	Personal history of irradiation

Select Safety Information (Continued)

Immune-Mediated Endocrinopathies

IMFINZI can cause immune-mediated endocrinopathies, including thyroid disorders, adrenal insufficiency, type 1 diabetes mellitus, and hypophysitis/hypopituitarism. Monitor patients for clinical signs and symptoms of endocrinopathies.

- **Thyroid disorders**—Monitor thyroid function prior to and periodically during treatment. Initiate hormone replacement therapy or medical management of hyperthyroidism as clinically indicated. Withhold IMFINZI for Grades 2–4 hyperthyroidism, until clinically stable. Continue IMFINZI for hypothyroidism.
  In clinical studies enrolling 1889 patients with various cancers who received IMFINZI, hypothyroidism occurred in 11% of patients, while hyperthyroidism occurred in 7% of patients. Thyroiditis occurred in 0.9% of patients, including Grade 3 (<0.1%). Hypothyroidism was preceded by thyroiditis or hyperthyroidism in 25% of patients.
- **Adrenal insufficiency**—Administer corticosteroids as clinically indicated and withhold IMFINZI until clinically stable for Grade 2 or higher adrenal insufficiency. In clinical studies enrolling 1889 patients with various cancers who received IMFINZI, adrenal insufficiency occurred in 0.7% of patients, including Grade 3 (<0.1%) adrenal insufficiency.
- **Type 1 diabetes mellitus**—Initiate treatment with insulin as clinically indicated. Withhold IMFINZI for Grades 2–4 type 1 diabetes mellitus, until clinically stable. In clinical studies enrolling 1889 patients with various cancers who received IMFINZI, type 1 diabetes mellitus occurred in <0.1% of patients.
- **Hypophysitis**—Administer corticosteroids and hormone replacement as clinically indicated and withhold IMFINZI until clinically stable for Grade 2 or higher hypophysitis. Hypopituitarism leading to adrenal insufficiency and diabetes insipidus occurred in <0.1% of 1889 patients with various cancers who received IMFINZI.

Immune-Mediated Nephritis

IMFINZI can cause immune-mediated nephritis, defined as evidence of renal dysfunction requiring use of corticosteroids. Fatal cases have occurred. Monitor patients for abnormal renal function tests prior to and periodically during treatment with IMFINZI. Administer corticosteroids as clinically indicated. Withhold IMFINZI for creatinine greater than 1.5 to 3 times the ULN; permanently discontinue IMFINZI and administer corticosteroids in patients with creatinine greater than 3 times the ULN.

In clinical studies enrolling 1889 patients with various cancers who received IMFINZI, nephritis (reported as any of the following: increased creatinine or urea, acute kidney injury, renal failure, decreased glomerular

Please see Important Safety Information continued on next page.

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Important Safety Information (Continued)

Immune-Mediated Nephritis (Continued)

filtration rate, tubulointerstitial nephritis, decreased creatinine clearance, glomerulonephritis, and nephritis) occurred in 6.3% of the patients including Grade 3 (1.1%), Grade 4 (0.2%), and Grade 5 (0.1%) nephritis. IMFINZI was discontinued in 0.3% of the 1889 patients.

Immune-Mediated Dermatologic Reactions

IMFINZI can cause immune-mediated rash. Bullous dermatitis and Stevens Johnson Syndrome (SJS)/toxic epidermal necrolysis (TEN) have occurred with other products in this class. Administer corticosteroids for Grade 2 rash or dermatitis lasting for more than 1 week or for Grade 3 or 4 rash or dermatitis. Withhold IMFINZI for Grade 2 rash or dermatitis lasting longer than 1 week or Grade 3 rash or dermatitis; permanently discontinue IMFINZI in patients with Grade 4 rash or dermatitis.

In clinical studies enrolling 1889 patients with various cancers who received IMFINZI, 26% of patients developed rash or dermatitis and 0.4% of the patients developed vitiligo. Rash or dermatitis led to discontinuation of IMFINZI in 0.1% of the 1889 patients.

Other Immune-Mediated Adverse Reactions

IMFINZI can cause severe and fatal immune-mediated adverse reactions. These immune-mediated reactions may involve any organ system. While immune-mediated reactions usually manifest during treatment with IMFINZI, immune-mediated adverse reactions can also manifest after discontinuation of IMFINZI. For suspected immune-mediated adverse reactions, exclude other causes and initiate corticosteroids as clinically indicated. Withhold IMFINZI for Grade 3 immune-mediated adverse reactions, unless clinical judgment indicates discontinuation; permanently discontinue IMFINZI for Grade 4 adverse reactions.

The following clinically significant, immune-mediated adverse reactions occurred at an incidence of less than 1% each in 1889 patients who received IMFINZI: aseptic meningitis, hemolytic anemia, immune thrombocytopenic purpura, myocarditis, myositis, and ocular inflammatory toxicity, including uveitis and keratitis. Additional clinically significant immune-mediated adverse reactions have been seen with other products in this class (see Warnings and Precautions Section 5.7 of IMFINZI full Prescribing Information).

Infection

IMFINZI can cause serious infections, including fatal cases. Monitor patients for signs and symptoms of infection and treat as clinically indicated. Withhold IMFINZI for Grade 3 or 4 infection, until clinically stable.

In clinical studies enrolling 1889 patients with various cancers who received IMFINZI, infections occurred in 43% of patients, including Grade 3 (8%), Grade 4 (1.9%), and Grade 5 (1.0%). In patients with Stage III NSCLC in the PACIFIC study, the most common Grade 3 or higher infection was pneumonia, which occurred in 5% of patients.

Infusion-Related Reactions

IMFINZI can cause severe or life-threatening infusion-related reactions. Monitor patients for signs and symptoms of an infusion-related reaction. Interrupt or slow the rate of infusion for Grades 1–2 infusion-related reactions; permanently discontinue for Grades 3–4 infusion-related reactions.

In clinical studies enrolling 1889 patients with various cancers who received IMFINZI, infusion-related reactions occurred in 2.2% of patients, including Grade 3 (0.3%).

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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.

Lactation

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 women not to breastfeed during treatment and for at least 3 months after the last dose.

Most Common Adverse Reactions

- In patients with Stage III NSCLC in the PACIFIC study (IMFINZI n=475), the most common adverse reactions (≥20% of patients) were cough (40%), fatigue (34%), pneumonitis or radiation pneumonitis (34%), upper respiratory tract infections (26%), dyspnea (25%), and rash (23%). The most common Grade 3 or 4 adverse reaction (≥3%) was pneumonia (7%).
- In patients with Stage III NSCLC in the PACIFIC study (IMFINZI n=475), discontinuation due to adverse reactions occurred in 15% of patients in the IMFINZI arm. Serious adverse reactions occurred in 29% of patients receiving IMFINZI. The most frequent serious adverse reactions (≥2% of patients) were pneumonitis or radiation pneumonitis (7%) and pneumonia (6%). Fatal pneumonitis or radiation pneumonitis and fatal pneumonia occurred in <2% of patients and were similar across arms.

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

Please see accompanying complete Prescribing Information, including 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 November 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. November 16, 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 November 16, 2017.
5. Noridian Healthcare Solutions. Revenue Codes. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes. Accessed November 16, 2017.
6. American Medical Association. *ICD-10-CM 2017: The Complete Official Codebook*. Chicago, IL: American Medical Association; 2017.

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

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